NATIONAL QUALITY FORUM

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MAP CLINICIAN WORKGROUP

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TUESDAY

JANUARY 12, 2021

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The Workgroup met via Videoconference, at 10:00 a.m. EST, Rob Fields and Diane Padden, Co-Chairs, presiding.

WORKGROUP MEMBERS:

ROB FIELDS, MD, Co-Chair
DIANE PADDEN, PhD, CRNP, FAANP, Co-Chair
JOY BLAND, Magellan Health, Inc.
RACHEL BRODIE, Pacific Business Group on Health
HELEN BURSTIN, MD, MPH, MACP, Council of Medical Specialty Societies
SCOTT FIELDS, MD, MHA, OCHIN, Inc.
WILLIAM FLEISCHMAN, MD, MHS, Individual Subject Matter Expert
STEPHANIE FRY, Individual Subject Matter Expert
WENDOLYN GOZANSKY, MD, MPH, Kaiser Permanente
LISA HINES, PharmD, Pharmacy Quality Alliance

SUSAN KNUDSON, HealthPartners, Inc.
ROBERT KRUGHOFF, Consumers' Checkbook
TRUDY MALLINSON, PhD, American Occupational Therapy Association
LISA McGIFFERT, Patient Safety Action Network
AMY MULLINS, MD, CPE, FAAFP, American Academy of Family Physicians
AMY NGUYEN HOWELL, MD, MBA, FAAFP, Individual Subject Matter Expert
DONALD NICHOLS, PhD, Genentech
CAROLINE REINKE, MD, Atrium Health
KIM RITTEN, HealthPartners, Inc.

KAREN ROTH, St. Louis Area Business Health Coalition
DAVID SEIDENWURM, MD, American College of Radiology
KATHLEEN STEVENS, RN, EdD, ANEF, FAAN, Louise Batz Patient Safety Foundation
J. CHAD TEETERS, MD, American College of Cardiology
WEI YING, MD, MS, MBA, Blue Cross Blue Shield of Massachusetts
YANLING YU, PhD, Patient Safety Action Network

MAP RURAL HEALTH WORKGROUP REPRESENTATIVE:

KIMBERLY RASK, MD, PhD, Alliant Health Solutions

NON-VOTING FEDERAL LIAISONS:

GIRMA ALEMU, Health Resources and Services Administration (HRSA)
PETER BRISS, MD, MPH, Centers for Disease Control and Prevention (CDC)
MICHELLE SCHREIBER, MD, Centers for Medicare and Medicaid Services (CMS)

NQF STAFF:

CHRIS QUERAM, Interim President/CEO
SHERI WINSPER, Senior Vice President, Quality Measurement
SAM STOLPE, PharmD, MPH, Senior Director, Quality Management
KATIE BERRYMAN, MPAP, PMD, Senior Project Manager
CHRIS DAWSON, MHA, CPHQ, CPPS, LSSBB, Manager, Quality Measurement
MICHAEL HAYNIE, Senior Managing Director, Quality Measurement
CAROLEE LANTIGUA, Manager
AMY MOYER, Director, Quality Measurement

ALSO PRESENT:

JOEL ANDRESS, PhD, Division of Quality Measurement, CMS
SUSANNAH BERNHEIM, MD, MHS, Center for Outcomes Research and Evaluation, Yale School of Medicine
DON CASEY, MD, MPH, MBA, FACP, FAHA, FAAPL, DFACMQ, President, American College of Medical Quality
NIRMAL CHORADIA, MD, Acumen, LLC
ROSE DO, MD, Acumen, LLC
ELIZABETH DRYE, MD, MS, Center for Outcomes Research and Evaluation, Yale School of Medicine
REBECCA ETZ, PhD, Larry A. Green Center, Virginia Commonwealth University School of Medicine
RONIQUE EVANS, PhD, Measures Lead, Center for Clinical Standards and Quality, CMS
DANIEL GREEN, MD, Medical Officer, Office of Clinical Standards and Quality, CMS
STEVEN JOHNSON, Division of Program Alignment and Communications, CMS
KATE KIRLEY, MD, MS, Director of Chronic Disease Prevention, American Medical Association
KASIA LIPSKA, MD, MHS, BS, Center for Outcomes Research and Evaluation, Yale School of Medicine
JULIE MALLOY, MOT, OTR/L, PMP, CPHQ, American Occupational Therapy Association
SRI NAGAVARAPU, Acumen, LLC
LISA SCHILLING, MD, Office of Value-Based Performance, University of Colorado Anschutz Medical Campus

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

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

(10:04 a.m.)

DR. STOLPE: Hello and welcome, everyone, to the MAP Clinician Workgroup measure review meeting. I'm delighted to be welcoming you today. We're going to be reviewing a total of 11 measures that are included inside of both the Merit-Based Incentive Payment System as well as the Shared Savings Program.

Now, today, we just have a couple of housekeeping reminders before we get started. First, we would just invite you to please mute your computer or line when you are not speaking. Also, well, we'd also ask that you ensure that your name is displayed correctly. You can do so by clicking on your picture and selecting "rename" to edit your name if it's not represented accurately.

We're going to be using a virtual platform for our meeting today, which, as you can see, allows for video. And so we would just ask that, in order to encourage engagement throughout

our time together, that you please turn on your video, especially during the measure discussions or when you are speaking. If you wish to switch your display, you can right-click view in the upper-right corner and select speaker or gallery.

Now, I'd also like to point out that we have a raise hand feature, which will allow for our workgroup members to be recognized by the co-chairs during the course of our deliberations. If you wish to provide a point or to raise a quick -- a question, we would just ask you to please use the raise hand feature. To do so, just click on the participants icon at the bottom of your screen and you will see a button that says "raise hand."

Now, we'd also invite you to use the chat feature to communicate with either the NQF host or with IT support if you experience some difficulties or have any questions during the course of our meeting.

For this meeting, we are using Zoom for presentations and discussions, and we're

going to be using a voting platform called Poll Everywhere for voting. So, for our workgroup members, please ensure that you have access to both of those platforms. Now would be a good time to login to Poll Everywhere. As a reminder, we ask you not to share the link for the Poll Everywhere platform over the chat.

So thank you very much. At this point, I'd like to just check to ensure that we have both of our co-chairs on the line. Rob Fields and Diane Padden, are you available?

CO-CHAIR PADDEN: I'm here.

CO-CHAIR FIELDS: Hey there. Yes, we are.

DR. STOLPE: All right. Very good. At this point, I'd like to hand it over to our interim President and CEO, Chris Queram, and following that, to our Senior Vice President of Quality Measurement, Sheri Winsper, to provide a welcome from NQF.

MR. QUERAM: Great. Thank you very much, Sam. As Sam indicated, my name is Chris

Queram and it's my honor to serve as the interim President and CEO of the National Quality Forum during this period of transition.

As I was preparing for this morning's meeting and reviewing the agenda as well as the participants, I recognized many names of people that I've had the privilege of serving and working with over the years, and I'd like to thank all of your for your dedication and commitment to this process.

This is, as has been noted, a -- many other venues, a most unusual year. It's necessitated a great amount of flexibility on the part of the members, experimentation with a new and, so far, very vibrant virtual platform to conduct the meetings, and we very much appreciate everybody's willingness to do what's necessary to adjust and adapt during these unusual times.

Also wanted to just acknowledge that this is the tenth year that the National Quality Forum has served as the convener and the facilitator of the Measures Application

Partnership.

During that period of time, the MAP has reviewed and come to decisions on over 1000 measures, so we're building on a rich history and legacy of work that has gone before us.

I would be remiss if I did not thank all of our federal colleagues and liaisons, but most especially, our colleagues at CMS. CMS has entrusted to the NQF, the stewardship of this important process, leveraging the quality forums' long and rich history of convening and facilitating multi-stakeholder processes in search of consensus on measures that are important to not only ensuring the quality and the overall value of healthcare, but also advancing health in our country.

And last, but not least, I would like to acknowledge and thank all of the members of the NQF team for their tireless dedication to this process and all of the work that goes into ensuring that we have a successful meeting today.

With that, let me turn to my colleague

Sheri for her comments, and again, thank you everyone for being with us today and I look forward to a productive day.

MS. WINSPER: Thank you so much, Chris. I really appreciate your opening comments and also, your support of this work. Welcome, everyone. We're excited to be able to get started on our Clinician Workgroup today. I appreciate both of our co-chairs and all of the members, of course, for joining us.

We know this takes a lot of time out of, especially today, since it's a full-day meeting, but also a lot of time to prepare for the meeting and to read through the measures and the preliminary analysis, et cetera, so we really appreciate that.

Although we have some changes in our timing and format this year, our purpose definitely remains the same. So we are here to provide CMS feedback from the lens of our consumers and our provider stakeholders groups, to informs the rulemaking process for CMS quality

and performance programs.

We are certainly, obviously, convening in the midst of a national healthcare crisis. Our nation's resources have been stretched as we face the challenges that COVID has presented us this year.

And now with two viable vaccinations on the market, we look to a future where we can prospectively overcome this crisis.

MAP will discuss the role that measurements and accountability should play related to COVID vaccination, among other very critical measurement issues. I think Sam mentioned 11 critical measurements.

So thank you as well, to CMS, for our partners, in preparation for this, and our partnership with MAP. CMS definitely continues to set the right tone for these meetings, and they are here today to provide support to the deliberations. But, most of all, they are here to listen to you and your feedback and input to these measures and payment programs.

So, thank you, everyone. Thank you, Sam, and thank you, NQF team, and I'll turn it back to you.

DR. STOLPE: All right. Thanks very much. At this point, we're going to review the objectives for today and then walk through our agenda.

So as Sheri mentioned, first and foremost, we're looking to gain insights for you to share with CMS, related to the pre-rulemaking process for the 11 measures under consideration for this cycle.

We have two other objectives that we're going to cover today as well. One is to provide general feedback on the overall strategic direction that CMS is taking in their quality action plan, as well as spending some time for both MIPS and SSP, to talk through measurement gaps and priorities from your point of view; where CMS should be focusing within those two programs.

Following these initial items with

welcomes and introductions, we'll be moving into a disclosures of interest, and then we'll hand it over to our colleagues at CMS for their opening remarks as well as a presentation on CMS' quality action plan.

Now, we'll be inviting your feedback on that plan and documenting it within our summary and final report.

Following CMS' remarks, we'll be moving into an overview of our pre-rulemaking approach, where we'll revisit the processes and procedures that we use for MAP and how our overall approach will take for the course of the day.

Then our discussion of the measures will begin in earnest. We'll start with the Merits-Based Incentive Payment System Measures, and then we'll move over to the Shared Savings Program Measure.

We'll have opportunities for public comment throughout, but we'll close the day with a final opportunity for comment before providing a summary, and then next steps, and then we will

adjourn.

At this point, I'd like to hand it over to our two co-chairs, Rob Fields and Diane Padden, for some welcomes and introductory remarks. Rob?

CO-CHAIR FIELDS: Hey, good morning, everyone. I appreciate your comment and energy today. I won't make too long of a commentary, but just appreciate everyone's effort, especially given all the craziness of the year and I know what a lot of folks are having to deal with with COVID, either treatment or vaccine distribution, all those various pressures going on, so I appreciate you carving out the time.

I'll hand it over to Diane.

CO-CHAIR PADDEN: Good morning, everyone. I, too, welcome everyone to this meeting and I'm looking forward to a robust discussion. And it is really nice to see so many familiar faces that and hopefully in the next year, we can all be back together in person, because I do enjoy all of the networking and

getting to visit with all of you.

Thanks again for your time.

DR. STOLPE: Thanks, Rob and Diane. At this time, I'll hand it over to our Senior Managing Director, Michael Haynie, to lead us through our disclosures of interest. Michael?

MS. HAYNIE: Great. Good morning, everyone. So as we begin with disclosures of interest, I would like to also offer a reminder that NQF is a non-partisan organization. So out of mutual respect for each other, we kindly encourage that we make an effort to refrain from making comments, innuendos, or humor relating, for example, to race, gender, or particularly, politics, or other topics that otherwise may be considered inappropriate during the meeting.

While we encourage discussions that are open, constructive, and collaborative, let's all be mindful of how our language and opinions may be perceived by others.

So we will combine disclosures with introductions today and we'll divide the

disclosures of interest into two parts, because we have two types of MAP members, organizational members and subject matter experts.

So I will start with the organizational members. These are folks who represent the interests of a particular organization, so we asked you to come to the table representing those interests.

Because of your status as an organizational representative, we only ask you one question specific to you as an individual, we ask you to disclose if you have an interest of $10,000 or more in an entity that is related to the work of this committee.

So we'll go around our virtual table, beginning with organizational members only, please. I'll call on anyone in the meeting who is an organizational member, and when I call your organization's name, please unmute your line, state your name, your role at your organization, and anything that you wish to disclose.

As a reminder, if you do not have

anything to disclose after stating your name and title, please just say, I have nothing to disclose, so we can keep things moving along.

I believe I'm going to start with our co-chairs here, so, Rob, would you like to go first for disclosures?

CO-CHAIR FIELDS: Sure. Rob Fields, National Association of ACOs. No disclosures.

MS. HAYNIE: Thank you. And, Diane?

CO-CHAIR PADDEN: Good morning. I would like to disclose that I participated in the episode-based cost measure development for the asthma, COPD, and the diabetes measure. I would also like to disclose that I participated in a workgroup on the patient-centered primary care measurements as well.

MS. HAYNIE: Thank you, Diane. And just for transparency, Diane has made these disclosures in writing previously, and she is going to recuse herself from discussion and voting on those measures. If you're tracking numbers, they're 15, 17, and 42, so as we continue

along here.

So American Academy of Family Physicians.

MEMBER MULLINS: Good morning. I'm Amy Mullins, the Medical Director of Quality and Science at the AAFP, and I have nothing to disclose.

MS. HAYNIE: Thank you. American College of Cardiology.

MEMBER TEETERS: Hi. My name is Chad Teeters. I'm a cardiologist up Upstate New York and the governor for the New York Chapter of the American College of Cardiology and I have nothing to disclose.

MS. HAYNIE: Thank you. American College of Radiology.

MEMBER SEIDENWURM: Hi. I'm David Seidenwurm and I represent the American College of Radiology here. I have an interest of greater than $10,000 in Sutter Medical Group, which might tangentially be related to some of the work here, and I participated in various aspects of the

Acumen measure development process, so I just want to put that as a disclosure. Thank you.

MS. HAYNIE: Thank you. American Occupational Therapy Association.

MEMBER MALLINSON: Hi. I'm Trudy Mallinson. I'm an associated professor at the George Washington University in Washington, D.C., and I'm a representative of the American Occupational Therapy Association. I have nothing to disclose.

MS. HAYNIE: Thank you. Atrium Health.

MEMBER REINKE: Hi. I'm Caroline Reinke. I'm a general surgeon and the surgical quality officer at Atrium Health.

MS. HAYNIE: Thank you.

MEMBER REINKE: No disclosures.

MS. HAYNIE: Blue Cross Blue Shield of Massachusetts.

MEMBER YING: Hi. This is Wei Ying. I'm a senior director of performance measurement and population health at Blue Cross Mass, I have

nothing to disclose.

MS. HAYNIE: Thank you. Consumers' Checkbook. All right. If you have trouble getting yourself off mute, we'll do a little loop and come back, just in case. You can also raise your hand if you're having audio problems. Council of Medical Specialty Societies.

MEMBER BURSTIN: Hi, everybody. Helen Burstin. CEO of the Council of Medical Specialty Societies. Nothing to disclose other than the fact that I've been here for every single frickin' MAP meeting since it started, so delighted to be here.

MS. HAYNIE: Congratulations and thank you. Council of Medical Specialty -- I'm sorry, we just did you. Genentech.

MEMBER NICHOLS: Good morning. My name is Donald Nichols. I am a principle health economist at Genentech and I have nothing to disclose.

MS. HAYNIE: Thank you. Health Partners.

MEMBER RITTEN: Hi. This is Kim Ritten with Health Partners. I'm the director of health informatics. I'm sitting in with Sue Knudson, the senior vice president of chief -- and chief health engagement and informatics officer, and we have nothing to disclose.

MS. HAYNIE: Excellent. Just a reminder, if you are representing an organization, you do need to make sure that your organization only votes once when we get there. Great. Kaiser Permanente.

MEMBER GOZANSKY: Good morning. Wendee Gozansky. I am an internist geriatrician. I'm the chief quality officer for the Colorado Permanente Medical Group and representing Kaiser Permanente as one of the national Permanente quality leaders.

MS. HAYNIE: Thank you. Any disclosures?

MEMBER GOZANSKY: I have nothing to disclose.

MS. HAYNIE: Thank you. Louise Batz

Patient Safety Foundation.

MEMBER STEVENS: Hi. This is Kathleen Stevens. I'm with the University of Texas Health Science Center in San Antonio as a full professor with representation on the Louise Batz Patient Safety Foundation Medical Advisory Board and I have nothing to disclose.

MS. HAYNIE: Thank you. Magellan Health.

MEMBER BLAND: Hi. I'm Joy Bland. I'm the VP of Quality and I have nothing to disclose.

MS. HAYNIE: Thank you. OCHIN, or perhaps it's OCHIN?

MEMBER FIELDS: Hi. Good morning. My name is Scott Fields. I'm a family physician and chief medical officer at OCHIN, which is a national collaborative of federally qualified health centers and rural health centers, and I have no disclosures.

MS. HAYNIE: Thank you. Pacific Business Group on Health.

MEMBER BRODIE: Hi. This is Rachel Brodie and I'm the senior director for measurement and transparency at Pacific Business Group on Health, and I don't have any disclosures to disclose.

MS. HAYNIE: Thank you. Patient Safety Action Network.

MEMBER MCGIFFERT: Hi. I'm Lisa McGiffert. I'm a patient safety activist in Austin, Texas. I am with the Patient Safety Action Network and I'm subbing today for Yanling Yu, who had a medical emergency, but she may replace me later in the day.

And I served for many years on the NQF Patient Safety Committee and Helen I -- I may have been at that first MAP meeting as a representative for Consumer Reports. I can't remember how far, but it was probably about ten years ago.

MS. HAYNIE: Okay. Thank you very much.

MEMBER MCGIFFERT: And I have nothing

to disclose. Sorry.

MS. HAYNIE: Okay. Have you done a written form as well, since you're substituting today?

MEMBER MCGIFFERT: You know, I have not. If somebody could shoot it to me, I'm -- this came up late last night and so I'm happy to fill it out.

MS. HAYNIE: Excellent. Staff, if we could get a form over and thank you for substituting. We wish your colleague a speedy recovery.

MEMBER MCGIFFERT: Sure.

MS. HAYNIE: Pharmacy Quality Alliance.

MEMBER HINES: Hi. I'm Lisa Hines. I'm vice president of performance measurement at PQA. PQA is a quality organization, measure developer, and steward, and I have nothing to disclose.

MS. HAYNIE: Thank you. St. Louis Area Business Health Coalition. All right. And

we'll loop back to Consumers' Checkbook. All right. So thank you all for those disclosures. What we'll do now is move on to disclosures for our subject matter experts.

So subject matter experts, you sit as individuals and because of that, we ask you to complete a much more detailed form regarding your professional activities. When you disclose, there's no need to review your resume, instead, we are interested in your disclosure of activities that are related to the subject matter of the workgroup's work.

So we're especially interested in your disclosure of grants, consulting, or speaking arrangements, but only if relevant to the workgroup's work.

So a few reminders for you, you sit on this group as an individual, so you do not represent the interests of your employer or anyone who may have nominated you for this committee. I also want to mention that we're not only interested in your disclosures for the

activities where you were paid, you may well have participated as a volunteer on a committee where the work is relevant to measures reviewed by MAP.

We are looking forward for you to disclose those types of activities as well. And finally, just because you disclose does not mean that you have a conflict of interest. We do oral disclosures in the spirit of openness and transparency.

So as we go around, please tell us your name, what organization you are with, and if you have anything to disclose. Please remember, say you have nothing if you don't. So, Amy Nguyen Howell.

MEMBER NGUYEN HOWELL: Hi. Amy Nguyen Howell, chief of the office provider advancement at Optum. Nothing to disclose.

MS. HAYNIE: Thank you. Nishant Anand. Stephanie Fry.

MEMBER FRY: Hi. Stephanie Fry. I'm employed by Westat and I don't know exactly how this falls into disclosure, so in full openness,

I participated in some early steps of the work that Acumen did with regard to the cost measures.

It's not related to -- it's not directly related to what's been submitted. I haven't worked on that for several years, but wanted to disclose that I had supported some of the work to collect patient voice for some of the early steps.

MS. HAYNIE: Good. Thank you for your transparency. William Fleischman.

MEMBER FLEISCHMAN: Good morning. Will Fleischman, Hackensack Meridian Health. I sit on the -- I'm a member of the American College of Emergency Physicians' Quality and Safety Committee, and I also used to work for CMS, and when I did, I participated in some of the work that this group does, including working on some of the cost measures as well; some of the early work on cost measures.

MS. HAYNIE: Okay. Thank you. Nishant Anand, could we have you join us? All right. Sounds good. So at this time, I'd like

to invite our federal government participants to introduce themselves. They are non-voting liaisons to this workgroup, so could I please have the liaison for the CDC?

DR. BRISS: Hi. This is Peter Briss. I'm with Centers for Disease Control and Prevention. I'm the medical director in the chronic disease center. Obviously, we're involved in -- our institution is involved in COVID vaccines and my center runs the National Diabetes Prevention Program. Nothing else to disclose, except, like Dr. Burstin, I've been around this table for ten out of ten years, but I'm going to sound more excited about it.

MS. HAYNIE: Great. The liaison from CMS?

DR. SCHREIBER: Michelle Schreiber from CMS. Nothing to disclose.

MS. HAYNIE: And the liaison from HRSA. Liaison from HRSA? All right.

DR. ALEMU: Hi. Can you hear me?

MS. HAYNIE: Oh, I can hear you now.

Yes.

DR. ALEMU: Yes, my name is Girma Alemu. I am representing HRSA. I am a public health analyst and I have nothing to disclose.

MS. HAYNIE: Thank you. And then a quick look back to our organizational members. I did hear that the St. Louis Business Group on Health was on?

MEMBER ROTH: Yes. Hi. I'm Karen Roth. I'm the director of research for the St. Louis Area Business Health Coalition and I have nothing to disclose.

MS. HAYNIE: Thank you so much for that. All right. So thank you all for your time on disclosures. I would like to remind you that if you believe that you may have a conflict of interest at any time during the meeting, if something comes up, please speak up.

You may do so in real time in the meeting. You can message your chair, who will go to the NQF staff, you can directly message the NQF staff. If you believe that a fellow committee

member may have a conflict of interest or is behaving in a biased manner, you may also point this out during meeting, approach the chair, or go directly to the NQF staff.

Does anyone have any further questions about any of the disclosures made today? All right. Well, then, I will turn things back over to Sam.

DR. STOLPE: All right. Very good. At this time, we'll go ahead and introduce our Rural Health liaison, is Kimberly Rask with Alliant Health on?

DR. RASK: Sorry, I had to get off of mute, yes, I am.

DR. STOLPE: Well, welcome Kimberly. Just wanted to note that while Kimberly is present and part of our meeting, she doesn't actually have voting privileges. She's here representing the MAP Rural Health Committee, which we'll speak bout in just a few moments.

At this time, I'd like to go ahead and introduce the NQF staff who will be helping to

facilitate today's meeting. I'm Sam Stolpe. I'm a senior director that oversees both this project as well as the MAP Coordinating Committee, and I'm joined by my colleagues Katie Berryman, who's a project manager, Chris Dawson and Carolee Lantigua, who are managers, and Michael Haynie, who is your assistant manager director for this project.

At this time, I am -- it's very much my pleasure to welcome and introduce Dr. Michelle Schreiber, who will be providing CMS' opening remarks. Dr. Schreiber serves as the deputy director for quality and value for the Centers for Clinical Standards and Quality at CMS.

And a very heartfelt welcome to Dr. Schreiber and appreciate you taking some time to provide us some overview of CMS' Quality Action Plan. Dr. Schreiber.

DR. SCHREIBER: Thanks, Sam, for that nice introduction. Can I just do a sound check? You can hear me okay?

DR. STOLPE: Sounds great.

DR. SCHREIBER: All right. Great. Thank you. So to all of you today, Happy New Year, first of all, and welcome to the Clinician MAP 2020 being held in 2021. We really appreciate everybody's flexibility in changing the dates and in really doing a tremendous amount of work in a short period of time, especially, really, for -- to NQF, so thank you for that.

Some of you, I see, are actually on twice. I saw you yesterday and I've seen some of you at the Rural Health, so you've dedicated a lot of time to this and thank you very much.

This goes without saying that it's been an unprecedented year and I don't think any of us when we were together in person last year, would have ever expected what happened over this year.

And I'm sure most of us hope that we never see it like this again, but really, who would have thought.

For our healthcare, this has just been a time of extraordinary challenge with the global

pandemic. At CMS, we've been working hard to try and reduce barriers and make it easier for you clinicians to do what's most important, and that is to care for patients, which you've done so well.

CMS has issued, actually, at this point, hundreds of waivers. We have implemented programs such as Hospitals Without Walls, now Hospitals at Home, licensing across state lines, and as I'm sure many of you are familiar with, kind of, unleashed telehealth, which has been, actually, a very exciting development.

I don't think healthcare will ever be the same, actually, going forward, but clinicians have obviously been particularly challenged and we're reminded of this with some nice data, actually, that's come from the AMA, but from stories that we hear across the country.

What clinicians have been doing and providing care at the frontlines has been nothing short of extraordinary and heroic. We recognize the challenges to people's practices, to their

personal lives, to their family, and can only say, from the bottom of hearts, profound and deep appreciation to everybody and to all of your organizations who represent clinicians. Thank you so very much.

You are actually, truly, the heroes of healthcare. I want to extend a few other thanks, obviously. We have a number of CMS staff on the phone today. Thank you to all of them. In particular, let me just note Dr. Dan Green, who is the chief medical officer for the MIPS program. He will be one of our experts leading our call today, as well as, we have numerous contractors on the phone.

We are here to answer your questions and to provide clarification, not to influence this independent body, but to help you with any questions that you may have.

A special shout-out to our federal partners, the CDC, of course, we speak to you every day these days, but thank you so much for your partnership. FDA, AHRQ, HRSA, and others,

and then last, but definitely not least, to the NQF.

Welcome, in particular, on behalf of CMS, a welcome to Chris Queram, who has jumped right in as the interim CEO and I will tell you that he has really jumped in with both feet into the deep end and has taken this, and is taking it, you know, exceptionally seriously and is moving NQF along very well.

To the chairs and co-chairs, Rob and Diane, thank you for that, and again, to each member of this committee, we really do appreciate it.

Just a word about the MAP, although others outlined this before, this process is mandated by law in 1890, 1898, the Social Security Act, if you ever wanted to know, as an independent, and I underline independent, expert body to provide recommendations to CMS for quality measures for use in our programs.

We really value your opinions, we value the conversation, and I will tell you that

I personally learn something at every one of these MAPs. This is my third MAP, so, Helen, I am nowhere near you in seniority, having been to every one of these, but I'm getting closer to, you know, having participated in a fair number.

And I learn from every one of you and from every one of these meetings, to thank you. You influence rule writing, what we put forward into rule writing, you have significant influence on and you have, I will tell you from, definitely, personal experience, changed the way that CMS has viewed things and changed what we have put into rule writing on many occasions.

But I also have to remind everybody that at the end of the day what is decided and what is finally put into rule writing, the government does have the final say.

With that, I'd like to spend just a moment to introduce the CMS Quality Action Plan. I know some of you have heard this before, hoping to make this conversational, because I'm more interested in, really, everybody's feedback, so

I'll pause after certain slides, and, Sam, if you'll help me open this up and facilitate conversation.

I know you saw us do that yesterday as well, so thank you for that. If we can have the first slide, please. This is really just our disclaimer that we're going to talk about CMS' strategy, but this isn't rule writing. This isn't, you know, something that we are formally -- we're not introducing a rule here, so this is, really, a disclosure that, for specific statutes and regulations, we would refer you to those appropriate ones, that this is not.

But this is a discussion of what CMS is seeing as future directions around quality measurement, so we appreciate everybody's input. Next slide.

Thanks. I think all of us have the same view, to use impactful quality measures to improve health outcomes and to deliver value by empowering patients to make informed care decisions, and also, by reducing burden to

clinicians and making measures meaningful to clinicians. Next slide.

There are four, and really, five, because there's another goal woven in this goals of the CMS Quality Action Plan, and let me just backup for a moment. There are a number of quality frameworks that exist in the country, and as many of know, and some of you participated in, last year, HHS, Health and Human Services, put together a group to advise around what I'm going to call the quality measurement enterprise.

And there were numerous stakeholder meetings regarding that and they put forward a HHS quality roadmap that has a lot to do with the quality measurement enterprise. It was released in May. And they've had three major findings.

One is to align, and streamline, and simplify quality measurement. Two is to really work on the data that underlies quality measurement. And three is to put in an external governance body over quality measurement.

All of those are sort of, in way or

another, underway. There is a team at HHS who is working on the HHS roadmap. It does involve CMS, VA, DoD, and others, so I'm sure all of us, there will be more to come on that, but CMS has been working for, frankly, decades on quality measurement and value-based incentive plans that we think have been essential and bedrock foundations to having moved the quality conversation forward in the United States, and improved healthcare outcomes for beneficiaries.

So the CMS action plan that we have been revising and re-framing, and have had significant external stakeholder on already, has, as I mentioned, four goals.

The first is to use Meaningful Measures and our Meaningful Measures Framework that we're revising, which you'll see, just streamline quality measurement, and to align quality measures across the enterprise from across CMS to all payer.

The second is to take the measures that we're using and leverage them to drive value

and to drive outcome improvement with modernizing many of our CMS value-based incentive programs, and we'll speak of that in a moment.

Next is to improve quality measure efficiency by transitioning to fully digital measures, which then allow us to also to use advanced analytics.

The fourth is, really, empowering patients to make best healthcare choices by promoting more patient-centered quality measures as well as more understandable public transparency.

This could include things like measures on shared decision making or goals of care, and it also includes more patient reported outcomes.

You may note that equity is not on here as a fifth goal. We have woven the conversation of equity into all four of these, but I'll be interested in your feedback about what's the best way to present equity, because clearly, that's very important and would be

interested how you all feel we should call that out. Next slide.

Many of you are familiar with Meaningful Measures 1.0, I know I've talked about this in the past two MAP meetings that I have been at. We had 6 areas of domain and 17 different focus areas, and with this, actually, we started aligning measures, certainly, across CMS, as well as in other alignment efforts.

And with this have also reduced the number of measures and shifted more towards outcome measures. Sam, if you could go to the next slide, please. You'll see that we've had accomplishments, really, by using this Meaningful Measures Framework since its inception, really, in 2017.

We've had a 15 percent reduction in the overall number of measures. I know we're frequently quoted as having thousands of measures in the value-based programs, we don't. We actually, in the Medicare fee-for-service programs, have, as of this year, 460. And

overall, we have also moved towards a higher percentage of outcome measures than process measures. You can see that the percentage of process measures has dropped from 52 percent to 37 percent. And streamlining measures has actually resulted in millions of dollars of savings and millions of burden hours reduced. The next slide.

CMS is working through Meaningful Measures 2.0. It was actually introduced at the CMS Quality Conference in February, a year ago, which feels like a lifetime ago, I recognize, and we're continuing to seek feedback on this, and I suspect it will change again, but let me take a moment to sort of walk through the house diagram.

The true north then is patients, and that's what you see, patients, at the top of the arrow, and we have seven specific domains, although we have eliminated the 17 different areas of focus to make it more streamlined.

Person-centered care, patient safety, and I will say we've had some pointed

conversation about if that should be patient safety, or healthcare safety, or person safety, or just safety, because obviously, we want to embrace workforce safety, and facility safety, and other.

Chronic conditions, seamless communication, which is also partly care coordination, affordability and efficiency, wellness and prevention, and we added behavioral health and substance use disorder, recognizing just how important behavioral health is here.

And this is all built on the foundation of the voice of the patient. We have spoken of the goals already. We're going to pause here and ask Sam if we could maybe open this up for public comment.

What I'd love to hear input on is, so looking at Meaningful Measures 2.0, are we missing something? I asked some specific questions, I know, around equity or calling patient safety, are there things that you think we are missing, or should add, or takeaway, or

what are your comments on, kind of, just this overall view of Meaningful Measures and the goals of the CMS action plan is. Thanks, Sam.

DR. STOLPE: Thanks very much, Dr. Schreiber. Wanted to, especially, give a hat to Dr. Scott Fields, raised his hand right away, so invite you to follow suit from Dr. Fields. If you have a comment to share with CMS at this time, we'll be recognizing you in the order that your hands are raised.

I'll hand it over to Scott for your comment.

MEMBER FIELDS: Thanks very much. I would just encourage, including diversity, equity, and inclusion overtly in your presentation. For instance, on this slide, I feel that that should be one of the primary goals as an example.

And you said it was woven into the other slide, but it's not visual, and I would just -- I think that that's actually the problem, to some extent. We're not being overt about the

issue and I would encourage us to do so.

DR. SCHREIBER: Thank you.

DR. STOLPE: Moving on. Helen.

MEMBER BURSTIN: Thanks so much. Very much building on Scott's comment. And thank you, Michelle, for that. I feel like I've heard it many times, but it's always illuminating. I want to reflect on your comment about equity, and again, this many sound a bit historical, but as somebody who was also around for the initiation of the first National Quality Strategy, when we did it at NQF, we had this exact conversation about equity.

And I think every time equity is just not on the page and listed as a cross-cutting priority, it does not happen. And so I think, given everything we've seen this year, particularly around fully needing to embrace, not just -- you know, not just equity, but actually, understanding what are the structural -- you know, how structural racism comes into play, issues around access are going to be critical

going forward, and I think I would really encourage CMS to make it its own domain, not keep making it just a cross-cutting thing.

Every time something is woven into something else it's, to Scott's point, it is not seen, and I think this is the year for CMS to make it seen. It's certainly something that's a huge priority for all of our societies, and it's time to just put it up front and center.

And then think about, actually, what are the measures we need that reflect structural racism and barriers, and rather than just, you know, stratifying by quality measures as helpful in terms of looking for disparities, but it won't get us to the underlying issues that are driving those disparities, and I hope CMS is ready to -- I know you are, and I hope CMS is ready to take that on. Thanks.

DR. STOLPE: Moving to Rob Fields.

CO-CHAIR FIELDS: Thank you. The other Dr. Fields on the call. Appreciate the comments. One, the, sort of, mechanics comment

and just in terms of future guidance and then another one, sort of, more subtle example of the equity piece.

The mechanics one is on the electronic and digital measures. I know there's certainly a push in the programs I'm most involved with at the MSSP to move to eCQMs pretty quickly, and just a voice of caution from someone who's operating in this space on a daily basis, that the eCQMs are just not ready and I mean, I think I'm expressing concerns, not just from ACOs, but from others across the country that, moving too fast without the vendors coming along and developing the way they need to in terms of the specs, are -- is a significant problem when it comes to using eCQMs for payment, because they're just not ready.

They're not like-for-like across different platforms. I can give you a very concrete example of a vendor that, in the not too distant past, told me that their reporting module was actually not meant for clinical care, so it

allowed for things like when someone suggested they were getting their breast cancer screening from their GYN, somebody could just type in a blank, you know, going to get it at their GYN, and it counted as complete, for example.

That's just a tiny example, but you can extrapolate from that. There are many, many dozens of ways where eCQMs just don't function because there isn't a standard way to measure completion of the measure in any particular platform.

So I just -- I worry a lot about that moving forward in terms of the mechanics of the programs and encourage the Federal Government to -- and I know they have, but continue to do whatever they can on the vendor side to make those standardized across the country and across platforms.

The second piece has to do with equity, but in a more subtle way, that there is a piece about including all payer data, which is also a move, actually, on the eCQM side to have

all payer data included in those quality standards.

And there is -- our most vulnerable patients, a disproportionate share of our most vulnerable patients, are cared for in FQHCs, for example, and in other areas, and so when you're comparing all payer data, when you're payer mix is predominantly, you know, either uninsured or Medicare/Medicaid, compared to healthy commercial patients, while I'm not a fan of risk adjusting based -- of quality measures based on payer mix, there are different benchmarks that have to be considered to make things like-for-like.

So if you have an FQHC and you compare them with a outpatient clinic that has primarily young commercial patients in it, or younger commercial patients in it, of means, it is much more difficult to perform at the same level.

And so would encourage, from a policy standpoint, to think about the implications of that. If you are reducing payment or affecting

payment to areas where you're caring for a disproportionate share of vulnerable populations, that that could be an issue.

DR. SCHREIBER: Thanks. Sam, how about if we take, maybe, one more comment and then we'll move on?

DR. STOLPE: Thanks, Dr. Schreiber. Wendee Gozansky has her hand raised.

MEMBER GOZANSKY: Thanks. I really just wanted to add on from the perspective that I think that actually calling out equity and being really specific about what it is that we need to do will get us to a new place, and then I also wanted to echo the concerns about the electronic measures, and that I just don't think we're quite there yet.

So really, just wanted to reinforce the points that have been made. Thank you.

DR. SCHREIBER: Okay. Well, thank you for your feedback. We have certainly heard the equity issue loud and clear, and at CMS, we do take it very seriously. I'm sure this is going

to be top of mind in the new administration as well, but many of you who know me know that I've been a primary care physician in the City of Detroit for many years.

This is something near and dear to my heart also, as Helen knew, when she alluded to knowing how I felt about it, and I suspect you're going to see our little house diagram change.

It is a very important topic, and actually, towards the end of this, have some thoughts on some specific steps for equity. Sam, if we could have the next slide, please.

So I want to walk through some of our specific goals and then pause at the end of that to, again, seek comment from all of you, because, really, your input is just incredibly valuable.

So the first is using meaningful measures to streamline quality measurement and really, to align to quality measurements. So we have used the Meaningful Measures framework to -- we annually look at every measure that is in every one of our programs.

We retire measures as appropriate if they are topped out, if they're no longer clinically relevant, if the evidence has changed, if there are one-off measures, you know, some that are similar to others, and as you've seen we have retired a number of measures.

At the same time, we also use this to identify measure gaps and to prioritize the development of measures and to be making multi-year plans, actually, for, maybe, replacing some measures as we development others.

So there's been a tremendous amount of alignment work that is ongoing. Some of it, I'm sure you're participating in or are familiar with, there are alignment efforts across CMS, which means CMS' fee-for-service, the Medicare Advantage Programs, the Medicaid Programs, the CMMI programs, the Marketplace programs, to try and align that.

We have active work going on with VA and DoD, and we'll be extending across the Federal Government, and as well, there's the Core

Quality Measures Collaborative with NQF, CMS, and AHIP, America's Health Insurance Plans, to try and development standardized core measure sets, these are all ambulatory, to be used by all payers.

We're also looking to shift the type of measures towards, as you've heard, more outcome measures, less process measures, but I do want to be very clear, there is still a role for good process measures, frankly, as well as structural measures. Next.

We look to use the meaningful measures in our programs. It's the programs that actually provide authority for public reporting, as well as payment incentives and penalties tied to this, which we really think has been instrumental in moving the needle, quite honestly, around public transparency.

We're working hard to modernize all of our programs for clinicians. Most of you know of the plan transition of MIPS to MIPS Valued-Based Pathways, which are meant to be smaller, more

cohesive, sort of, sets of measures that tie together, so quality links to the improvement activities, to the cost measures, to promoting interoperability, with foundational measures that also gear towards population health.

We are developing these in close collaboration with many of the specialty societies so that these will be much more relevant to individual clinicians and their practices.

We're also continuing to look at and modernize other of the value-based incentive programs. For example, this year, we introduced rule writing to revise hospital stars based on a lot of public feedback.

We have now, in the Consolidated Appropriations Act that, frankly, was recently passed, as part of COVID funding, an expanded skilled nursing facility value-based program that had had just one measure, but we have congressional authority to improve that and have a more comprehensive nursing home value-based

program.

We're looking to provide additional confidential feedback and to be incorporating robust quality measurement in all of the pilot CMMI innovation models as well.

So we're working very hard to really streamline and modernize the value-based incentive programs as well. Next.

Thanks. As some of you have alluded to as well, you are very well aware of CMS' desire to move to fully digital measures. And I will say that the administrator announced our intent to move to fully digital measures in 2030, and has also increased that timeframe to publicly announce a move to all-digital measures in 2025.

Many of you will see on the MUC list that we have a preponderance of measures, actually, that are digital. Now, we take a board view of what a digital measure is, right?

So, obviously, there's the traditional eCQM, which I recognize many of the challenges with. I, myself, have implemented

many electronic medical records, I've sat on Epic safety committees, Cerner academic committees, I'm deeply embedded with electronic medical records from my history, and we recognize the challenges, but also think that, really, we have to move forward with digital measures for several reasons.

Number one, it's the only way to get all of this information and make sense of it. Number two, it's a way to be able to provide more rapid feedback reports to organizations to kind of create that learning network.

So rather than quality and quality measures being so retrospective, we need to make them, you know, if not real time, certainly closer with feedback that is more timely.

And then finally, the ability to leverage digital information to use whatever you want to call it, advanced learning, machine learning, neural networks, artificial intelligence, but to really be looking at measures, we think, in an entirely different way.

This also allows the ability to look at all payer data, and so we think that it's essential. When done right, it will also reduce burden, although, please don't misunderstand me, we understand the work up front in building these, and in embedding these, and really, figuring out the workload that it takes to make these function, but nonetheless, we are fully behind the transition to digital measures and think that that's a key part of this strategy. Next slide, please.

And I want to speak about, sort of, this patient-centered notion. Equity and diversity, in part, comes in here, in part, it comes with some of the other strategies, such as providing confidential feedback information that is stratified based on, possibly, race and ethnicity, or certainly, by duals, but making sure that within our programs and our measures, we're developing measures for social determinants, but here, person-centered care also embraces diversity and equity, because I don't

think you can have true quality without equity. We see them as two sides of the same coin.

But patient reported and measures and the voice of the patient is fundamentally important and we believe that when you, sort of, turn on, as it will, patient reported outcomes and patient reported information that, we'll view healthcare, frankly, in an entirely different lens.

So CMS is committed to increasing patient reported outcome measures by 50 percent, by ensuring that we have measures that are patient centered, such as shared decision making and appropriate goals of care being met.

We've also been working hard to make transparent information more understandable and actionable for patients. Many of you have seen that we revised all of our compare sites this years, just several months ago, to make them actually easier to use and introduce the provider data catalog that has much more information that's available for clinicians and researchers.

We're also, this goes back to the conversation on digital measures, really, leveraging FHIR and FHIR APIs for a quality measurement, and for our quality measures, but also, we've been using it to allow patients to receive their health information electronically, so patients, through MyHealthChart, or through Blue Button, can actually access a lot of CMS claims information through FHIR APIs.

And so FHIR APIs is something that CMS is actually leading the efforts with and in concert with ONC. Next slide.

And finally, leveraging quality measures to highlight disparities and close performance gaps. I spoke of the confidential feedback reports. We have plans to introduce how we can close some of the equity gaps by leveraging pay-for-performance programs and incentives, working on developing appropriate social determinants of health measures, stratify measures, certainly, by duals, and I have another thought on that in the future, and we're

partnered with the Office of Minority Health regarding the use of HES scores, which is the health equity score, to feed back to organizations and providers, how they are doing.

Fundamentally, we also think we have to engage, certainly, hospitals and then other facilities, and ultimately, clinicians in looking at their data, based on REL, so that they can be making the best decision.

All right. I've said a mouthful. Let me pause here, and, Sam, if you will, wouldn't mind facilitating some comments back on these goals. Thanks.

DR. STOLPE: Excellent. Okay. We'll open it up. We've got some hand raised already, but just to reiterate what Dr. Schreiber has covered, so we'd invite your comments on the goals to streamline quality measurement, to drive value and outcome improvement, to improve quality measures through the use of digital measures and analytics, to empower patients to make the best healthcare choices through patient-directed

quality measures and public transparency, and lastly, to leverage quality measures to highlight disparities and close performance gaps.

So please provide comments based on those five goals that Dr. Schreiber articulated. We'll begin with Scott.

MEMBER FIELDS: Thank you. I just wanted to focus on the issue of the alignment of the measures and just reinforce how important it is that CMS work collaboratively with the states as well as with private payers to go beyond aligning and to have those core measures that you described actually be identical.

So to move from alignment to them being the same will decrease the burden that practices are dealing with on a daily basis, and decrease costs significantly. The fact that CMS has its standards, Medicaid has its standards, every health insurer has its standards, they're all the same standards, but they're really not the same because the numerator or denominator is just a little bit different, and that's a real

problem.

DR. SCHREIBER: And just, Scott, to your point, at least across CMS, that is what we're looking at, to make them the same. I will say, though, that for every time I've had this conversation, somewhere there's pushback about how they can't be the same, and the populations are different, so I think we just have to recognize that it's not straightforward.

MEMBER FIELDS: Of course. I accept that, but I just, at a time when our system is stretched to the max, the burden that this places on the practices is not insignificant.

DR. SCHREIBER: Now, please recognize, I'm not disagreeing with you.

DR. STOLPE: Thank you. Moving to Caroline.

MEMBER REINKE: Morning, everybody. Thank you for that overview. I just want to comment on the concept of transparency of data and public reporting as an option to empower patients.

I'm unaware of any data that demonstrated that that is something that's frequently used by patients to make healthier decisions and I'm just concerned that relying on the patients to do that wholly without closing some other gaps in our system could not be a straightforward process.

DR. SCHREIBER: Thank you.

DR. STOLPE: Thank you, Caroline. Any other comments?

DR. SCHREIBER: You know, if there's no comments, I'm just going to assume you all agree with us.

MEMBER MCGIFFERT: This is Lisa and I thought maybe I would just piggyback on the last comment. I think often, the measurements that are being done, and I've been involved for decades on this, are really, sort of, being done to help providers improve their quality.

That's sort of their -- the goal, it seems, and often, those measures don't translate to patients. So I think that the struggle is

getting something that's reliable and with evidence, and how do you translate what that means to the public.

And just as an observer and a participant, I think the people responsible for creating the measures are very cautious and mindful of the provider's viewpoint, and thus often, you get something that isn't really that clearly understood by patients or the public on why these measures are important.

So a lot of it's in translation.

DR. SCHREIBER: Thank you.

DR. STOLPE: Thank you. We'll go to David Seidenwurm and then William Fleischman.

MEMBER SEIDENWURM: Hi. Thanks for the information and always great to see you. I was wondering, is the harmonization process also going to include the direct contracting entity that comes in a different pathway, but I'm wondering if that's part of the harmonization project or is that divergence from the current approach considered a pilot project that would

merit independence.

DR. SCHREIBER: Can you define for me exactly what you mean by the contracting entity?

MEMBER SEIDENWURM: Yes. CMMI-DCE project.

DR. SCHREIBER: Got it. You know, the CMMI projects are a little bit different, to be honest with you, and they work in a somewhat different way, and part of it has to do with how they can measure success, but I will tell you that all of the CMMI projects, CMMI is part of CMS' work for alignment, and they're more and more engaged.

I personally sit on many of their committees, so the answer is, yes, this will ultimately, and does, in many ways, include CMMI.

MEMBER SEIDENWURM: And just a quick follow-up, if it's permissible, in order to improve, and develop, and innovate, divergence from harmonization is almost a requirement. How does one balance that?

DR. SCHREIBER: Isn't that the

million-dollar question? I think you're absolutely right. There have to be opportunities to innovate, as CMMI does, opportunities even for new measures, as we have places where we introduce new measures without penalties, such as the hospital IQR programs, and I think that obviously has to remain.

But it doesn't mean, because, you know, I think we're hearing over and over again, we've heard it on this call, you know, the burden of having so many different measures is not to be underestimated.

And so although there has to be a pocket, clearly, of innovation, I think that, overall, reducing the burden remains to be something that we, as all of us are, stewards of this quality measurement enterprise, need to be working to make burden less.

DR. STOLPE: William Fleischman?

MEMBER FLEISCHMAN: Thank you and actually, just taking off what you just left off, Michelle, the challenge in driving to digitizing

all the measures by 2025 will be to do that while not increasing the burden, because when you're removing the burden from organizations on extraction, you can see immediately where it'll go.

We'll become even more click-boxy and computer doctors, and providers, and nurses, as opposed to being at the bedside, so that is the challenge, and that I think CMS, and the measure creators, and us, as a review group, will face to not shift the burden on to the people that are documenting into the EHR.

DR. SCHREIBER: Yes, and actually, let me just piggyback on a comment there for a moment, because you're right, obviously. Even on NQF committees, as all of these measures are going to be considered, we need to develop our expertise of exactly what it takes to have digital measures, because the workflow that it takes, it's not just, you know, changing a box or something that's more IT tech, it's, what is the workflow that it takes, because we have to be

careful that that is, kind of, seamlessly part of the clinical care, and therein lies the challenge.

But when done right, and we've seen this, we've seen this in many occasions, it really does and can work well. It can be integrated seamlessly into the clinical workflow as well as the clinical decision support that follows.

Perhaps a bit optimistic, shall we say, but we know it can be done. Sam, maybe just one or two more comments.

DR. STOLPE: Great. We have hands raised by Rachel Brodie and then Helen Birstin.

MEMBER BRODIE: Okay. Thank you. Hopefully you can hear me. I wanted to comment on the empower patients objective just to say that, you know, I'm very pleased to see, you know, the effort and, you know, that's recognize by CMS to increase patient reported outcome measures by 50 percent.

Related to that, I just know that from

other committee work that I've done, you know, from working with CQMC on the core measure sets, et cetera, that there's often pushback on PROMs because folks recognize that they're harder to do, that it requires changes in workflow, patient engagement, data infrastructure that may not exist.

So if there's ways to -- you know, for -- to encourage CMS and other payers to consider payment models that would support and incentivize providers to do that up-front investment, and reward them for building that capacity, because, you know, PROMs, they just continue to get kind of shot down in these forums, and so just think about that.

And just a quick comment on the health equity comments before. If there's mechanisms or policies that CMS can put in place to make sure that the data is available and collected to support those measures, because, I mean, what we see is that it's just, we don't know -- we can't measure some of these things because we're not

collecting the data, so anyway. Thank you.

DR. STOLPE: Dr. Burstin?

MEMBER BURSTIN: Thanks so much and very much agree with what Rachel just said. Delighted to see PROMs there. I think we all would love to work collaboratively with you, Michelle, and CMS to think about what that path looks like. I think it's really critical that it be part of this next generation of measures.

I do want to make a comment about affordability and cost, which is in the house as well, and I know we're going to talk about some of the episode-based cost measures later today that are proposed for the MIPS program, and I just think it's important to remember that at least a lot of the work we did at NQF around measures around cost was really with the recognition that they should always be looked at alongside quality measures.

And I know that that's not the case for what we're talking about this afternoon, so maybe just a future thought discussion as well,

is really thinking about how we can, in fact, be able to start looking at costs and quality at the same time.

We proposed some work several years ago looking at different models of doing that, a threshold model, for example, that you would only look at quality once you've reached a threshold a cost and about five other different methods, but I think the ability to look at those together will increase our ability to really move more rapidly to understanding, truly, the impact of costs and resource utilization, and ensuring that we're not seeing lower costs as a result of stinting.

DR. SCHREIBER: Yes, thanks, Helen, and let me just comment on that for a moment before we move on. We're hoping that one of the vehicles to do that are, indeed, the MIPS value pathways, because they are measure sets around improving a certain area, such as improving prevention, I'll just use that as an example, that tie cost measures relevant to that area with

quality measures, and frankly, with improvement activities as well, along those same lines so that they are tied together.

So that is, perhaps, at least one vehicle moving forward. Thank you, all, for your comments. I would also encourage any of you, if you have other comments or thoughts, if you put them in the chat, I know NQF will be collecting them and including them as a report back.

Please, feel free to reach out, call me, email me, NQF certainly knows how to find me, as do many of you, because the more we can have these open discussions, the better CMS can do with putting these ideas out there.

One of the advantages of CMS is signaling things like how important patient reported outcomes are, digital measures are, really does engage others in the community, like the EHR vendors, for example, to be taking note and hopefully moving along with us in these directions, so your feedback is very much appreciated.

All right, Rachel. I'm going to get to an issue that you recently raised about data supporting equity. If we can have the next slide, Sam. Keep going.

We recognize that, frankly, we have to put efforts into collecting appropriate data on race, ethnicity, and language in order to stratify measures, in order to actually have data to make decisions around equity, because the reality is, we don't.

Many organizations create -- actually, collect race, ethnicity, and language data, CMS does not have it. Many organizations actually don't have it. And you can see that as we try and do stratified reporting, the sensitivity and specificity around race and ethnicity, in some cases, is okay, but particularly for ethnicity, look at the sensitivity for the Hispanic/Latino population, it's terrible.

And for some other ethnic communities as well, so we won't have the ability to make

correct decisions or policy if we don't have correct data. So, Rachel, you had a perfect segue. Thank you so much.

One of the things that CMS is talking about and considering doing, and I bring this to you for your feedback today, is whether or not we should be using some indirect models to impute, as it were, race and ethnicity.

So, Sam, may I have the next slide, please? We know that there are several methods for the indirect estimation of race and ethnicity. There's one by RTI, there's one by Rand, these are commonly used in some programs, NQF and the Institute of Medicine have actually supported indirect estimation for population based equity.

And you can see, compared to the last data that I showed you, the correlations are actually much better than what we have with our current data when it comes time to determining between Whites, and Blacks, and Hispanics, and other ethnic populations, using indirect

estimation actually does provide, although not perfect, better data.

But we also recognize that there's a sensitivity around imputing what race and ethnicity might be. So an individual might say, well, I'm just married to somebody whose name, you know, is a more Latino name, but that's not me, and yet, in an indirect estimation, that person who married somebody is going to be categorized as being Hispanic.

And so there are some challenges with doing that. So I'm asking your feedback, and we'll throw this last topic open for discussion, of what are your thoughts of CMS using indirect estimation and really models that impute race and ethnicity in confidential feedback reports?

So I talked about providing more confidential feedback reports with stratification, largely using dual-eligibility, because certainly, we have that data, but I'm looking for feedback on, should we also maybe even do pilot programs of providing information

back to providers, and certainly, organizations on stratification, based on using indirect estimation for race and ethnicity.

I think we have one final slide on this one, Sam. Okay. And that, I think, just basically sums up what I said. So we have just a couple of minutes left. If we can throw this open for conversation, Sam, and then I know I'm standing in the way of break, so I'm sensitive to time.

DR. STOLPE: Very good. Thanks, Dr. Schreiber. We'll go with Scott Fields first.

MEMBER FIELDS: I don't always need to be first. Sorry. I appreciate the fact that getting this information is hard, and therefore, using a statistical method is okay, but I would argue that we spend so much time trying to get accurate data that if it's important to get, which I think this is, we should get it.

And I would encourage more effort in getting the data and using the real data, if you will, than trying to infer from populations. So

my thought would be to put more effort into the collection of data, which, I appreciate, is a burden.

So I -- which I'm kind of against, in a general sense, so but I, like you mentioned, worry a lot about inference and using data in that way.

DR. STOLPE: Thank you. Amy Mullins.

MEMBER MULLINS: Yes, I just want to agree with what Scott just said. I think that we really need the real data. And like you said, there's health systems that are gathering that data, physicians gather that data, I think if CMS wants that data, they need to gather that data.

You know, I had two anecdotes just pop in my head as you were talking. My brother-in-law is full Hispanic; his last name is Brown, because he's adopted. I have a girl I go to church with who is, her last name is Hodge (phonetic). Her family is White; she is African-American, because she is adopted.

I mean, you're just not going to get

accurate data. And if we want accurate data, we need to gather that, and there are ways to do that. Lots of people are doing it, so let's do it.

DR. STOLPE: Helen Burstin?

MEMBER BURSTIN: Thanks so much, Michelle. I think this is an incredibly important topic. I guess one question might be, is this really something to be thinking about at the clinician level or is this really an opportunity, I think, for CMS to think about some of your more population health oriented kind of measures as a starting point.

I think if, you know, the indication of being able to look at a community, and a community's quality and equity, I think is a really interesting opportunity, and may be an easy way, while we work on getting the individual level data, to at least get your feet wet with it.

Certainly, when we did a webinar this summer on COVID-19 and clinical disparities,

Kirsten Bibbins-Domingo from ECSF was able to just present extraordinary data, looking at sub-census tracks, and looking at, you know, particular essential worker groups who were Latino, who were not getting tested with high rates of COVID.

That's how I hope we would at least rollout some of the community-based equity indicators as a way to keep pushing this forward as, maybe, a first step.

DR. SCHREIBER: One more comment, Sam.

DR. STOLPE: Any other comments from MAP? I'm not seeing any other hands raised, Michelle. Oh, David --

DR. SCHREIBER: All right.

DR. STOLPE: -- at the buzzer. David, go ahead. You're still muted, sir.

MEMBER SEIDENWURM: Yes, I have one question, this would -- these methods would only be employed, if I understand correctly, when the patient or the provider did not include the information somewhere else, or the information

was otherwise unavailable.

If the patient, for example, checks off the decline to state, would there be any ethical concern with imputing their race when they had thought that that was, you know, irrelevant, or improper, or for some reason, for some other reason, they preferred not to report?

DR. SCHREIBER: I actually don't know the answer to that. Definitely worth thinking a lot about.

All right. Well, Sam, thank you so much for facilitating and to all of you today. I hoped to provide, sort of, a window of insight as to some of the directions that CMS is thinking about quality measurement, certainly in terms of aligning, simplifying, moving towards digital measures, increasing the voice of the patient and conversations about equity.

Please feel free to submit comments, even on chat, or back to NQF, or to myself. I really very much value everybody's feedback and opinions, and thank you very much, and, Sam, turn

it back to you.

DR. STOLPE: All right. Very good. At this time, we are going to allow for any questions from the workgroup before we go to break, and if you have a question, feel free to just jump in. No need to raise your hand.

MEMBER FIELDS: Actually, Sam, I have a quick question. Michelle, I was wondering if you could comment on the role of the core quality measures collaborative and the harmonization piece, especially in things like, you know, the MSSP and the various programs.

I ask specifically because of the newly-published measure set for the MSSP was a little bit of a departure there, or a significant departure, I think, depending on who you ask. Certainly in terms of the number of measures that, you know, based on what the CQMC has as their ACO measure set, but also on the specs on the ECQM side.

And I'm wondering if it's still the goal of CMS to use that -- the core quality

measures collaborative as a substrate, if you will, for that.

DR. SCHREIBER: It is. And so we're making every effort to use the CQMC. We're obviously a sponsor and an active participant in the CQMC, but some programs haven't completely incorporated that, but are in the process of doing so, including Medicaid has this on their list to do.

And I'll also add, I don't want to speak for them, but that's under active conversation by both the VA and the DoD, and so the intent is definitely there. I hope that answers your question.

MEMBER FIELDS: It does and I don't know if you have any --

DR. SCHREIBER: It doesn't answer your specific question about MSSP.

MEMBER FIELDS: But the broader question, yes, it does. Thank you.

DR. STOLPE: All right. Well, let's go to break. We're a little bit over, but a very

big thank you to Dr. Schreiber for the presentation and for the conversation. We'll return at 11:30 Eastern Time to begin our overview of the MAP pre-rulemaking process. Thank you. See you in a few.

(Whereupon, the above-entitled matter went off the record at 11:24 a.m. and resumed at 11:31 a.m.)

DR. STOLPE: Okay, everybody, let's go ahead and get started with our next section. We'll now be doing an overview of the pre-rulemaking approach, and this'll be led by my colleague Chris Dawson. Chris, over to you.

MR. DAWSON: Okay, thank you, Sam. So before we allow the co-chairs and Sam to move into discussing the actual programs and the measures, we'll do an overview of the pre-rulemaking approach.

And so we'll discuss the preliminary analyses, the decision categories, the voting process, and the MAP World Health Charge.

So we'll start with the preliminary

analyses. So next slide, please. So for all measures under consideration, NQF completes a preliminary analysis of the measures to provide MAP members with a succinct profile of each measure, and to serve as a starting point for MAP discussions.

To complete these preliminary analyses, NQF's staff use an algorithm developed from the MAP measures selection criteria, which was approved by the MAP coordinating committee. Slide.

So the preliminary analysis algorithm includes seven areas of assessment. And please note that for each assessment area, MAP may provide a rationale for the decision to not support, or make suggestions on how to improve the measure, or potential future support categorization, as applicable.

The first assessment is to assess if the measure addresses a critical quality objective not adequately addressed. The measures in the program, measures that are under review.

This is defined as if the measure addresses key health care improvement priorities, such as CMS's Meaningful Measures framework, or the measure's responsive to specific program goals and statutory or regulatory requirements. Or the measure can distinguish differences in quality as meaningful to patients and consumers and providers, and/or just as a high-impact area or health condition.

If this criteria is met, the review can continue. And if not, it will receive a recommendation, do not support.

The second assessment is to determine if the measure is evidence-based and either strongly linked to outcomes or an outcome measure.

You can see here that for process and structural measures, the measure has a strong scientific evidence base to demonstrate that, when implemented, it can lead to the desired outcomes, while for outcome measures, the measure has a scientific evidence base and a rationale

for how the outcome's influenced by health care processes or structures.

This criteria's met, the review can continue, and again, if the measure is not met, this criteria is not met, the measure will receive a recommendation of, do not support.

The third assessment is to determine if the measure addresses a current quality challenge, such as a topic with a performance gap, a serious reportable event, or unwarranted or significant variation in care, that is evidence of a quality challenge.

If the measure does address a quality challenge, the review can continue. If not, the measure will receive a recommendation of, do not support. Next slide, please.

The fourth assessment is to determine if the measure contributes to efficient use of measure resources and/or supports alignment of measurement across programs.

For this, the measure is either not duplicative of an existing measure, or measure

under consideration in the program, or is a superior measure to an existing measure in the program, or the measure captures a broad population, or it contributes to alignment between measures in a particular program, or the value to patients and consumers outweighs any burden of implementation.

This assessment is met, the review can continue. If not, the highest rating can be, do not support, with potential for mitigation.

The fifth assessment is to determine if the measure can be feasibly reported, which is defined as the ability to be operationalized.

If the measure can be feasibly reported, the review can continue. If the measure cannot be feasibly reported, the highest rating can be, do not support, with potential for mitigation. Next slide, please.

The sixth assessment is to determine if the measure is applicable to and appropriately tested for the program's intended care setting, levels of analysis, and populations.

The measure would meet this criteria if it is NQF-endorsed or fully developed, and full specifications are provided, and measure testing has demonstrated reliability and validity.

The assessment is achieved, the measure can be supported or conditionally supported. If not, the highest rating can be, conditional support.

The seventh and final assessment is to determine if the measure is in current use and no negative unintended issues to the patient have been identified. This is determined through feedback from implementers and/or end users with the feedback being supported by empirical evidence.

If no implementation issues have been identified, the measure can be supported or conditionally supported. If the implementation issues are identified, the highest rating can be, conditional support. Next slide, please.

Before we pause for questions, we will

take a moment to review the MAP voting decision categories. Slide. So there are four decision categories which MAP may recommend, and you can see their definitions and evaluation criteria listed here.

Support for rulemaking demonstrates that MAP supports implementation with the measure as specified, the measure is fully developed and tested in a setting where it will be applied, and meets Assessments 1 through 6 of the algorithm that we just discussed. If the measure is in current use, it also meets Assessment 7.

Conditional support for rulemaking demonstrates that MAP supports implementation of the measure as specified, but has identified certain conditions or modifications that would ideally be addressed prior to implementation. The measure meets Assessment 1 through 3, but may need modifications.

Designation of this decision category assumes at least one Assessment of 4 through 7 is not met. Ideally, the modifications suggested by

MAP would be made before the measure is proposed for use.

Do not support for rulemaking, with potential for mitigation, demonstrates that MAP does not support implementation of the measure as specified, but agrees with the importance of the measure, and has suggested material changes to the measure specifications.

The measure meets Assessments 1 through 3, but cannot be supported as currently specified. Designation of this decision category assumes at least one Assessment of 4 through 7 is not met.

And then finally, do not support for rulemaking demonstrates that MAP does not support the measure, and it does not meet one of the first three assessments.

And so we'll pause here to see if you have any questions about the criteria used in conducting the preliminary analyses or the decision categories.

(No response.)

MR. DAWSON: Okay. So we will move on here, and on, we'll move on to the MAP voting process. Next slide, please.

So we'd like to highlight several key principles of the voting process. First, quorum is defined as 66 percent of the voting members of committee present in person or by phone for the meeting to commence.

Quorum must be established prior to voting, and the process to establish quorum includes taking roll call and determining if quorum's present. If the quorum is not met, MAP will be able to vote via electronic ballots after the meeting, if necessary, during which we will send a recording of the meeting and all relevant materials.

MAP has established a consensus threshold of greater than or equal to 60 percent of the voting participants voting positively, and a minimum of 60 percent of the quorum figure voting positively.

If any member needs to recuse

themselves from voting on any given measure, please note that those abstentions do not count in the denominator.

And then lastly, please note that every measure under consideration will receive a decision. Next slide, please.

There are five steps within the work group voting procedure. Step 1 is for staff to review the preliminary analysis for each measure under consideration, using the MAP selection criteria that we previously reviewed, along with programmatic objectives.

During this step, co-chairs may choose to present similar measures of the group in the interest of time, or to prevent redundant conversations. However, any work group member can request any item to be removed from the group and discussed individually if desired.

Step 2 is for the co-chairs to ask for clarifying questions or concerns from the work group, then compiling this information once received. As your developers, we'll respond to

questions and concerns on measure specifications, and NQF staff will respond to questions and concerns on the preliminary analysis.

Step 3 is voting on acceptance of the preliminary analysis decision. After the previously-mentioned questions and concerns have been resolved, the co-chair will open for a vote on accepting the preliminary analysis decision, framed as a yes-or-no vote.

If greater than or equal to 60 percent of the work group members vote to accept the preliminary analysis assessment, then the preliminary analysis assessment will become the work group recommendation.

If less than 60 percent of the work group votes to accept the preliminary analysis assessment, then discussion will open on the measure. Next slide, please.

Step 4 is discussion and voting on the measure under consideration. So during this step, the lead discussers will review and present their findings, responding to the preliminary

analysis, stating their own point of view, including if it is in alignment with the preliminary recommendation. The MAP Rural Health liaisons will also have a summary of their work group's discussion.

The co-chair will then open for work group discussion, and after the discussion, the co-chair will open the measure under consideration for a vote.

Co-chairs will summarize the major themes of the work group's discussion with support from NQF staff. The co-chairs will determine what decision category will be put to a vote first, based on potential consensus emerging from the discussion.

If the co-chairs do not feel there is a consensus position to use to begin voting, the work group will take a vote on each potential decision category, one at a time.

The first vote will be on support, then conditional support, then do not support, with potential for mitigation, and then lastly,

do not support. Next slide.

The fifth and final step is to tally the votes. If a decision category put forward by the co-chairs receives greater than or equal to 60 percent of the votes, the motion will pass, and the measure will receive that decision.

If no decision category achieves greater than 60 percent to overturn the preliminary analysis, the preliminary analysis decision will stand. This will be marked by staff and noted for the coordinating committee's consideration. All right, and we'll pause here to see if you have any questions regarding this voting process.

(No response.)

MR. DAWSON: Okay. Hearing none, we will move on lastly to the MAP Rural Health Work Group charge. Next slide, please.

So the charge of the MAP Rural Health Work Group is to provide timely input on measurement issues to other MAP work groups and committees, and to provide rural perspectives on

the selection of quality measures in MAP.

The MAP Rural Health Work Group also seeks to address priority rural health issues, including the challenge of low case volume. We'd like to recognize Kimberly Rask of Alliant Health as the Rural Health Work Group liaison for this clinician work group. Next slide, please.

So the Rural Health Work Group reviews all measures under consideration and provides feedback to the setting-specific work groups, including relative priority and utility of measures, in terms of access, cost or quality issues encountered by rural residents, data collection and/or reporting challenges for rural providers, etiological problems of calculating performance measures for small rural facilities, potential unintended consequences of inclusion in specific programs, and gap areas in measurement relevant to rural residents and providers for specific programs. Next slide.

The feedback from the Rural Health Work Group is provided to the setting-specific

work groups using the preliminary analysis, including their discussion and voting results on suitability for various programs, and also by sending a Rural Health Work Group liaison to each setting-specific MAP work group review meeting, which, as I just mentioned, in the case of this clinician work group is Kimberly Rask.

All right. We'll pause there for any questions regarding the roles and contributions of the Rural Health Work Group.

(No response.)

MR. DAWSON: Okay. Hearing none, I will turn it to over to Sam to discuss the MIPS measures.

DR. STOLPE: Very good. Thanks very much, Chris. Now we're moving on to our main event, where we will be discussing the measures under consideration, beginning with the Merit-based Incentive Payment System measures. Let's go to the next slide, please.

Quick overview of the Merit-based Incentive Payment System, or MIPS. This is a

quality payment program. The incentive structure is pay-per-performance, in which there are four connected performance categories that affect the way a given clinician is paid.

Each performance category is scored independently, and has a specific weights. Within the 2020 weights, we have quality accounting for 45 percent of a given clinician's score. Promoting interoperability is 25 percent. Improved connectivity's at 15 percent, and cost at 15 percent, as well.

The final score serves as the basis of the MIPS payment adjustment, assessed for each eligible MIPS clinician.

The program goals, as articulated by CMS, are to improve quality of patient care and outcomes for Medicare fee-for-service beneficiaries, to reward clinicians for innovative patient care, and to drive fundamental movement towards value in health care. At this time, I'll hand it over to Rob Fields to open us up for public comment.

CO-CHAIR FIELDS: Thanks, Sam. So I would like to note, anyone that would like to make a public comment about either the program or measures, and if you do, just make sure that you limit your comments to the recommendations of the work group and any comments specifically on the measures under consideration.

(No response.)

CO-CHAIR FIELDS: Not hearing any comments, Sam.

DR. STOLPE: Let's just give it a moment.

DR. CASEY: It's Don Casey. Can you hear me?

DR. STOLPE: Oh, there we go. Yes, sir. Go ahead.

DR. CASEY: Thank you. Yeah, I just -- Don Casey, President of ACMQ -- just a brief comment about the fact that care coordination seems to have slipped off the explicit radar screen here, and that's a concern of many of us. And I'll leave it at that.

DR. STOLPE: Okay. Thank you. Lisa, I see your hand up.

DR. SCHILLING: Yeah, hi, this is Lisa Schilling. I'm the Medical Director for the Office of Value-Based Performance at the University of Colorado.

And I just want to say, I think that some of the promoting interoperability measures are particularly burdensome, and may not be aligned with the other measures. And it would be helpful if the PI measures were aligned with the other quality measures.

So I'll just say that, as an example, the reconciliation of problems and medications, we still continue to get, like, a very large kind of look-back period on that, and for a provider to reconcile those during a visit, probably takes upwards of 20 minutes. So anyway, I think there could be some, you know, refinement of that.

DR. STOLPE: Thank you. Any other comments? I'm not seeing anything in the chat, Chris. I don't know if you're seeing anything

different from what I see.

DR. SCHREIBER: Hey, Sam, this is Michelle. Can I just make one comment on a slide recently? I just want to remind the committee that the cost measures, by statute, will have to count for 30 percent by 2022.

DR. STOLPE: Thank you. All right. I think at this point, we will turn it over to CMS to review the cost measures.

DR. SCHREIBER: Can I have the slide? Okay, so let me just kick this off, and I'm going to turn to over to Ronique Evans, who is our subject matter expert for cost measures, as well as Acumen, who is our contractor who's working on them.

So as I just recently said, in the MACRA legislation, Congress mandated that we include cost measures and that it would be 30 percent of the MIPS program by 2022. So incrementally over time, CMS has been increasing the weight of the cost measure. And it will continue to do so, because this is what's

mandated.

We also need to have cost measures that clearly are more applicable to practices and to clinicians. And over time, CMS has been working on not only just using Medicare spend-per-beneficiary total cost per capita, where we have been doing a lot of work on attribution, but also in describing episode-based cost measures. So we have five of those that we're bringing forward today.

The first one in a chronic condition is asthma and COPD, and then as you can see, surgical around colon and rectal surgical reception on all our reception and then overall care of prediabetes, in this case, recognizing that that's important to the management to -- actually, no, this is cost. I'm getting confused with quality measure.

My apologies to the AMA. This is episode cost for diabetes and then for sepsis. So we will be not so much presenting them -- I know you're presenting them. We look forward to

your feedback. We are here to provide answers to any questions or clarifications. So Ronique, let me turn the conversation to you and to Acumen.

DR. EVANS: Thanks, Dr. Schreiber. Can we go to the next slide, please? So just to reiterate some of the points that you guys have already covered, I think Dr. Schreiber did a good job at kind of providing an overview for the basis of why we are pursuing the development of episode-based cost measures.

And then, just to reiterate that these five are a part of the effort to expand the subset of cost measures for the MIPS program. I think we can move on to the next slide.

So here we wanted to provide a little bit of some background information, or a little introduction into the five measures that we will be discussing, in an effort to, you know, answer some of those questions that may be lingering, prior to getting into discussion.

So these measures are constructed using the same framework as other cost measures

reviewed by the MAPs in previous years. I know you guys have probably already seen some of our procedure and acute inpatient medical and additional episode-based cost measures.

But this wave, we've introduced the chronic condition episode-based cost measures. And these are similar to the other measures that we've seen previously, but they are a little different in that these are spending an episode much longer than the procedure and acute inpatient episodes.

So they share elements from other episode-based cost measures, and the TPCC measure. And with these chronic condition measures, the attribution requires two visits to identify start of clinician-patient relationship, but also, features to account for chronic condition management were developed with stakeholder input through multiple meetings over an 18-month period.

So as you guys may be aware, episode-based cost measures are developed in waves, and

these waves are 18 months long. And over those waves, we have numerous technical expert panels held in an effort to give the stakeholder -- was heard throughout the development.

So cost measures for at least one year to reflect the ongoing nature of care and encourage care coordination, and these are tailored to capture care specific to the management of diabetes and episode COPD, and those are our two chronic condition episode-based cost measures for this wave.

And with that, I may -- I think it's a good idea to kind of open it up to my Acumen team to add any key points they think would be good before we get into discussion, and if not, Sam, I can hand it back over to you.

DR. CHORADIA: Okay, so thank you, Michelle and Ronique, for the introduction. My name's Nirmal Choradia, one of the clinicians from the Acumen team.

So we've been working with CMS on cost measures for over the past several years, and as

a quick overview, today's measures are episode-based cost measures. These are risk-adjusted measures based on Medicare spending during the well-defined episode of care.

An episode of care includes the services identifying the clinician tasked with management of the medical condition or procedure, any routine services, and any adverse outcomes that may have resulted from that care within a specified time frame, which is called the episode window.

It doesn't include services that are clinically unrelated to the initial care. These measures sum up these costs during the episode window, and then risk-adjust them to calculate the measure.

In 2021 MIPS performance period, there are 20 measures in the cost-performance category. Eighteen are based on episodes that span the range of procedures, like knee arthroplasty and acute hospitalizations, like stroke. And there are also two global or population-based measures,

which were in MIPS from Year 1, and which underwent comprehensive reevaluation in 2018. We've brought all these measures before the MAP over the years, and taken your feedback into account.

Our process for measure development spans 18 months, as Ronique said, and involves collecting a wide range of stakeholder input. Specifically, we worked with TEP, patient-family caregivers, and a panel of subject matter experts, to ensure that the measures meet CMS's Meaningful Measures goals by assessing most critical areas.

First, we convene a clinical subcommittee composed of clinicians affiliated with an array of specialty societies. For instance, for the chronic disease subcommittee, which chose to develop -- or chose to prioritize asthma and COPD and diabetes for development, this consisted of 74 clinicians across -- associated with 71 specialty societies.

After the measures were confirmed for

development, we convened a panel of clinical subject matter experts or workers, using multiple in-person virtual meetings.

These meetings were informed by data analytics, the perspective from people who lived with the experience, and iterative improvements of measure specifications confirmed through systematic voting processes.

All the measures you see today in total had 85 clinicians associated with 73 specialty societies closely involved in the development.

We then conducted national field testing when we calculated the measures for all the attributed clinicians. In 2020, we created over 214,000 reports.

We also posted measure specifications, results of statistical testing, and documentation on a CMS website. And then we took all of the feedback that we gained from this back to the work group for measure refinements.

While the cost measures share the same

basic framework, they're tailored to be specific to capture the clinicians' role in taking care of patients.

Two of our measures focused today on procedures -- melanoma resection and colon and rectal resection. These are attributed to a clinician doing the procedure, and the types of services included in these measures are specific to the procedure.

You can think about this as, at a high level, these include preoperative testing, imaging, the procedure itself, and routine follow-up care, as well as consequences of care.

Another of our measures focuses on hospitalizations for sepsis. This measure is similar to procedural measures, except the attribution is that it's attributed to clinician or clinicians who play significant roles in inpatient care.

We identify this as TENs, billing at least 30 percent of the evaluation and management codes during the hospital stay.

This methodology, which is identical to our other inpatient measures, and to our other inpatient measures considered by the MAP in previous years, reflects and encourages coordination of care.

This year, we also have two chronic measures, the asthma/COPD and diabetes. We started working on the framework with our TEPs input in 2018, and have been developing testing and refining it with a panel of clinician experts.

The framework identifies the start of clinician-patient relationship by looking for a TIN billing either two ENM code or an ENM code and a condition-specific code within 180 days. For asthma and COPD, for example, this could be an initial clinician visit plus a pulmonary function test.

Once we see the start of a relationship, this opens up the period where the TIN is being monitored for the patient's care. That initial period can be extended if we see

more services showing continued relationships, based on rules that were vetted by clinician panels.

This ongoing care is then divided into episodes, or segments, of at least a year, so that the clinician can be assessed for each performance period.

Just like other measures, the chronic measure uses a variety of techniques to ensure fair comparison between providers. Patient population is stratified into smaller, similar clinical cohorts. For example, diabetes is sub-grouped into people with Type 1 diabetes, such that they're only compared to other people with Type 1 diabetes, and people with Type 2 diabetes.

Also, the measure only includes costs related to the condition. For example, the asthma/COPD measure includes things like nebulizers and home oxygen, as well as acute exacerbations of complications.

Finally, we account for patient factors through a robust risk adjustment model.

In addition to a base model with 79 comorbidities, we work with our expert panels to add adjustors that have an empirical and a conceptual relationship to expected cost. As an example, the asthma/COPD measure risk-adjusts for sleep apnea and use of a CPAP machine.

Like with all of our measures, we've done extensive testing to make sure that the measures are capturing what they intended to, and that they can fairly compare clinicians.

We're of course happy to answer any questions that you may have about measure development, specifications, or testing, during the meeting. Thanks.

DR. SCHREIBER: So thanks, Sam, for the opportunity to let CMS comment and provide some introduction. We turn it back to you.

DR. STOLPE: All right. Very good. so let's go ahead and get started. Rob is still conducting, but he's just going to hand it over to me, so Rob, if you don't mind, I'll just proceed with providing --

CO-CHAIR FIELDS: Sure. Yeah.

DR. STOLPE: -- that preliminary analysis. So, wanted to note that this, in our staff preliminary analysis, that we provided a recommendation for this measure of conditional support, and an NQF endorsement.

In our assessment, we took a look at how the measure contributes to quality objectives, where we noted that this is a statutorily-mandated series of activities that CMS is undertaking related to the development of the episode-based cost measures. So they're required to do so.

But they also align with the patient-focused episode of care goal, with CMS's meaningful measure initiative, as well as the MIPS high-priority area of efficiency and cost reduction.

We noted that the measure does have basis for evidence and that the resources used to inform clinical decision-making, especially those associated with COPD and asthma, are

reflected in that cost of an episode care. And incentivizing cost and effective interventions have shown that this knowledge and awareness of the evidence-based practices and treatment risks can actually influence clinician decision-making and lead to lower costs.

It was noted that this does represent a quality challenge with many Americans diagnosed with asthma and COPD.

The measure is not duplicative of other measures currently within the MIPS program. While there are two quality measures related to asthma control and one measure related to medication management for COPD, and other measures scattered throughout CMS programs, this is a unique cost measure currently proposed for MIPS.

So the measure uses Medicare claims data, which is easily reported, and a low burden source. And in NQF's assessment, the measure is appropriately specified for clinician individual and clinician group practice levels of analysis.

This measure is not in current use, but we also wanted to note a couple of things related to the feedback from the rural group, that the access to pulmonary specialty providers, smoking cessation programs, might be challenging for rural settings. As noted, the conditional support for rulemaking is contingent on NQF endorsement.

Lastly, I'll summarize the seven public comments that we received. First, AdvaMed offered support of the measure.

The American Physical Therapy Association recommended physical therapists should be included within the asthma cost measure.

University of Colorado Medicine asked for some more clarity around episode start and end times.

The American Medical Association noted that many patients are incorrectly diagnosed with asthma by non-specialists, and called for delayed implementation pending

additional field testing and resolution of the COVID crisis. They also noted that risk adjustment by disease severity and social determinants of health would be appropriate.

American Association of Medical Colleges noted that risk adjustment by disease severity -- or, excuse me, by SDOH was concerning, and also that academic medical centers care for more vulnerable populations, and therefore the vulnerability of populations should also be considered inside of the overall approach. They also called for transparent attribution and NQF endorsement.

The American College of Allergy, Asthma, and Immunology requests some additional testing and delayed implementation.

And finally, Roji Health Intelligence expressed concerns related to the inability of physician groups to replicate episode-based measure data, noting that all scores are retrospective, and this may make the data more challenging, in terms of its actionability to

help providers improve.

Roji further suggests that claims data should be provided on an ongoing basis to providers who are accountable for these measures, so that they can perform the analyses necessary to make the measures actionable in real time. Rob, handing it over back to you.

CO-CHAIR FIELDS: Yeah. Thanks, Sam, for that summary. So at this point, we'll take questions from the group. Any clarifying questions or concerns from the work group as a start?

(No response.)

CO-CHAIR FIELDS: Amy? I think I see your hand first. Please use the raise-hand feature. Amy, go ahead.

MEMBER MULLINS: Yeah, so I had a clarifying question. On the document that we received, it said, what area of specialty best fits this measure? It said family medicine.

Is that just a translational error? Like, that was just something that was pulled out

of the measure specs and given to us? Or why is internal medicine, geriatrics, others, not included in that descriptor?

DR. CHORADIA: Sure, if I can answer. So I --

DR. STOLPE: I think we're just gathering questions now. Sorry. So let's continue to gather questions.

DR. CHORADIA: Oh, okay. Sorry about that.

DR. STOLPE: No, it's --

CO-CHAIR FIELDS: Caroline, please?

MEMBER REINKE: Yeah, just wondering if there's any age limits or exclusions around these diagnoses?

CO-CHAIR FIELDS: Okay. Helen, go ahead.

MEMBER BURSTIN: Thanks. So more of a general question, applicable to this measure but I think applicable to all of them, as well.

I went back and looked at the experience of the scientific methods panel with

the previous measures that were submitted, and for the most part, they either did not reach consensus, or did not approve the measures, based on concerns about reliability and validity.

And I know there's lots of variation and the reliability of the measures we'll see today, but I was curious if we could also, as part of the review, have some further discussion about the fact that the group, at least on all the prior eight measures, had significant concerns about the validity and the validity testing. Thank you.

CO-CHAIR FIELDS: Wei Ying, please?

MEMBER YING: Also, it would be helpful to hear a little bit more of any validation of the expected population, basically, the benchmark is truly a fair comparison to the observed.

I understand that the developer mentioned that they have a robust risk-adjustment model, but it would be helpful to hear a bit more detail on that.

CO-CHAIR FIELDS: Okay. Sorry, just taking some notes here. Anybody else?

(No response.)

CO-CHAIR FIELDS: All right. So at this point, Sam, if I understand correctly, so now the staff will respond to those? Is that right?

DR. STOLPE: So we'll pivot to the MIPS developers to respond to the clarifying questions and comments, unless there's any questions about the preliminary analysis, which the staff can answer.

CO-CHAIR FIELDS: All right. So otherwise, we've got questions on -- the specialties considered for this measure was brought up, and then age limits and exclusions, and concerns about reliability and validity of the measure itself, and then also on population variations that arose to benchmarking.

So I don't -- Nirmal, if you want to -- I think you were going to comment a little bit ago?

DR. CHORADIA: Sure. So I'll answer the first two questions, and then I think I'll hand it off to probably Sri, on our team, to answer the second two.

So in response to the first question, no, the measure actually is not -- the measure is not just for family medicine physicians. It addresses all people who take care of asthma and COPD patients. This is similar to the diabetes measure.

So we've done a little -- internally, we've done a little work to ensure that it's specifically only those people who are taking care of the asthma and COPD as a whole, and diabetes as a whole. So not to get, like, the ophthalmologist who's treating diabetic retinopathy, but rather the internal medicine doctor who's treating diabetes or the pulmonary doctor who's treating asthma and COPD.

In regards to the second question, for exclusions, I'm bringing up -- well, internally, I'm getting a list of exclusions. But we

attempted with the exclusions to basically take out those people that would either have very severe disease due to some sort of condition or criteria.

So you could think about it as, we exclude people with IPF. We excluded people with cystic fibrosis, prior lung surgery, lung transplants, stem cell transplants, sickle cell disease, previous LTCH stay.

And these were exclusions that were specifically decided by the clinician group that looked at this measure. And their thoughts were, we want to exclude patients where applying this measure would -- basically, it would be inordinately expensive for the people that are taking care of these patients, and inappropriately so.

So we excluded basically those extremely high-cost patients and patients that even though they would be included in this measure, probably shouldn't really be included in this measure.

And then I think I will hand it over to Sri Nagavarapu, who is also -- who is also at Acumen, to answer the last two questions.

MR. NAGAVARAPU: Yeah, thanks, Nirmal. And there's a question about age and exclusions as well. There aren't specific exclusions for age, although we are focused on the Medicare population. So that could include some younger than 65, if they're entitled to disability or ESRD, for instance.

For the other questions, there was a question about the scientific methods panel, and previous measures that had used some more sorts of frameworks.

I think the determinations of the scientific methods panel were mixed, across measures. Three of the measures from the first wave of measure development were NQF-endorsed, so they went through the whole process with the test and scientific methods panel and the standing committee, and were NQF-endorsed.

The asthma/COPD measure shares

features with all of those, and importantly, the process used to develop them, including the systematic voting process that Nirmal discussed with the clinical subcommittees, completely paralleled those measures.

There was also a total per-capita cost measure, which was NQF-endorsed recently by the standing committee. And there are elements of the asthma and COPD measure that build on the total per-capita cost measure.

Now, a question that a lot of people have had about the total per-capita cost measure is the inclusion of all costs in the measure.

Here, the asthma/COPD measure does not include all costs. As Nirmal mentioned, it includes only costs related to the management of asthma and COPD.

And so you can think about this measure as a blend of episode-based cost measures and some aspects of measures in general that have been NQF-endorsed in the past, even though there are some measures that -- there were questions

about the scientific method panel, as mentioned.

So the other question, the last one, I think, was about risk adjustment and the validation of the population. We, yeah, we spent a lot of time looking at this to try and make sure that the risk adjustment model is capturing average costs properly across the full range of population.

What we've done is essentially, one, look at predictive ratios. So divide the population up into low to high risk, often in the form of deciles of risk, to make sure that average predicted costs are similar to average observed costs within each of those categories.

And that's fortunately true for the asthma/COPD measure and for the other measures that we're looking at today. There's also quite a bit of consistency in that result.

The other aspect that we've done is look at, as Nirmal mentioned, the measure exclusions, and making sure that we understand what the size of those populations are, making

sure that the clinical work groups that we worked with had a good understanding of what the implications of those impacts on the population are.

And then finally we've done a lot of testing on the measure scores, the final measure scores across providers, and so on.

There is one note on the MAP Rural Health comment that was made. There were some questions in the MAP Rural Health about what the differences are between urban and rural for measures.

So we looked into that, and essentially measure scores are very similar across urban and rural providers for asthma/COPD. The rural measure scores on average are slightly lower than urban providers. And so I think that was a question that had come up in that rural health, and I just want to speak to that.

The last thing was on a public comment, there was another question about risk adjustment in population, talking about social

determinants of health.

The asthma/COPD measure does include risk adjustors for full dual-status and partial dual-status. This is because during testing, we looked at the impact of social risk factors for measures typically where the impact of social risk factors is very small, and the correlations with and without adjusting for them are very high.

What we've done is not include social risk factors in the risk adjustment. This is partly due to concerns about masking disparities if social risk factors are included.

However, there are cases we recognize where social risk factors can make a larger impact, and in that trade-off, it's something we continuously evaluate.

And for the asthma/COPD measure, we did see a larger impact and so we did decide to adjust for full-dual and partial-dual status in the asthma/COPD measure. I'll leave it there. Thanks very much.

CO-CHAIR FIELDS: Great. That's helpful. We have questions on tap, but I think you just addressed one of them, which is this risk for duals -- and I'm sorry, Sri.

If I can clarify, then, is your primary method for adjusting, when you do adjust for social factors -- is dual-eligible the primary way you're doing that, or what other data are you using to adjust for that?

MR. NAGAVARAPU: Yes, thanks for bringing that up. Yeah, in the risk adjustment, what we're including are full-dual and partial-dual. But during the testing, we included a much more comprehensive set of social risk factors in the testing, including things like income, education, unemployment, at the census group level, as well as the AHRQ SES index.

And so we've looked at testing with and without that, and what we've seen is that adjusting for dual status in the asthma/COPD and diabetes measure accounts for the vast majority of the changes that are due to social risk

factors. And so we feel comfortable with adjusting just for dual status in the final model.

CO-CHAIR FIELDS: Thank you. Very helpful. There are two additional questions. So a question on, are there any other condition-specific episode-based cost measures endorsed to date? And I don't know if that's actually for NQF staff, perhaps. Do we know?

MR. NAGAVARAPU: There are, if -- the three that are endorsed that are episode-based cost measures are knee replacement, cataract surgery -- cataract removal, and colonoscopy.

CO-CHAIR FIELDS: Okay.

MR. NAGAVARAPU: And so we're happy to answer other questions about those measures and their relationships with the measures you see here today.

CO-CHAIR FIELDS: Great. And I know this came up in the public comments, as well, in terms of rehab services that might be included in the cost measure, if someone can comment on that.

DR. CHORADIA: Yeah. Sure. So rehab services specifically related to asthma and COPD are included in the cost measure.

That being said, for example, if a patient has a COPD exacerbation, then has an extensively long post-acute-care stay, that is curtailed, just given that the provider that would be attributed the episode probably doesn't have the ability to affect a post-acute-care stay beyond a certain limit.

CO-CHAIR FIELDS: Got it. Thank you. There was an additional comment in the chat, and I believe it speaks to sort of the episode, that the examples, Sri, that you gave, in terms of conditions that are more procedural, where the episodes of care are a little clearer.

I'm reading into a little bit of the chat, but I believe part of the -- because it came up in the public comment, in terms of the definition of the episode, given that it's a chronic condition, as opposed to a procedure.

And again, I'm reading into the chat

question. That's where the concern's coming from. Is there any way that either one of you could address that a little bit before we move to voting?

MR. NAGAVARAPU: Sure, yeah. I'd be glad to. I really think of the chronic condition measures, the asthma/COPD measure, the diabetes measure, as a mixture of the positive aspects of the episode-based cost measures for procedures. And the total per-capita cost measure, the population-based measure.

The total per-capita cost measure is also -- was voted for NQF endorsement recently. The total per-capita cost measure is a measure that looks at all costs, that's really focusing on primary care and really is akin to thinking about primary care management for chronic conditions.

The asthma/COPD measure is a blend of the procedural episode-based cost measures and the total per-capita cost measures, in a lot of ways.

And I think one of the pieces of hesitation that people have expressed about the total per-capita cost measure, despite the fact that it's NQF-endorsed, is the fact that it includes all costs of care, potentially ones that an attributed clinician -- may be different from the specific area they're working in.

And so the chronic condition measures are really like an effort to address that and try and get complementary measures that are really focused on what the attributed clinician is managing. And so that's what you'll see from both the asthma/COPD and diabetes measure.

CO-CHAIR FIELDS: Great. Thank you. And actually, there's another clarifying question that I think is helpful to deliberate on before we move to vote.

It's on pharmacy costs, and if you could clarify, when you answer that, if it's Part D or Part B or Part B costs, if either or both of them are excluded.

DR. CHORADIA: Sure. So both Part B

and Part D costs are included in this measure. The idea is basically that, as the person who asked the question said, a person can look great if you're only looking at Part A and B costs, but then they're prescribing extremely expensive drugs. So for that reason, Part D cost is included.

That being said, the Part D cost is standardized so that you're not -- you don't have, like, two people prescribing the same drugs and one person is showing exorbitantly high costs, whereas one person is extremely low.

CO-CHAIR FIELDS: Great. Thank you. All right. We do have another one in the -- well, now we're kind of blowing up here.

Sam, I'm going to look for some guidance from you in terms of how to -- should we keep going in trying to address these? Because we just have, I think, four just immediately pop up, so I'm just conscious of time, here. Provide some guidance here about how you want to proceed.

DR. STOLPE: Yeah, thanks, Rob. I

think that's a fair question. We do need to get to a vote, but I'm also noting that we've got five cost measures, where a lot of these questions may arise again. So perhaps we go through some of them --

CO-CHAIR FIELDS: Keep going?

DR. STOLPE: -- we'll prioritize.

CO-CHAIR FIELDS: Okay. All right, well, let's start with -- since we're on the sort of reliability and validity track here, there's a question, I think you guys can see it in the chat, on what the findings of the scientific methods panel, if one of you wants to address that. I'm assuming you can see it on the chat, about going beyond face validity. It comes from Helen.

MR. NAGAVARAPU: Oh. Sure, sure, I'd be glad to. Yeah, the scientific methods panel, we also looked at, regarding that question about validity, we do go beyond face validity.

So while there is a lot of face validity to these measures, in that there were a

large number of clinicians affiliated with the broad array of specialty societies that were directly involved in making all the decisions about the measure components, we do a lot of testing on the empirical validity side of things to try and understand the extent to which measures scores are varying in ways that we might expect.

And so in the past, for measures that we've taken to NQF, the types of empirical validity tests that we looked at are often looking to see whether, for instance, patients who tend to have more readmissions in episodes, whether providers treating those patients are seeing higher measure scores, as we'd expect, since readmissions are costly.

We've also looked at other aspects of complications, such as ER visits and so on, to make sure that the occurrence of those things are correlated with more costly measure scores.

And we'll do the same with these measures, when we take them for NQF. The other

aspect of validity testing that we've done extensively is on the risk-adjustment side, to make sure that expected costs are tracking observed costs in a reasonable way.

And then, just being mindful of time, there -- I won't go into the details, but during the course of developing the measures with the work groups, there's often a set of very detailed questions that come up about various specific aspects of the measure, such as, you know, how long of a period of time should a clinician's relationship hold? Or exactly what types of codes should you be looking for in order to reaffirm that a relationship between a clinician and patient is continuing?

And so we do validity testing along the way for those sorts of questions, to try and provide the work groups as much empirical information as there's time for, so that they can help make decisions based on that sort of information.

CO-CHAIR FIELDS: Thank you. I'm

actually going to go to a different question related to the relationship of condition-specific cost measures compared to total cost of care measures.

And this specific question has to do with, if you're managing a specific chronic condition well, you may have higher associated costs for that condition, but have positive impact on total cost of care on a per-capita basis across a broader population. Right? Because you're investing more, perhaps, in terms of greater medical management, for example, other interventions that might add to the cost of that condition specifically.

Can you comment on sort of measuring both the condition-specific and total cost of care measures in that way, and the tension, perhaps, between those two?

DR. CHORADIA: Sure. I'll start, and then Sri, if you want to jump on and add on. But we really view this measure and the total per-capita cost measure as complementary, the idea

being that the total per-capita cost measure is of course going to measure basically everything that a provider does for a patient.

But that being said, these measures are very specific and very focused. So while the TPCC measure may include, I don't know, a hospitalization for a knee arthroplasty surgery or something of that nature, the asthma/COPD episode-based cost measure is going to focus only on the chronic care for asthma/COPD, as well as any exacerbations of that disease. So it's not including -- it's not including external things that may happen to patients.

That being said, there of course is an understanding that one thing that may be done for COPD may also have an effect on another disease process and vice versa.

And we understand that, that that is the case, and the group that helped us develop this asthma/COPD cost measure wanted to be very focused on specifically asthma and COPD.

And so those interventions that could

go either way, they focused it such that there's a diagnosis check or some other check in there that is for asthma or COPD, and if it's for something else, then it's not included.

CO-CHAIR FIELDS: Great. Thank you. And I was wondering if either of you could comment on -- let's see, on locations of care, for the episode, in terms of that changing, and if that's accounted for at all?

And the example given in the chat, if you're not seeing it, is, you know, you can get them under control, for example, in a hospital setting, perhaps, and then they change locations or sites of care, and how that might be handled in terms of the overall episode.

MR. NAGAVARAPU: Yes, Nirmal, feel free to jump in, but maybe I can take a crack at that.

Yeah, I think this really gets at the care coordination point that was brought up earlier. And we think one of the really nice features of the asthma/COPD measure is, there

already is an episode-based cost measure for management of inpatient COPD that's really centered around the hospitalization.

And so you can really think about these two measures as working in tandem and being complementary. And so the MIPS program has this incentive with inpatient COPD measure for those managing the care of patients in the hospital setting, when there is an acute exacerbation, to try and track costs as much as possible, avoid re-admissions, avoid any unnecessary post-acute care by prescribing necessary post-acute care.

And being able to have this measure complementary with that is useful, I think, because it is the case that -- suppose you have a primary care physician that's managing a patient for chronic illness, for asthma/COPD. There definitely would be an interest in ensuring that if that person goes to the hospital for an exacerbation, that those who are managing that hospitalization are trying to keep the costs in mind, and lowering readmissions in mind, and so

on.

And so we think that is a nice feature of this measure, that it's aligned with the inpatient COPD measure.

DR. CHORADIA: And just to quickly add on, one of the other things this measure does is, it has overlapping episodes.

So the idea being that the internal -- or the primary care provider can have an asthma/COPD episode, but also the pulmonary provider can have an asthma/COPD episode as well, and they can be at different times, but they overlap, such that the costs for either one is completely separate, but it basically influences them to try and work with the other provider to decrease costs and provide appropriate care.

MR. NAGAVARAPU: And I see a few follow-up questions on this, from Dr. Schilling, Mullins, and Fleischman, in the chat.

For Dr. Schilling's question, noting that she was asking about outpatient care settings and severity, yeah, it's a great

question.

So for outpatient care settings, I would think about this as -- the work group looked to include any sort of routine follow-up care or complications associated with the initial management that could occur in other outpatient care settings, but specifically was trying to apply a rule of what is care that is likely to be under the influence of the attributed clinician?

And so if people are interested, I think Nirmal could give more clinical examples here. But the basic idea would be that care and outpatient care settings, that the work group felt was under the influence of the attributed clinician managing the care, is included as a cost in the measure, whereas care that may be further flung from the initial management and less in the sphere of influence was not included.

And I think those are tough calls, and a big part of the reason that we were working with the clinical work group was to help make those sorts of decisions.

And then Dr. Mullins and Dr. Fleischman had other questions. Dr. Mullins asked about -- the measures, while being complementary, are distinct measures?

The measures are distinct, but to the extent that those are practicing in the same group, in both inpatient setting and outpatient setting, I think there's sort of a direct opportunity for collaboration.

But even in cases where the clinicians managing inpatient care are distinct from those managing outpatient care, this, to us, based on our discussions with our technical expert panel, is an important step toward trying to incentivize that sort of care coordination across different group practices.

And then Dr. Fleischman's question had to do with hospitalization and attribution. The attribution rules for the chronic asthma/COPD measure is based on engagement with the clinicians outside of the hospital setting. So someone who first sees a patient for an acute

exacerbation is not going to be attributed the chronic condition asthma/COPD measure.

CO-CHAIR FIELDS: Great. I think we only have a couple of outstanding questions. And one was, was there any concern that there would be sort of a disincentive against the use of preventive and wellness services, in terms of how the cost is calculated?

DR. CHORADIA: Sure. I'm happy to address that. So you can think about it -- so there shouldn't really be a disincentive, because the idea is that if you're providing earlier services, if you're providing those -- basically you can think about it as if, for my patient with asthma and COPD, I'm making sure that they take their medications and doing appropriate PFTs and things like that, you're going to decrease downstream hospitalizations, downstream acute care visits.

And so for the individual provider, you're not -- I mean, the ideal is to eliminate all ER and hospital visits, but, I mean, that's

perfect, and it's not really feasible.

So at the end of the day, you're just trying to decrease the risk, the chance that they go into the hospital or have to go to the ER for this disease. And so for that purpose, doing the right things is going to decrease that risk, and eventually decrease the downstream costs.

Similarly, using medications that may be slightly higher cost, if it decreases the risk of them going into the hospital, it's going to decrease your overall costs, because, for example, a COPD hospitalization is $400,000-ish.

CO-CHAIR FIELDS: Right.

DR. CHORADIA: So if you're using a medication that is, I don't know, like, $1,000 a year, $3,000 a year, if it decreases even one hospitalization, you've done better.

CO-CHAIR FIELDS: Thank you. And I'll try to sort of crowd this so we can sort of move to some sort of vote, but maybe a couple comments.

One is a question that relates to the sort of use case in a real-world setting. Have

you seen this work in such a way where there are measurable impacts to care, where a provider received the data with information on this measure, and then changed operations as a result to provide improved clinical care? I don't know if we have any real-world experience.

DR. SCHREIBER: This is Michelle. I'll take that on a little bit. I think that, you know, kind of underlines, why do we do measures and quality improvement.

So there are numerous examples, particularly in the CMMI programs and some of the ACO programs, where we provide feedback on costs frequently, and it does hopefully change behaviors of clinicians to get that kind of information.

And so I think that there are lots of examples, and frankly it's the basis of quality improvement, that the assumption is, when we provide data back and people are able to see their performance, especially compared to others, then it does lead to change in practice.

But specifically to this, in the CMMI models, that has been shown to be true, because cost information is provided.

CO-CHAIR FIELDS: Great. Thank you. And I know, Ronique, you had your hand up a second ago, and I know, I see that it maybe has come down, but I wanted to give you a chance to provide a comment.

DR. EVANS: Yeah, no, thank you. I did. I actually wanted to add a brief remark to Sri's response to Dr. Mullins on her comment about -- the measures may be complementary in this, but they are measures that -- standalone measures.

I just wanted to -- I'm sure, Dr. Mullins, you're already aware of our work on the MVPs. I just wanted to kind of bring up that with the work that we're doing there, for example, we may have an asthma/COPD MVP, but we will use this measure specifically, and not the TPCC.

So I just wanted to kind of add that

in there as maybe some clarity around a use for these specific episode-based cost measures on our MVP work.

CO-CHAIR FIELDS: Great. Thank you. Okay. All right. Sounds like that's a response there in the chat. And then maybe one comment, and I imagine this is going to come up again with some of the other ones, and I'm hopefully going to try to move us to a vote after this one. But there was a comment.

If upstream care decreases cost, you know, then why is the validity of the measure so low? That would suggest the measure is not measuring real differences in care.

And I wonder if you guys -- I imagine any time we're going to talk about upstream interventions like this, we're going to get that, so might as well address it now.

MR. NAGAVARAPU: Sure. No, I -- thanks for the question. So in terms of validity of the measure, in all of the validity and reliability testing that we've done so far, and

we've put the testing out there publicly along with the field testing, we've seen high validity and reliability for the measures.

For mean reliability, for instance, if you look at the TIN level for an episode case threshold of 30, the mean reliability is .698, so very close to .7.

And in terms of validity, as I mentioned, we've looked at the risk-adjustment model very carefully, done a lot of iterative testing on that, in order to ensure that measure scores are reflecting what we think we want to measure.

And so the fact that the precision is high, I think, is suggesting that we're picking out the types of clinicians that have been performing consistently well across their episodes in this measure.

And then from an accuracy and validity point of view, I think the testing that we've done so far, as well as all the discussions that we had with the specialty societies members and

in the work groups, can help ensure that.

And we'll be doing additional validity testing to submit for NQF, and as I mentioned, the measures that share the methodology here have been NQF-endorsed in the past, and been shown to have the validity sufficient for that.

The last thing I'll note, in the chat there's questions about balancing this with quality, which is a great point, and gets back to the discussions earlier today.

One aspect of the process that we haven't stressed so far, but is useful to keep in mind, is that, when the clinical subcommittees are making decisions about which measures to develop, one of the pieces of information they see is how many quality measures are already out there for the different conditions.

And in the past, there are conditions that people have been interested in developing into cost measures that people would -- decided against because there wasn't a sufficient number of quality measures out there to balance them

against.

And so this is a factor that's taken into account. For the asthma COPD measure, there are six related quality measures in MIPS, and so we realize that there are aspects of quality that are not going to be, let's say, re-admissions or ER visits, and things that are captured in a cost measure, but maybe other aspects of quality that are important.

And that really demands considering the cost measure in line with quality measures that are out there, and that's one of the factors that was taken into account in developing these measures, as well as in selecting them from the beginning, of which ones should be developed into cost measures.

CO-CHAIR FIELDS: Great. Thank you. Caroline, you have your hand up.

MEMBER REINKE: Yeah, I'm actually raising my hand on behalf of Donald Nichols, who's unable to have that button on his participant list. So hopefully he'll be able to

join us.

MEMBER NICHOLS: Thank you, Caroline. I actually do not have a question right now. It was just a general comment.

CO-CHAIR FIELDS: Okay. All right.

MR. NAGAVARAPU: Oh, this is Sri Nagavarapu. One really quick note -- sorry about that.

I realize that there was a question about other sorts of empirical validity testing, and we did look at the correlation of this measure with the total per-capita cost measure, which is NQF-endorsed.

And the correlation there is 0.3, which is, I think, a good sign. I think the fact that it's a positive correlation with an NQF-endorsed measure is useful from a converted validity sense.

But I also think that it is complementary, and so we shouldn't expect or even want a complete correlation with the TPCC measure.

And so, you know, the work group, I think, developed this measure to try and target the management of asthma and COPD, and do so in a meaningful way that they could get actual information specifically about this condition, and the measure turns out to also be positively correlated with an NQF-endorsed measure.

CO-CHAIR FIELDS: Okay, thank you. I'll just make a comment. There were several comments about the correlation to associated quality measures for those conditions. It's not really a question, but it's come up now a few times; just to highlight that for the team.

MR. NAGAVARAPU: Sure. Thanks for bringing that up. We've looked at the correlation on quality measures, which is tougher, because the quality measures are voluntary and so the sets of people who are picking any given MIPS measure right now is quite a bit smaller than the proportion of people with cost measures.

I think the MVPs that Michelle

mentioned are really designed to get at that, to create a situation where people are being measured on both cost and quality measures at the same time. And so I think in the future, these sorts of correlations will be more meaningful.

We do see very small positive correlations with the quality measure that is reported more often, smoking cessation. So we see a correlation of .03 there. So a positive correlation, but small.

I think that is likely not to be surprising, because that's a process measure, and it's measuring sort of an aspect of quality that's important, but is different from the types of quality that this measure is getting at, in terms of hospital re-admissions and so on.

But the positive correlation is encouraging. And I think as more participants in MIPS are reporting these other quality measures, we'll be able to get meaningful correlations with the other quality measures in MIPS.

And again, what we would expect is

some correlation, but a limited correlation, because really, what CMS is trying to do, as Michelle noted with the MVPs, is create a full picture of cost and quality for providers, without creating duplication across the measures.

And so this is certainly something that we can update the MAP and NQF on in the future, as more MIPS participants are reporting these other quality measures.

CO-CHAIR FIELDS: Awesome. Thank you. Okay. I think that it's very possible that we are ready to vote on the acceptance of the preliminary analysis. I hope that we've covered most, if not all, of the comments in the chat. So I just want to clarify one last time.

All right. There are a couple others. Did you have Part D info? Did you look at basic quality measures such as adherence to correlate with the cost measure? I don't know if you guys have any comments on that, on that adherence. I know the Part D step has come up a couple times.

MR. NAGAVARAPU: Oh, yes. Thanks for

-- yeah. Thanks for bringing it up. Yeah, I think the challenge is really the number of people reporting the quality measures. So for example, in 2017, there was only 376 participants that reported the optimal asthma control measure, MIPS 398. And so this is something that we can definitely track.

There are, as I mentioned, six MIPS quality measures that are potentially related for looking at similar patients, and as more people report these measures, this is something we can track going forward, in terms of getting these types of information for folks.

MR. DAWSON: Okay. So just to clarify what we're voting on, the next step is that we're going to open up for a vote on the recommendation for conditional support for rulemaking, based on the -- or we're going to accept the assessment here, in the NQF recommendation as it is.

It's a yes-or-no vote, and if we don't get an adequate vote, then we move on to the next step, where we have more discussion. So I will

defer to the team to open it up to voting.

DR. STOLPE: All right, let's go ahead and proceed with the vote. As a reminder, the staff recommendation for this measure is conditional support, pending NQF endorsement. Chris, are we doing a test vote first?

MR. DAWSON: So if you'd like, I can go back to that. I just opened the vote for this measure.

DR. STOLPE: All right, let's go ahead and proceed with the vote. I'm assuming we're going to reach quorum. If not we'll work with --

MR. DAWSON: Okay.

(Simultaneous speaking.)

DR. STOLPE: -- reach a quorum.

MR. DAWSON: All right. Just a moment here. Okay. So voting is now open for MUC2020-15, Asthma or Chronic Obstructive Pulmonary Disease, COPD, Episode-Based Cost Measure for the MIPS program.

Do you vote to support the staff

recommendation as the work group recommendation, which, as I mentioned, is conditional support? Yes or no.

(Pause.)

CO-CHAIR FIELDS: I happen to see some folks voting using the Zoom tool. Don't do that. Please use Poll Everywhere. There was an email that was sent earlier this morning, if you don't have it, that has all of that information in it.

MR. DAWSON: Okay, we have 14 results so far. Do we want to give it a few more seconds?

DR. STOLPE: Yes, we do, Chris. I don't think that gets us a quorum.

CO-CHAIR FIELDS: If anyone's having trouble with the Poll Everywhere, can you say so on the chat or out loud, please? Looks like Karen may be having some trouble with the link.

So the clarifying question, when you vote, it just highlights blue, that it's correct. Right? There's no enter button or anything like that. Right?

DR. STOLPE: So Sue, you should be

good.

MR. DAWSON: Okay, we're up to 16 votes.

CO-CHAIR FIELDS: Does someone mind, if they haven't already chatted with Karen, to see, make sure we can troubleshoot her? The Poll Everywhere problem.

Thank you for that. There was a comment, if you can see that, it says, response recorded right below the heading once you click the yes or no button, which I didn't notice before. Thank you.

PARTICIPANT: If you are voting, and are having trouble, please message NQF post on the Zoom platform, and we will send you the link through the chat.

MR. DAWSON: Okay, we're up to 18 votes.

MEMBER MULLINS: Can someone remind us what quorum is?

CO-CHAIR FIELDS: I was just going to ask. Thanks, Amy. I was just going to ask the

same thing.

DR. STOLPE: I believe quorum is -- we have 24 members, so quorum would be 16.

CO-CHAIR FIELDS: All right.

DR. STOLPE: So we are at quorum. Rob, if you want to call the vote, you may. If you want to double-check to make sure everybody has their vote in on time, you're welcome to do that, as well.

CO-CHAIR FIELDS: Karen, have you been able to log your vote? Just want to make sure. We need to resolve these technical issues anyway. I mean, I'd like to try to just get it done.

PARTICIPANT: Karen has voted.

CO-CHAIR FIELDS: Great. We've got up to, in that little bit of time, we got another vote in, so yeah, let's go ahead and call the vote at this point.

MR. DAWSON: Okay. So the voting is closed. The results are 11 yes, and eight no. Can someone on the team check the percentage on that?

DR. STOLPE: So that puts us at 58 percent, so the motion does not carry. So now we will open it up for discussion.

CO-CHAIR FIELDS: All right. So at this point, we'll have the lead discussants review their findings. And so for this measure, that would be Wendolyn Gozansky and Stephanie Fry, if you don't mind presenting your findings.

Wendolyn, you want to start?

MEMBER GOZANSKY: Hi, can you hear me now?

CO-CHAIR FIELDS: We can. We can.

MEMBER GOZANSKY: All right. Sorry. I was talking on mute, being eloquent and now I won't be so eloquent.

(Laughter.)

MEMBER GOZANSKY: So I think that, you know, overall, as a measure, I think that this definitely is -- it's relevant, it's highly important for our Medicare members.

I think the concerns, you know, and I would say that my issue is that I think this

probably should be -- my vote would be a, do not support, with potential for mitigation, because I just feel like there's too much lack of clarity right now, specifically with the idea that doing the right quality thing will actually result and translate into the lower-cost outcome.

And I think that that's sort of something that it has more clear face validity and tie to the quality activities, that you would be able to do with a patient who you've seen twice for asthma or COPD, in an outpatient setting. I just don't feel that that's been well-clarified.

And, you know, in looking at the validity, I still think that, you know, well, it might be, you know, in the .6s, close to .7, I still think that that raises a lot of questions and concerns.

And then the issue that, if folks are having high costs, how are they going to, you know -- if this is sort of the question about the ability to have continuous quality improvement; it's great that it is low-burden with a claims

measure, and yet it's also somewhat difficult to then understand, you know, whether people are making changes that actually drive improvements in the cost outcomes.

So, you know, my personal take on this is that it is in need of better clarity, and the reason I would go for do-not-support is really tied to the fact that, you know, is this measure truly speaking to the outcome? Meaning that, providing better upfront patient care for a member in the office, in a preemptive way, is really what is translating to what the measure is measuring around cost. And I still feel like that is what is not quite clear.

And I get that we got very small numbers of folks who are participating in the quality measures. But it seems like without having, you know, a .03 correlation between smoking cessation and the cost outcome, it's just not making me feel that we're actually sure that we know what we are measuring.

And so that would be why I would

recommend that I don't think it hits Criteria Number 2 on being sure that it is tied to the outcome, and why I would suggest that I do not support for rulemaking.

DR. STOLPE: Sorry, did you -- did not support with potential for mitigation, or are you going, do not support?

MEMBER GOZANSKY: Oh, no, no, no. With potential for mitigation. Sorry. With potential for mitigation. Totally.

CO-CHAIR FIELDS: Got it. Thank you. Stephanie or others, comments?

MR. NAGAVARAPU: In case it's helpful, this is Sri Nagavarapu, to speak to the thoughts just now from Dr. Gozansky, we could go through the types of downstream adverse consequences. They're included in the cost measure.

And I'll turn it over to Nirmal in a second to go through that, because I think the work group was interested in exactly what you're trying to get at, Dr. Gozansky, to ensure that there are downstream outcomes that the attributed

clinician can affect that are included in the measure.

And just from the point of view of some statistical results on this, the risk adjusted spending is about three times higher for episodes that have downstream hospital admissions.

And so I think that's, like, a very strong signal that there is an incentive here to avoid one of the most costly adverse outcomes from the perspective of a patient. Nirmal, I don't know if you wanted to give a few other examples.

MEMBER GOZANSKY: Can I ask a more specific question, though? I think the problem I have with that is, I have no -- it's not surprising to me that, you know, high cost predicts costs, and that, you know, that your risk-adjusted model is predicting the hospital admissions. I mean, that makes sense to me.

The issue is that we are trying to lower costs, and so we would want to be sure that

what I can do as a primary care doctor in my office is actually associated with lowering costs.

Because otherwise, it may simply be that, you know, so if I can get my patient to stay on their chronic inhaled steroid or to take their therapies correctly, or to monitor their peak flow, I know that that's what the evidence base suggests should translate to less ED visits, less hospital admissions, better quality of life for my patient.

And so unless you can show me something that says that it's not just the high end of costs, but that if I do those right things on the process side, that it actually, for a similarly risk-adjusted person, that it actually is decreasing costs, that's sort of the piece I'm missing.

Does that make sense? So to me, it's the opposite. It's not -- of course, you know, people who go to the ED and have lots of exacerbation are going to cost more in the

measure.

The question is, did I do something or not do something to help avoid them going to the ED? Does that translate?

DR. EVANS: Hi, Dr. Gozansky --

CO-CHAIR FIELDS: So -- oh, sorry. Go ahead.

DR. EVANS: This is Ronique Evans. I'm the CMS lead for the MIPS cost project work. And Sri, I'll pass it back over to you.

But I think it may be helpful if I provide a little context around our intended use for the measure. And I think, you know, Dr. Schreiber has already kind of touched on our development of MVPs.

So ideally, this measure won't be used alone. This measure will be used in concert with quality measures around asthma/COPD, and improvement activities around asthma/COPD.

So some of the answers you may be looking for, I think, we'll definitely see them as the MVPs kind of ramp up and the work on those

continues and we can put this asthma/COPD MVP into implementation.

But I thought it may be helpful to provide a little bit more around our intended use for measures like these, before --

MEMBER GOZANSKY: And so maybe what I need is clarification, because my understanding is that, what we are talking about voting on is the use of this measure not as part of a pathway that has balancing quality measures. If that's not the case --

DR. SCHREIBER: No, you are correct. This is used in the MIPS program as it stands right now.

MEMBER GOZANSKY: Stands right now. Yes.

MR. NAGAVARAPU: Nirmal, I was wondering if you want to talk through some of the considerations of the work group, in terms of how they felt that the types of costs that they were including in the measure could be influenced by the initial management of an attributed

clinician?

Because I think what you're bringing up, Dr. Gozansky, is exactly the sorts of considerations that people went through on the clinical work groups, like these members affiliated with the specialty societies. And so maybe going through some examples of that would be helpful, and Nirmal, I'll turn it over to you.

DR. CHORADIA: Sure. So you make a good point. The problem is -- so the idea is that if you're providing good care, you should theoretically see decreases in ER visits, hospitalizations, downstream.

That being said, as you expect, like, there's no -- this is expected. There's no specific measure that says, like, do this and this happens, it's been proven time and time again. It's just, we expect it because studies have suggested it, and so on and so forth.

That being said, we -- basically, the clinical group that helped us develop this measure went through a lot of the same questions

that you had, in creating this measure.

And it was specifically that that -- it was specifically due to that that they wanted to basically curtail this and make this as specific an episode as possible, not including things that may or may not be related, and things of that nature.

So, I mean, they included specific things, pulmonary function tests, admissions for COPD, things of that nature, but didn't include others which, theoretically, you could think of a relation, if you walk enough steps down the -- enough steps down the pathway.

Like, probably the most -- one of the salient things that they had a discussion on was including or not including surgical treatments of, basically, inflated lungs.

And in that discussion, they decided that that was too far down the line and basically to not include that, because those people are going to have exorbitantly high costs.

And with everything that they're being

treated for, this is something that would actually save costs in the long run, and is more appropriate. But the cost for that is just so exorbitantly high that it's not included in the measure.

So with that being said, they do include a lot of things that are appropriate to do, which theoretically are linked to decreasing admissions, decreasing ER visits.

And so you can think about it like that, so if you are treating a patient appropriately, you're going to decrease the chance of these high-cost occurrences, whereas if you're just saying, okay, cool, you have COPD, here's an inhaler, go forth and exist, and not really doing much, then that person's probably going to have an admission, going to have an ER visit, going to have some complication that's included as a cost, and that's going to make you look worse.

MR. NAGAVARAPU: And the one thing I'll add quickly to Nirmal's point there -- I see

a comment from David in the chat about other aspects of practice that can influence these sorts of outcomes that we're talking about, the sorts of adverse outcomes that Nirmal mentioned, whether it's re-admissions or ER visits, and so on.

That could be, you know, things like same-day appointment access, after-hours access. Those are things that would be hard to capture in quality metrics, would be hard to measure in claims, because we don't see it in claims data, but can impact these sorts of outcomes.

And so what -- you know, the process that the work group went through is, I think, exactly the sort of process that you're pointing to, Dr. Gozansky, in terms of looking at the evidence base that's out there, and trying to include outcomes in the measure that are related to things that could be influenced.

And some of those actions that people can take are things that could be measured, but I think a lot are also things that couldn't be.

And our hope is that, by putting a cost measure like this together with that sort of work group discussion and field testing and now putting that information out to providers, people will be able to get a sense of the relationship between the types of work that they're doing with patients and those sorts of later downstream outcomes.

Because right now, there's not a vehicle to easily see what those downstream outcomes are for providers, and I think this fills an important measurement gap in that way. And it's based on the sort of evidence base that you're talking about, that the work group was also familiar with.

CO-CHAIR FIELDS: I'd like to move us to -- I think Dr. Fields is next, Scott Fields, and then David next.

MEMBER FIELDS: Thanks. I've been sitting here listening to the discussion. And I'll acknowledge that I initially voted yes on this, but I was struck by the chat box and Helen's comment.

And what was unsettling to me, even before I voted yes the first time, is the disconnect, if you will, between cost and quality.

And while this measure and all the cost measures speak to, you know, trying to do the right thing, unless it's directly attached to quality, I'm unclear that we're going to get the right action and reaction.

So I don't know what to say about that, but it worries me at, I'll say, a systematic level, about having costs, criteria, metrics, sitting independently. And I don't know what to do about that. I appreciate the pressure to have cost metrics, but without the quality attachment, it's pretty hard for me.

CO-CHAIR FIELDS: Thank you. David, please?

MEMBER SEIDENWURM: Sure. So first thing I want to say is that I did participate in the measure development for this measure, so please, you know, take that into account as you

listen to my comments.

The first thing, as I understand it, it's part of the law that there have to be cost measures, and the cost measures have to be, you know, a certain proportion of the MIPS score. So we need to have cost measures.

So the challenge, then, is to develop cost measures that have as much clinical validity as possible, and that fit into the program, and that also are relevant to the clinicians involved.

And I think that there's, you know, kind of a push and pull here, because on the one hand, we hear -- and I'm sorry, that's an automatic printer going off behind me that I don't have control over.

The tension is, the more valid, statistically broader, cost measures, and then we complain that they're not relevant to our practices, because it only, you know, captures a small element.

And then we develop a focused cost

measurement, and then the criticisms is that it, you know, doesn't match up with all of the other factors that contribute to cost. So it is a difficult challenge.

I can say that there was a great deal of effort that was put into the severity adjustment, put into the codes that were included or excluded. And I do believe that there is the maximum feasible degree of rigor that can be achieved at the current state of knowledge, based upon the administrative data that this is based on.

And so the question is, are we going to say to docs that we aren't going to have things that are relevant to their specialties? Or are we going to accept something that is imperfect, but is about as good as we can do with the current state of things right now? And that's the question that's before us, I think, when we vote on these measures.

CO-CHAIR FIELDS: Thank you. I'll just make a comment. I'm not seeing a whole lot

else in the chat, but one or maybe two quick comments.

One is, a lot of these things will obviously come up in the diabetes measure, which is coming up hopefully after we eat, at some point. So I think it's good to go through this now.

But also the second piece is that, certainly on the value side, it's always been a question about the link between quality performance and process measures and total cost of care, and both in terms of direct correlation, as Wendee was alluding to, but also on the timing.

For example, you could do lots of things right, in terms of your process and quality measures, and not see a quote/unquote return on total cost of care, sometimes even for decades.

And so there can be a mismatch between the timing of a measure like this and the process measures that feed it. So just, you know, a comment there from our perspective.

All right, so what I'm hearing right now, not seeing, is that we've got a thought about starting off the next vote on a, do not support with potential for mitigation, I believe is what I was hearing, as a potential next step in the voting.

Does anyone disagree with that as a potential next step here? And if not, it sounds like we will move it to a vote otherwise. Maybe we've got a couple other comments here.

DR. STOLPE: Let's just be clear on what mitigation points are, if we could please have the committee speak to what they would consider important mitigation points? We need to have those teed up --

CO-CHAIR FIELDS: Yeah.

DR. STOLPE: -- before we go to a vote.

CO-CHAIR FIELDS: Okay. Thank you. Sorry about that. So as I understand, I'll try to summarize, but Wendee, please guide me if I'm not doing it correctly.

But the guidance here is further evaluation and/or testing on the interventions that might impact total cost of care so that we can have a direct corollary between clinical quality measures, may those be process or outcome measures, and how they correlate with total costs of care.

So some sort of evaluation or study on those kinds of correlations. That sound right? I don't know if I did a good job of that, but --

MEMBER GOZANSKY: I think you did a great job on that.

DR. DO: Hi, this is Rose from Acumen. Is it okay if I make a quick comment? I'm one of the cardiologists, or one of the clinicians, at Acumen who was --

CO-CHAIR FIELDS: Sure.

DR. DO: -- involved in the cost measures.

CO-CHAIR FIELDS: Sure.

DR. DO: Yeah, I just really wanted to address -- oh, thank you. Thank you so much. I

wanted to address some very important comments that have been coming up in the chat and also in our discussion about, you know, correlation with quality and whether these cost measures should be used or not.

I mean, I do want to point to the fact that we send field testing reports to the clinician groups. And to David's earlier point, you know, about the after-hours visits, we can't provide that kind of granular detail, but we provide information to clinician to try to empower them.

So on the flip side, you know, if you're a physician or you're a physician group, doing really worthy activities such as after-hours visits, extensive phone counseling, extensive face-to-face counseling, how do I know if that is actually useful?

You know, I operate in a vacuum, I spend a lot of time talking to my patients, but does that actually translate to something? And we won't know that unless we actually measure.

We also won't know how we compare to the rest of the country.

And so these reports are intended to fill that gap, so that, you know, we can look at things such as tobacco cessation, which we actually were able to study in our measure, you know, medications used for tobacco cessation and how those correlate to cost savings.

But other, you know, holistic types of practices that we know, on a granular level, within our group, do they actually translate to something?

The other thing that we do with our field testing reports is try to break down the cost into something that's clinically meaningful. They're designed by clinicians so that they're interpretable by clinicians.

And we also received some important feedback from the American College of Allergy, Asthma, and Immunology, where they did give us, you know, a pretty extensive comment letter with useful suggestions of how we can make these

reports more actionable. And we will take that into account with CMS for any future reporting.

So I just kind of want to circle back to, you know, the purpose of measuring, because at the end of the day, we are trying to measure value in health care. And I definitely can understand from the clinician's standpoint, you know, what we have in our control. But I also understand that, you know, we can't really make steps forward unless we undertake this type of practice. So I just wanted to speak to that. Thank you.

CO-CHAIR FIELDS: Thank you very much. All right. So I think we've clarified the mitigation steps, and at this point we're ready to open a vote for, do not support with potential for mitigation. I think that's what we're voting on at this point.

MR. DAWSON: Just a moment, and I will pull that up.

CO-CHAIR FIELDS: Just as a reminder, as Chris is pulling that up, use Poll Everywhere.

MR. DAWSON: Okay, voting is now open for MUC2020-15, Asthma/Chronic Obstructive Pulmonary Disease, COPD, Episode-based Cost Measure for the MIPS program. Do you vote do not support, with the potential for mitigation? Yes or no.

CO-CHAIR FIELDS: Sorry, so there's a question on what does a no vote mean? A no vote means that we do not support this status, and then we'd have to take on the other statuses, if we get the majority vote -- or the majority votes no here, we would move on to the other status potentials, and vote on those independently. Is that right, Sam? I think I have that procedure right.

DR. STOLPE: Correct. So I know the language is a bit confusing, but just to reiterate, if you vote yes, then that means that you're voting for, do not support, with potential for mitigation, under the further evaluation on impact points to actionability, as was described by Dr. Gozansky.

MR. DAWSON: Okay, we're up to 18 votes. We had 19 in the last vote. There was 19.

DR. STOLPE: There we go.

MR. DAWSON: Should I go ahead and close that?

CO-CHAIR FIELDS: Go ahead and close that. Yeah.

MR. DAWSON: Okay. Voting is closed. The results are 16 yes and 3 no. The work group does not support the rulemaking, with potential for mitigation, MUC2020-15, Asthma/Chronic Obstructive Pulmonary Disease, COPD, Episode-based Cost Measure for the MIPS program.

DR. STOLPE: All right. Very good. I'm going to propose at this point that we break for lunch, given that we're quite a bit over. And if it's okay with everybody, we're going to keep this pretty tight. Let's go with a 15-minute lunch, so it'll put us back at -- I have at 1:40 p.m.

I'm going to suggest a sidebar with

the co-chairs, and with our CMS colleagues. So if we could go ahead and set up that discussion at this point, I would welcome the co-chairs and the CMS to briefly join us for a conversation while everyone is at lunch. And we will return at 1:40. Thanks, everyone.

(Whereupon, the above-entitled matter went off the record at 1:24 p.m. and resumed at 1:45 p.m.)

CO-CHAIR FIELDS: All right. I've got a couple things for everyone just to try to be conscious of -- make the best use of our time this afternoon. We obviously invested a lot of time on that very first measure, but part of the point of that was to not re-deliberate all these same points for measures that are similar on these sort of cost-containing measures.

So I'm hopeful that we keep that in mind and have invested the time appropriately so as to not go through a lot of those similar questions again, so -- with that context in mind.

And the second thing is while the chat

is often really helpful, I would really try to encourage folks -- especially with complex questions -- to use the raise hand feature and we will call on you, so that if you have follow-up questions we can just address those in the moment rather than trying to go back and forth on a long stream in chat with follow-up questions. So if we can keep those two things in mind, hopefully we can move forward faster for these next measures. Okay? I appreciate everyone's time. So let's move on to MUC20-0017.

DR. STOLPE: Great. Well, Rob, just a couple of other items.

CO-CHAIR FIELDS: Oh, sorry.

DR. STOLPE: So, one, we want to please be succinct in your comments. Now, we had a sidebar during the break where we talked about some concerns that we have in ensuring that we're able to cover all of our measures today. So we wanted to offer up a poll to see the extent to which you may be available after our proposed stop time of 6:00 p.m. Eastern.

Let's go ahead and open up that poll to gauge everyone's availability in the event that we do run over.

Now, while we open up this poll -- which I'll go ahead and read to you now. It's: should our meeting run late, do you have the availability to stay past 6:00 p.m. Eastern Time to continue our measure discussion? If we do not have quorum at the end of our call, we will continue the discussion, but we would be finishing our voting in an asynchronous voting. Which, of course, adds a little bit of burden and doesn't afford us a lot of opportunity for a long review on the part of the workgroup. And, of course, we don't have the same robust discussion with all of your feedback.

I'm seeing 15 results. Let's get a couple more.

DR. SCHREIBER: Sam, I know since I'm not a voting member and you have some other people on this call who aren't voting members, I don't know how you're going to hear from them. I

personally -- just so people know -- have to make arrangements to have someone else pick up my dog at doggy daycare. Otherwise, I need a break and to come back, in which case I'm willing to give you the rest of the evening.

DR. STOLPE: Very good. Thanks, Dr. Schreiber. I'm seeing 18 results. Let's go ahead and close our poll. So we're at 13 yes and --

MEMBER FIELDS: So, I responded, but I mean, it kind of depends on how much time we're talking about. You know, 30 minutes, an hour, you know, two hours. It depends a little bit.

DR. STOLPE: Understood. All right, thanks, Scott. As we're getting a little bit closer towards the close of our time together, we'll make some approximations on how much more time we may need and we'll proceed from there.

DR. SCHREIBER: Sam, the other question -- and I know that they don't have a vote either, I will try and poll them with CMS reaching out to them -- but I don't know the

availability of our contractors.

DR. STOLPE: All right. Thank you, Michelle. We'll leave it to CMS to try to determine the availability of the contractors.

DR. SCHREIBER: Thanks.

DR. STOLPE: Especially those a little later in our agenda. Well Rob, with that being said, should we move forward with our next cost measure?

CO-CHAIR FIELDS: Yeah, let's do it. Sorry, I forgot about the poll. Go ahead.

DR. STOLPE: I'll try to keep this punchy. So this is a review of the preliminary analysis for MUC20-0016, colon and rectal resection episode-based cost measure. So this measure was at the preliminary recommendation of conditional support pending NQF endorsement. Now this is very similar to the other measure and same measure developer. And it addresses similar concerns -- or excuse me, similar quality objectives. Excuse me.

NQF staff did feel that this was

evidence-based on what was provided by the developer, noting that it addresses a quality challenge with colorectal cancer representing 8.2 percent of all cancer diagnoses, impacting nearly 150,000 patients per annum. We noted that this measure is a claims-based measure that is feasibly reported at a low-burden data source specified for the clinician individual and clinician group practice levels.

Now I'm going to summarize the comments that we received, six comments in total. AdvaMed strongly supported the measure. The University of Colorado School of Medicine recommended clarity on attribution language. The American Medical Association called for minimum reliability thresholds of 0.7, then noted that the metrics exhibited generally dubious reliability for TINs of the 10-episode case minimum, 20-episode case minimum, and 30 with a reliability of 0.44, 0.56, and 0.63 reported by the developer. For TIN/NPIs, the reliability was somewhat lower as well at the 10, 20, and 30

episode case minimums at 0.33, 0.45, and 0.54.

American Association of Medical Colleges had the same concerns that they expressed with the previous measure, namely concern for risk adjusted by a COH, transparent attribution, and a call for NQF endorsement.

The American College of Surgeons had a fairly extensive comment that suggested the measure was not actionable because the development of the measures was fundamentally fought, and that Acumen presented the basic framework that all clinical subcommittees were required to follow to develop the cost measures. And they further expressed that Acumen and CMS had already determined the general framework for measuring physician costs and therefore the subcommittees felt that they had little say over whether this was the appropriate strategy.

ACS notes that because procedures in patient populations are vastly different, a one-size-fits-all approach by the developer would not be as actionable. And the commenter also

questioned the developer's exclusive use of claims data and that it introduces too many limitations for critical tasks such as risk stratification, subgrouping, and defining accurate appropriate inclusion and exclusion criteria, as well as concerns about applying the CMS hierarchical conditions categories risk adjustment methodology.

And lastly, Roji Health Intelligence reiterated their concern related to the inability of physician groups to replicate episode-based measure data that all scores are retrospective and there is no actionable data to help providers improve and suggested that claim status should be provided on an ongoing basis.

That is the summary of the NQS staff evaluation and the comments. Back to you, Rob.

CO-CHAIR FIELDS: I realized I was on mute. Great. Any clarifying questions from the workgroup that I can collect?

MEMBER BURSTIN: Just one question, Rob. Was this measure adjusted for duals as the

other one was? I didn't see it in the write-up.

CO-CHAIR FIELDS: Okay. Thank you, Helen. Any other clarifying questions from the group? Okay. Hearing none, Nirmal, do you want to take it? I don't know if Sri or which of the two of you might start.

DR. STOLPE: So our first order is to vote on the NQF staff recommendation and the preliminary analysis of conditional support if we're done with questions and comments. Oh, sorry. Sorry.

CO-CHAIR FIELDS: Yeah. I thought we were going to respond to some of the clarifying questions first.

DR. STOLPE: No, yeah, go ahead. My apologies.

MR. NAGAVARAPU: Yeah. This is Sri from Acumen. Thanks for the chance to respond. Yeah, there's a question about dual status. This measure does not adjust for dual status. The reason is that the testing results did not show an impact and a meaningful impact of adjusting

for dual status. So the risk adjustment model showed that R-squared barely budged when adjusting for dual status. So there wasn't a lot of predictive value above and beyond the comprehensive set of risk adjusters that are already in the model. That seemed to be capturing a lot of the affected dual status. So the R-squared is adjusted on the order of 0.001 and 0.002.

And then we also looked at the correlation of cost measure scores with and without the adjusting for dual status. And the correlation was extremely high, greater than 0.994. So unlike the case of asthma, COPD, and diabetes, there was not a large impact. And so we did not adjust for dual status in these models.

And then the other question that came up in the comments, you know, I think that Dr. Seidenwurm and -- David Seidenwurm and Diane Padden can both speak to this if people are interested in the way that the clinical subcommittees and workgroups work. What we did

with the technical expert panel with external experts is come up with a framework for -- like a broad framework for the way that the measure should be constructed in order to create some sort of uniformity across the measures.

But within that framework, the clinical workgroups were able to make a huge amount of decisions and had tremendous flexibility to define how the trigger codes work, how an episode is started, what specific costs are counted in an episode, what the risk adjustors are in an episode, how long the episode lasts, and so on. And so I'd be happy to provide more information about that process.

CO-CHAIR FIELDS: Thank you. Can you also comment, there was -- in the public comments, clarity on the attribution, which I imagine might come up and some of the reliability questions sort of with the low volume caseloads?

MR. NAGAVARAPU: Sure. On attribution, the clinician performing the procedure is attributed episode here. So the attribution role

is very straightforward. And then for the question about reliability, the reliability has an important interplay with the case minimum, as you suggested. And the decision about the case minimum for these measures would be made during the process of rulemaking with CMS, where CMS takes into account how the liability changes at different case volume thresholds.

In our empirical results for the MAP, we presented the reliability to alternative case thresholds of 10, 20, and 30. But we don't want to pre-judge what the actual reliability will end up being because the case minimum will be selected by CMS at the time of rulemaking.

To give you an idea here for TINs, if you look at the measure scores at 10, 20, and 30, the reliability is 0.44, 0.56, and 0.63 for TINs. For TIN/NPIs, it's a bit lower. But an important note is that only 6 percent of clinicians participating in MIPS participate as TIN/NPIs, the rest participate under groups. And so really the TIN score is the most relevant score for

people. But again, CMS will be making a decision about the case minimum for these measures, so we presented a range of reliability for different case minimum.

CO-CHAIR FIELDS: Great, thank you. And I just want to review before I call on the next couple, is it -- so this part of the discussion, we quickly kind of want to get to clarifying questions and get to those and then come up to an initial vote before we get into more robust discussion, so just to clarify that. But I have two hands up currently and we'll move to those, and then hopefully kind of move to that first vote. So Amy, you want to go next?

MEMBER MULLINS: Yes. I see in the notes that this was field tested in the summer of 2020. And I just had questions. Do you think that was a valid time to test -- field test a surgery measure?

DR. CHORADIA: Sure. I'm happy to respond to this. So this measure was field tested on data from 2019. So even though we did field

test it during the summer of 2020, it was field tested on data before the COVID pandemic.

CO-CHAIR FIELDS: That's helpful. Thank you. Caroline?

MEMBER REINKE: I think my question may piggyback off of one that just came up in the chat. I was curious, the conversation and the measure seems to go back and forth between cancer and diverticulitis, which are some fairly separate diagnoses. And I assume those were risk adjusted for, but wasn't sure. I wonder if there's been any looking into the NPIs to see if there are actually surgeons versus other roles. Sometimes I've seen this data and it's actually a radiologist or a pathologist who gets assigned to that primary physician.

And then the other conversations and the measure around use of ostomies, enhanced recovery, and the surgical approach, and I was wondering how those were controlled for since they were highlighted as opportunities. But maybe that's for after the vote, sorry.

CO-CHAIR FIELDS: I'll leave it to you guys if you guys can knock those out. That would be great.

DR. CHORADIA: Sure. So that was a number of questions. Really quickly, so the measure did risk adjust for staged procedures and the creation of ostomies, as well as excluded certain rare procedures. I can bring up the exact exclusions if you will give me a second. Otherwise, I think for the middle question, I wanted to hand it over to Sri.

MR. NAGAVARAPU: For the measure specific exclusions actually I have it here. Patients that are excluded are those with a left ventricular assist device, patients who have had recent major bowel surgery, patients discharged against medical advice, transfers within three days prior to the inpatient admission where the procedure is performed. And then any sorts of episodes that occur where the procedure happens to be happening during a completely different in-patient stay where the hospitalization is not

relevant to the procedure. And --

(Simultaneous speaking.)

CO-CHAIR FIELDS: Yeah. Sorry, I was wondering if you could repeat the other provider's question.

MEMBER REINKE: Yeah, of course. When we had looked at our internal data on this, some of the attributable providers were radiologists and pathologists, not surgeons. And I was wondering if that was something that you guys had looked for or found in the larger data analysis.

DR. CHORADIA: So --

MR. NAGAVARAPU: Thanks for that question. So -- or I could answer a quick memo and then feel -- you know, feel free to jump in. I was just going to say that we did an analysis of the most frequently attributed specialties. And if you look at TIN/NPIs that were attributed, the top two specialties --- I'm just looking at a table here that we have -- accounted for about 90 percent of the attributed cases in total. And those were general surgery and colorectal

surgery. And so yeah, the vast majority of cases are general surgery and colorectal surgery. But that's about 90 percent or you know, over 1,000 TIN/NPIs, but we did provide more detail if you're interested.

DR. CHORADIA: And I'll go into a little detail about the billing/clinical side. So the episode is triggered by billing of the HCPCS code associated with colon and rectal resection. So theoretically the surgeon is going to be the one billing that code. I mean, if you have someone else billing that code, it's probably incorrect or something -- or maybe they're labeled incorrectly. I'm not sure. That being said, yeah --- oh, and I also wanted to go back to your question quickly about patients with cancer versus diverticulitis and so on.

So our workgroup was -- did actually bring that up and was incredibly concerned about that. And so they included a number of risk adjustment variables specifically related to that. First off, there's a risk adjustor for

recent chemotherapy or radiation. There's also a risk adjustor for performing an ostomy.

And then I can go through the others, but there's a risk adjustor for anemia, dementia, smoking or nicotine dependence, previously ventilator dependence, partial or total laparoscopic colectomy, recent PCI, and a host of others. And I can go through them if you would like. But those are the risk adjustors that are added in addition to the base -- to the base model.

CO-CHAIR FIELDS: Great. I'd like to move us to a vote at this point, and then if we need to go into it further we certainly can. But I'd like to kind of take that next step. So if we can open the vote, this is again a reminder, yes/no vote to accept the NQF recommendation of conditional support for rulemaking. So we can go ahead and open that up.

DR. STOLPE: And once again, the staff recommendation for the condition was NQF endorsement. All right, we're down a few from -

- okay, there we go. Well, we had the --- there we go, here's the magic 19. I haven't seen anything higher than that thus far. So let's go ahead and close.

MR. DAWSON: Okay, thank you. Voting is closed. The results are 13 yes and 6 no. So at 68 percent. So the workgroup conditionally supports for rulemaking MUC20-0016 colon and rectal resection episode-based cost measure for the next program.

CO-CHAIR FIELDS: Thanks for your votes. And this leads us to our next cost measure, I believe. Sam, back over to you. Oh Helen, you're going to --- go ahead.

MEMBER BURSTIN: I just -- it's a little bit of an odd process. I've never seen that. You're having the lead discussant only come into play after the vote has happened. So that those of us who are waiting to sort of make a comment as lead discussant don't get to speak. So it doesn't change the vote at all. The vote is the vote. But I do think it's -- you know,

the issues around reliability have been mentioned. I know they're significantly better at the TIN level, but there's no guarantee these measures will not be considered at the NPI level, and those are really quite dreadful. So I just want to put that out there.

And then I want to just also emphasize the point that the American College of Surgeons had made in their -- in their comment that reflects a lot of my earlier comments about the need to correlate these cost measures with quality measures. There are many existing complication measures for surgery that are already available at the TIN level that should not be a heavy lift that I think before this measure is brought to NQF for endorsement, it's really critically important that we actually begin to see how these measures work with quality measures, not in isolation. Thanks.

MEMBER KRUGHOFF: As far as I'm concerned, I like what has just been said. And -- but I'm okay with the yes.

DR. STOLPE: Okay. We've documented those concerns. Helen, thank you for raising that. We'll include those inside of the notes. Okay, are we ready to move on to the next measure?

CO-CHAIR FIELDS: We are, yes.

DR. STOLPE: All right, very good. So this is the diabetes episode-based cost measure. The staff preliminary analysis was again conditional support, conditional on NQF endorsement. We saw this measure as aligning fairly similar with the other measures in that it addresses CMS's Meaningful Measures initiative priority areas, as well as those identified in other important quality goals.

The evidence base for this measure included an aim to improve episodic costs associated with the management of diabetes, where this is evidence presented by the developer that clinicians can initiate a number of interventions that have been shown to reduce costs and risks for more serious complications. It was noted that approximately one-third of Medicare patients have

diabetes, with higher rates among minorities. And the cost for diabetes exceed $350 million approximately annually.

The measure is not duplicative of other cost measures currently inside of the MIPS program. And there are a number of other MIPS quality measures associated with diabetes. This measure is again a claims-based measure with a low burden data source specified at the individual and group practice clinician levels. The measure is not in current use, but was seen as an overall appropriate measure for a common condition in rural settings.

Now just a quick review of the comments that were received. There were a total of six comments. APTA again suggested the inclusion of physical therapists. AdvaMed strongly supported it. The University of Colorado noted that the numerator should mention risk-adjusted standardized costs just for clarity. The Diabetes Advocacy Alliance supports the measure and encourages physicians to work with

patients on self-care, supports the risk adjustment approach, but encourages additional social risk inclusion.

AMA once again reaffirmed their encouraging the developers and CMS to focus on minimum case thresholds to produce a reliability above 0.7. And the AAMC expressed their concern again associated with risk adjustment in SDOH, noting that academic medical centers care for more vulnerable populations, that this should be adjusted, that there should be transparent attribution and NQF endorsement. Roji Health also reaffirmed their concern related to inability of physician groups to replicate episode-based metric data and that claim status should be provided on an ongoing basis.

This is a summary of the staff recommendation and the comments that were received. Rob, back to you.

CO-CHAIR FIELDS: Great. So with this one, we'll open up for clarifying questions on the measure and the recommendation. And then

again, just one more reminder, we'll vote on the acceptance or not of the preliminary recommendation. And then if not, we move into deeper discussion. So Amy, I think you're first.

MEMBER MULLINS: So I'd like some clarification again on this -- on the sheet we received saying that this would be most applicable to Family Medicine and no other specialties were listed. And just in case -- to Helen's point -- I don't get a chance to speak again, I want to speak against the reliability of this measure, especially at the TIN/NPI level, being just really bad.

And I know you said earlier -- it probably wasn't you -- when you were speaking of the surgery measure that, you know, most people report MIPS as a group and so, you know, don't have to worry about the TIN/NPI level. Well, we really actually do because those people and physicians that are reporting at the individual level, their MIPS score really matters a lot to them, probably more than the ones that report as

a group. And so we really do actually have to worry about those that are reporting at the TIN/NPI level. So I just think we really need to pay attention to that score, and the reliability scores of this measure were not good at that level.

CO-CHAIR FIELDS: Thank you. Caroline?

MEMBER REINKE: Yeah, my clarifying question was around any risk adjustment for BMI or exclusion of metabolic surgical procedures as those are recommended as best practices for patients with diabetes at different BMI thresholds.

CO-CHAIR FIELDS: Thank you. Any other clarifying questions? There's one in the chat here. Oh, I see. This is a -- seems like a technical question that on -- in the diabetes mellitus section, page 48, that the information there appears to be related to -- be related to COPD and not diabetes.

Wendee, I see you have your hand up.

Also I don't know if you have another question, but please. Sorry, you're on mute. You're on mute.

MEMBER GOZANSKY: Sorry. No, that was just my question is what the -- whether the data are correct as far as numbers and so forth because it's unclear.

CO-CHAIR FIELDS: Okay, thank you. And then we have a question in the chat about -- same as before, if rehab costs are included. All right, so we've got questions about reliability in particular at the TIN/NPI level, questions about any adjustments for bariatric procedures and the like in terms of costs since those are suggested as best practice, but certainly would negatively impact costs, I think is the gist of that. And then certainly rehab and how that's included or not in costs.

DR. STOLPE: And just a quick note, Rob, to Dr. Burstin's previous point. If either of the lead discussants -- either Joy Bland or Amy Mullins -- have questions or comments that

they would like the measure developer to address before the vote, you should feel free to raise those.

CO-CHAIR FIELDS: Okay, thanks. I'm just following the script.

(Laughter.)

DR. STOLPE: Yeah, any departures from our normal process. But that is our normal process if the lead discussants would like to express any questions or comments before the vote, you're free to do so. So sorry if that wasn't clear, Dr. Burstin.

CO-CHAIR FIELDS: Wendee, is your hand up for a new question or is that the same one?

MEMBER GOZANSKY: No, sorry. I need to learn how to put my hand down.

CO-CHAIR FIELDS: That's all right. Ronique?

DR. EVANS: Hi, yes. I really just wanted to ask a quick question about the reliability. I'm hearing you guys' concerns about the reliability scores on TIN/NPIs. For

this measure, 20 episodes is 0.55 and 30 episodes is 0.59, and then 40 episodes is 0.62. So I'm just wondering if you guys could share with me at least for my reference the type of scores you would want to see in terms of a good reliability score for the TIN/NPI.

CO-CHAIR FIELDS: Amy or Liz, would you care to comment on that since I think in particular you guys brought it up as a concern. Or others as well.

MEMBER MULLINS: Point seven. I say 0.7. Helen, what do you say?

MEMBER BURSTIN: Yeah, usually 0.7. But I think the point Amy was trying to make earlier was that just looking at the TIN level isn't really sufficient here. That this would really apply to a lot of primary care docs in practice who might be really at the NPI, which had much lower reliability.

CO-CHAIR FIELDS: Yeah, exactly. So I don't know if the right next step here is that Sri or Nirmal, if you guys want to comment on in

particular the reliability issues at the NPI level and then also rehab costs are really the pending questions.

MR. NAGAVARAPU: Sure, sounds good. I'll try and be quick. So real quick, Family Practice is just one of the main specialties that is attributed in the measure as an example there. We weren't sure whether to list all of them there. But the top specialties are Internal Medicine and Family Practice. There are other specialties as you'd expect that are attributed to the measure as well, such as Endocrinology and General Practice.

Then for the other questions, on -- right, there's a question about the -- I think the performance gap results. There was a translation issue across measures. I think we re-sent in these measures specific to diabetes. But the performance gap results for diabetes are -- looking at a table here, for TINs, the mean score is about $7,000, with the interquartile range at about $2,400, the percentiles for 10, 25, 50, 75,

and 90 are 4,700, 5,700, 6,850, 8,100, and 9,400. If that update didn't come through to you, we're happy to send it.

And then there's a question about reliability. We definitely appreciate the importance of reliability metrics also for TIN/NPI. I think for context, you know, you want to minimize the TIN/NPI issue, but at the same time it's -- of the 900,000 to a million clinicians participating in MIPS, about 6 percent participate as TIN/NPIs. And that's based on a choice to participate as a TIN/NPI. And so it's likely the case that a small number of clinicians are affected here.

At the same time, we recognize that, you know, any clinicians who are affected are important. And the mean reliability scores are as Ronique said, that at case minimum of 10, 20, and 30. In the past, CMS has considered reliability numbers in setting the case minimum. And has even had cases where a measure was used only for TINs and not TIN/NPIs based on

reliability results. And so I wanted to make sure that that was clear.

And then in our understanding of the NQF SMP's recent discussions about reliability standards, there was a lot of discussion about what the standard should be and a recognition that the threshold that had been seen in literature from the help literature to the education literature varied very dramatically in terms of what's moderate reliability from all the way from 0.4 up to 0.7. And some authors will say in-between there and some will say higher. And so the SMP, this is like an active area of debate as to what area of reliability that they'd like to accept. And there have been many NQF-endorsed measures with reliability that's below 0.5. I saw one recently that was approved for patient safety with a reliability well below that.

Nirmal, I think you were going to respond to the risk adjustment question. Right?

DR. CHORADIA: Yeah, so I was. To

respond to the risk adjustment question, so we -- so there is already an HCC risk adjuster for obesity. On top of that we added a risk adjuster for previous bariatric -- previous gastric bypass or bariatric surgery just to -- well, the group developed that this developed this measure, they were of course concerned that obesity runs hand in hand with diabetes. And they wanted to try and get it -- the possible -- well, including that, as well as the concerns that -- of people who are obese, who are getting diabetes, how they can appropriately control for that. Yeah, and then --

MEMBER REINKE: There's not an inclusion for -- if a patient had a metabolic surgery, would that be included in the cost calculation?

DR. CHORADIA: That would be included. There is a risk adjustment variable for it to -- there is a risk adjustment variable for it.

CO-CHAIR FIELDS: Can one of you comment on the rehab costs? And actually before

you do that or just before we lose that point, because I'm going to guess what Amy is thinking here. Sri, in terms of your comments of making it a choice between if someone reports like TIN/NPI, I wouldn't say that's entirely accurate. I think in particular in the rural setting, you're going to have folks that really don't have an option. So I think that's not entirely accurate in terms of it being purely a choice in terms of reporting by TIN/NPI or group. Amy, is that --

MR. NAGAVARAPU: Oh, sorry. Sorry, I meant in terms of MIPS participation that clinicians can choose whether to report quality measures on the TIN level or TIN/NPI level. But I totally understand that in rural areas, that you know, a TIN/NPI may be the same as a TIN, and --

CO-CHAIR FIELDS: Exactly, that's the point.

MR. NAGAVARAPU: Yeah, and so -- and you know, I think exactly for that reason that

the choice of case minimum is really important. And this choice of whether to even have the TIN/NPI version of the measure at the time of rulemaking is important. Thanks.

CO-CHAIR FIELDS: Yeah, if we can comment on the rehab stuff, that would be great.

DR. CHORADIA: Oh yeah, for sure. So rehab costs are included only if they are specifically related to an inpatient admission that's included in the -- in the episode. Otherwise, rehab costs aren't included. That would be like taking a patient to rehab for, you know, losing weight or I think for knee surgery or things of that nature.

MS. MALLOY: This is Julie. I want to clarify one thing on that. What about say OT services in an outpatient setting where they're doing like preventative care, but it's diabetes-related?

DR. CHORADIA: Sorry, can you repeat your question?

MS. MALLOY: Yeah. I just meant for

rehabilitation, what if it's an outpatient service that's diabetes-related, like Occupational Therapy working with the patient on their lifestyle skills. Is that going to be included in the cost?

DR. CHORADIA: I will check on that and I will get back to you in a second.

MS. MALLOY: Thanks, appreciate it.

CO-CHAIR FIELDS: All right, I'm going to move us to William. Sorry, go ahead.

MR. NAGAVARAPU: Sorry, one last thing that we were able to look up that speaks to some of the questions from earlier about quality measures. Again, here there's a limitation that the quality measures are not reported by very many people because the quality measures have to be chosen. But there is a quality measure here that about 2,300 TINs report. This is still just a fraction of the TINs that are attributed to the cost measure.

Taking that with a grain of salt, with these 2,300 TINs that report, they report the

hemoglobin A1c measure in MIPS and the correlation at the TIN level for that was 0.245. So a positive correlation. But again, you know, it's a -- it's dependent on the effects of TINs that choose to report these quality measures.

CO-CHAIR FIELDS: Okay, great. William Fleischman?

MEMBER FLEISCHMAN: Thanks. Largely addressed already by Sri, I just want to say a word about the reliability. This has been a longstanding, I think, thing that's come up last year and previously where AMA and other groups want very high reliability numbers. The demand actually used to be, I think, 0.8 if I remember correctly. Now people have set the threshold at 0.7.

The colon resection measure we just looked at actually had much poorer reliability compared to this one. And it didn't seem to be much of an issue. So we should try to develop some sort of -- in our minds at least -- some sort of threshold where -- that we think is

appropriate and apply it equally, I guess, across the measures that we're looking at.

CO-CHAIR FIELDS: Understood. I think there's a comment in the chat, I think a lot of folks didn't vote on it for that reason, indicating some of the individual threshold. And I think that -- well, your point is well-taken in terms of do we need to -- is there some other standard we need to look at? We're not going to solve that right this second unfortunately.

I'm going to actually ask if we can talk a little bit about the risk adjustment because I think this will come up with these other measures as well. Nirmal, when you talk about risk adjusting for metabolic surgery, it would be helpful to know exactly what you mean by that as opposed to excluding those costs to Caroline's point on the chat. So there's a ton of cost and I understand you put a risk adjustment, but it would be helpful to understand how that -- what that actually means in terms of the -- in terms of the measurement, rather than excluding the

costs.

DR. CHORADIA: Yeah, sure. So risk adjusting is completely separate from cost included, so we'll talk about that first. So risk adjusting is specifically looking in the period before the -- period before the episode to see if they had a -- if they had a bariatric surgery or really for any risk adjustments in general. Service assignments or including the costs is looking during the episode period to see if that's a cost. That being said, so it is a risk adjuster, but in service assignment, the group developing this did understand that it's an extremely high cost procedure and it has long-term benefits, but in including it they decided that it's probably better not to include it because it's something that a patient is going to do in order to help in the long run downstream.

And also to just quickly change gears to speak to PT/OT. So PT/OT is included in the measure if it is in-home health, either related to -- related to a hospitalization or also

related to diabetes, also medical nutrition therapy is included and wound care therapy for diabetic wounds.

CO-CHAIR FIELDS: Got it, thank you. Okay, unfortunately the response on the risk adjustment generated a follow-up question. And again, I think it's going to come up with some of these melanoma and sepsis ones potentially. So if you can just kind of clarify that one more time.

DR. CHORADIA: Sure. So this is included as a risk adjuster, but then you look at the episode. So say a patient got a bariatric surgery 60 days ago and then is starting an episode, then they would have a risk adjustment variable included for getting a bariatric surgery.

Now say a person started the episode and has planned to get a bariatric surgery 90 days into the episode, so that is not included as a cost. And since we're not doing prospective risk adjustment, it's not included as a risk

adjuster until the following episode, basically.

CO-CHAIR FIELDS: It has to do with the timing of where the cost is assigned --

DR. CHORADIA: Exactly.

CO-CHAIR FIELDS: -- relative to when the episode started. If it's before, it's included in risk adjustment. If it's during the episode, it's not included or -- and not included in the risk adjustment either.

DR. CHORADIA: Right. That's correct.

CO-CHAIR FIELDS: Okay, thank you. That's helpful. All right, I think -- it looks like there's a question about home health based on the comments on rehab. I don't know what that was referring to. Would you mind unmuting?

MEMBER MALLINSON: Yeah, hi. This is just a quick question to clarify. So is it only home health related OT/PT costs that are included in the measure?

DR. CHORADIA: No, it's not. I was just using home health as an example. But it is home health, as well as -- as well as outpatient

PT/OT, as well as --

MEMBER MALLINSON: Okay.

DR. CHORADIA: -- the other things that I have mentioned.

MEMBER MALLINSON: Okay, thank you.

CO-CHAIR FIELDS: All right. I think we are out of votes on the yes, no vote to accept the preliminary recommendation here for conditional support for rulemaking on this measure. That's where we'll start our vote. And we can go ahead and open that up.

DR. STOLPE: Very good. And just as a reminder, the NQF condition for conditional support was NQF endorsement.

MR. DAWSON: Thank you. Voting is now open for MUC20-0017, diabetes episode-based cost measure for the MIPS Program. The votes support the staff recommendation as the workgroup recommendation of conditional support for rulemaking. Yes or no? Okay. It looks like we have 20 votes very quickly there. So --

(Simultaneous speaking.)

CO-CHAIR FIELDS: Yeah, yeah, I'm good.

MR. DAWSON: Voting is closed. The results are 10 yes and 10 no. The workgroup does not support the decision there, so we need to go into discussion.

CO-CHAIR FIELDS: So it goes back to our lead discussants at this point, so that would be Joy and Amy. I don't know who wants to start. Joy, if you would like to start maybe.

MEMBER BLAND: Yeah, I can start and then -- I know Amy has shared quite a bit. I think with this measure as I've looked at some of the decision categories, a lot of concerns that were raised with the asthma/COPD and some of that really related to me when I looked at this particular measure. I still feel there are concerns with the correlation of quality measures and the episodes of care, and really wanting to see more further evaluation on that aspect of the measure.

So I know we spent a lot of time on

that particular measure. And I think I'll pause there and let Amy add. But those were some of my preliminary concerns of -- you know, I really don't support, but would consider, you know, potentially supporting with some mitigation or some further, you know, evaluation on the quality correlation, cost of care, and the episodes of care that we'd be looking at. So I'll turn it over to Amy, if you have further to add to the discussion.

MEMBER MULLINS: Yeah, I think that -- you know, I've kind of said my piece already. But I have, you know, the big concerns about the reliability specifically at the TIN/NPI level. So, you know, I couldn't vote to support. I could vote to -- for the do not support with the potential for mitigation for the things that Joy was saying. I could agree with that. But the reliability at the TIN/NPI level is not okay with me.

CO-CHAIR FIELDS: So can I clarify actually so that -- so we would -- right now what

we're hearing as the current -- although we may have further discussions -- do not support with mitigation based on similarities before correlating it with quality interventions around diabetes. And then would we want to see anything specific in regards to TIN/NPI? Is that part of the --

DR. STOLPE: There's a valid suggestion for MAP to consider. The reliability and validity concerns can be mitigated through what we traditionally do, which is going through the NQF endorsement process. So if the measure passes an NQF Committee reliability standard, we would consider that appropriate for MAP. So our suggestion is to roll that into as one of the conditions that the measure receive NQF endorsement.

CO-CHAIR FIELDS: Got it. Thank you.

MEMBER BLAND: So what you stated is pretty much -- yeah, exactly as what we presented.

CO-CHAIR FIELDS: Great, thank you.

So we've got do not support with potential for mitigation based on correlation with quality measures and NQF endorsement. Any other further discussion at the moment? If not, we'll proceed to vote with that as the next potential level of approval. Going once.

MEMBER FLEISCHMAN: I'm curious, given that this is such a common condition, did we look at whether -- if you use double the episode minimums than you use for something like resection -- which is a not so common condition -- but do you actually improve reliability significantly?

MR. NAGAVARAPU: Yeah. We've gone up to different episode counts. And by increasing the case minimum, you can get to different levels like 0.7 that people have mentioned. Our concern is that there isn't a uniform prescription for a reliability standard. For instance, there was a measure yesterday that received unanimous support at the MAP that had a reliability of 0.5. And so, we wanted to just present a range. But yeah,

we could show other case minimum that have higher reliabilities. And you can kind of get up as high as you want to. And the tradeoff is that you lose the number of TINs that are able to get this information.

CO-CHAIR FIELDS: Great, thank you. All right, not seeing any other comments, I think we should move to a vote. And the vote would be to approve a do not support with potential for mitigation based on correlation with quality measures and NQF endorsement. So we can go ahead whenever you're ready, Chris.

MR. DAWSON: Okay, voting is now open for MUC20-0017, diabetes episode-based cost measure for the MIPS Program. Do you vote do not support with the potential for mitigation, yes or no?

CO-CHAIR FIELDS: All right, I guess we've got -- we're back down to 19. So let's go ahead and close it. All right.

MR. DAWSON: Voting is closed. The results are 16 yes and 3 no, the workgroup does

not support for rulemaking with potential for mitigation in MUC20-0017, diabetes episode-based cost measure for the MIPS Program.

CO-CHAIR FIELDS: Great. Thank you, Chris. We're going to move on to the next measure, MUC20-0018.

DR. STOLPE: Thanks very much, Rob. My apologies. I was struggling to get off mute. Okay, so this next measure has the same preliminary analysis recommendation from the staff, that is conditional support contingent upon NQF endorsement.

MUC20-0018 is the melanoma resection episode-based cost measure. Again, addresses the same critical quality objectives noted in the previous measures with a comparable evidence-based. Measure was noted to address a quality challenge in that melanoma is especially common in the Medicare population, with nationwide estimates exceeding 190,000 melanoma cases in 2020.

The measure was noted to be relatively

low burden associated with claims data that it was specified for the clinician individual and group practice levels and not currently in use. The Rural Health Group -- the Rural Workgroup, excuse me, expressed that this measure was in order to be reliable at low case threshold for a relatively common type of cancer.

Now, there were four comments received related to this measure. And they noted a lack of quality context for the measure and opposes the use of Part D data and episode-based task measures, suggesting that clinicians should not be accountable for costs that are negotiated between CMS and prescription drug plans.

AAMC expressed their similar concerns from previous measures associated with risk adjustment by SDOH, and that Academic Medical Centers --- AMCs -- care for more vulnerable populations. They call for transparent attribution and NQF endorsement.

The American Academy of Dermatology Association offered support for the measure. And

Roji Health reiterated their concern related to the inability of physician groups to replicate episode-based measured data. And that is the summary of the comments and the NQF staff recommendation. Rob, back to you.

CO-CHAIR FIELDS: Great. Caroline, I see your hand up. We'll take questions from the workgroup. Go ahead, Caroline.

MEMBER REINKE: Yeah, absolutely. In the --- although this item has much higher reliability, in the evidence of performance gap section, there was a discussion around margins and sentinel lymph node biopsies, which really should be very clearly guideline-based based on the depth of the melanoma, not really related to clinician choice and its impact on cost. So it's unclear how that component was addressed in an outcomes and quality of care perspective.

Additionally, the details around the timing of reconstruction, the references that were provided cited that there should be delayed reconstruction in desmoplastic and cheek

melanomas. And I didn't see this as specific criteria in risk adjustment or exclusion. And while the data was fairly clear I think for primary closure and skin grafting, it seems that there was ongoing controversy around the appropriateness of immediate versus delayed reconstruction tri-adjacent tissue rearrangements.

Finally, it was unclear how the concerns around attribution were going to be managed and how the reducing access to care would be addressed in this work. Thank you.

CO-CHAIR FIELDS: Thank you. Sorry, just taking notes. Any other clarifying questions? All right, so if we can move us here. So let's start with the ones that were just brought up. So centers around additional procedures like lymph node resection and based on depth of the cancer and how that would be addressed. And also issues around sort of the timing of reconstruction in terms of the episode based on clinical recommendations and how that's

addressed. Let's start with those, then we can move on to the others.

DR. CHORADIA: So for -- so both of these were actually discussed in detail by the committee. So in regards to depth of melanoma, there was substantial discussion and agreement that basically there are a number of providers who do sentinel lymph node biopsies or lymph node resections for melanomas that don't necessarily meet that criteria. And there are people that don't go far enough. And so those -- so there is risk adjustment to account for doing sentinel lymph node biopsy and lymph node resections. That being said, those are included costs to make sure to assess those.

In regards to -- in regards to reconstruction, the -- doing a melanoma resection plus reconstruction is actually risk adjusted for to ensure that those people aren't -- those people aren't unfairly -- basically they don't unfairly get increased costs for the reconstruction.

CO-CHAIR FIELDS: And then I think there were ongoing -- there were a couple of questions both in the public comment and then Caroline, you brought it up as well on the attribution piece. Can we just talk about this because it's now come up a couple of times.

MR. NAGAVARAPU: This is Sri from Acumen. For attribution, the episodes are attributed to the clinicians who are billing the actual procedure -- who are conducting the procedure. So that's in line with three NQF endorsed episode-based measures and colon resection measure.

The other question that came up on the public comment that I just wanted to make sure was clear is this measure does not include Part D costs. The workgroup did not see it as a key area to include, unlike some of the other measures. So that was just a clarification.

CO-CHAIR FIELDS: Caroline, any -- Go ahead.

MEMBER REINKE: I mean if the

discussion was around variability and sentinel lymph node biopsies and appropriate margins, it doesn't seem that cost is really the best way to address that issue. Additionally, the reconstruction was identified as an area to save costs and you were adjusting for it. So it's a little bit of both sides.

And I guess at the end of the day, one of my concerns is around particularly in urban areas how difference in practice patterns are addressed. So you know, if my dermatologist sees lots of not deep melanomas and my surgical oncologist sees a lot of very deep melanomas, is that difference in practice patterns risk adjusted for or is it that the variation that we're seeing that's appropriate variation based on the depth of the melanoma?

DR. CHORADIA: Sure. So based on the depth of the melanoma, we do risk adjust for sentinel lymph node biopsy and lymph node dissection. The idea being that of course the group was concerned about exactly what you're

saying. And so they didn't necessarily want to -- they didn't necessarily want to basically put those providers that do see deeper melanomas in a hole simply because that's the group of patient that they see.

CO-CHAIR FIELDS: We've got some dog care happening here at the same time, I think. All right, great. I'm not seeing any other need for clarifying questions from the group. And so I think at this point, we will move to vote on the recommendation from the NQS staff on conditional support for rulemaking. Sam, you're on mute.

DR. STOLPE: Just as a reminder, the staff recommendation for conditional support was the receipt of NQF endorsement.

MR. DAWSON: Thank you. Voting is now open for MUC20-0018, melanoma resection episode-based cost measure, for the MIPS program. Do you vote to support the staff recommendation as the workgroup recommendation of conditional support for rule making, yes or no?

CO-CHAIR FIELDS: Okay, there we go. Go ahead and close.

MR. DAWSON: Okay, voting is closed. The results are 15 yes and 4 no. The workgroup conditionally supports for rule making MUC20-0018, melanoma resection, episode-based cost measure for the MIPS Program.

CO-CHAIR FIELDS: Excellent. Alright and we're moving to the last of the cost measures. Sam, I'll take it over to you.

DR. STOLPE: Alright, very good. This last cost measure is MUC20-0019, sepsis episode-based cost measure. 0019 addresses the same critical quality objectives identified in the other measures, namely the episode-based Care goals of the Meaningful Measure Initiatives and MIPS high priority area of efficiency and cost reduction.

This cost and resource use measure -- This cost and research use measure aims to inform clinical decision making that's related to sepsis by reflecting a cost of an episode of care and

incentivizing cost-effective interventions. Studies have suggested that a knowledge and awareness of evidence-based practices and treatments can influence decision making associated with sepsis.

This is a significant share of hospitalizations and Medicare costs where a recent study that was submitted by the developer indicated that from 2012 to '18, the annual number of Medicare Part A and B beneficiaries with sepsis hospitalization rose from 800,000 to 1.1 million with annual total costs for hospitalizations rising from $17.8 billion to over $22.4 billion. The measure is not duplicative of other measures currently within the MIPS Program. Measure uses claims data specified that the clinician individual or group practice levels and is not in current use.

The Rural Health Work Group input included that this measure was noted to be relevant to rural clinicians and hospitalizations and especially to Internal Medicine. The measure

suggested to be potentially more reliable for clinician groups over individual clinicians. And the average cost for rural providers may exceed the national average cost and therefore may unduly impact rural providers.

Just a couple of notes on the public comments received. There was five total comments where AdvaMed expressed strong support. APCA once again suggested that Physical Therapy be included. AMA noted some questionable reliability presented especially for TIN/NPIs. It was also noted that AAMC and Roji Health Intelligence expressed concerns previously noted in other measures.

That's the summary of the staff recommendation of conditional support contingent on NQF endorsement and the five comments received. Rob, back to you.

CO-CHAIR FIELDS: Great. Thanks, Sam. Any other clarifying questions or comments from the Workgroup?

MR. NAGAVARAPU: One quick note is

from Sri from Acumen speaking to the urban/rural question that was just mentioned. We looked into this after MedPro Health Group. For TINs, the mean score for urban providers is 1.02 and for rural is less than that of 0.97. For TIN/NPI also for urban is 1.04 on average. In rural, it's again close, but slightly less at 1.01. These are the risk-adjusted cost ratios that go into the measure scores.

CO-CHAIR FIELDS: That's helpful. Thank you. Any comments from our lead discussants at all or others before we move to a vote?

MEMBER FIELDS: Yeah, this is Scott. I was and continue to be uncomfortable with the NPI reliability on this and therefore feel that it should not be supported.

CO-CHAIR FIELDS: Thank you. Caroline?

MEMBER REINKE: Yeah, I have a question around exclusion of hospice patients and if that had been considered.

CO-CHAIR FIELDS: Go back to the team here. Nirmal or Sri, exclusion of hospice.

MR. NAGAVARAPU: Nirmal, do you want to go ahead with any discussion about hospice or related issues during the Workgroup meeting?

DR. CHORADIA: Yeah, sure. So that was -- that was definitely brought up. And this is something that we've done in all of our measures. We don't include hospice costs. That being said, if a patient who is on hospice is admitted to the hospital, it will trigger an episode. That being said, any costs that patient has associated with hospice -- so say if they have a sepsis episode, then go home and all of their costs are covered by hospice, that patient is going to look pretty normal or maybe cheaper.

That being said, we also don't include any episodes where a patient has sepsis and then dies within the episode period just noting that those patients tend to definitely -- well, if they die early during their hospice period, of course they look cheaper. If they die later in

the period, then they look exorbitantly more expensive. And it's something that was of course concerning and we felt that it shouldn't necessarily be included.

(Simultaneous speaking.)

MR. NAGAVARAPU: I know Nirmal covered a lot of ground on the hospice question right there just to make clear for those who do like have hospice or comfort care upon admission, those patients are excluded. And then Nirmal also spoke to patients who later on may end up going into hospice and the hospice costs are not counted in the observed costs.

CO-CHAIR FIELDS: I'm sorry, can I restate that because it looks like -- and it came up in the chat. So if they were enrolled in hospice prior to the episode starting, those costs are -- they are excluded.

MR. NAGAVARAPU: Sorry. To make the distinction clear, if a patient is in hospice at the time of the admission that starts the sepsis episode, those patients are excluded because of

the concern about the clinical complexity and the different sets of expectations for those patients. It is possible as Nirmal mentioned that there are other patients who are not in hospice at the time of admission, but that eventually go on to hospice --

CO-CHAIR FIELDS: Right.

MR. NAGAVARAPU: -- those patients are included in the measure, but their hospice costs are not --

CO-CHAIR FIELDS: Are excluded.

DR. CHORADIA: -- in the cost. Yeah, that's right.

CO-CHAIR FIELDS: Yeah, that's helpful. And then another clarifying question is that based on, Nirmal, what you just said a few minutes ago. You were only looking at those patients who survived their sepsis episode in other words because if they either die at some point during the episode, they are excluded, correct, just to reiterate.

DR. CHORADIA: Yeah, that's correct.

CO-CHAIR FIELDS: Okay, great. And then we'll take one more clarifying question here from William Fleischman.

MEMBER FLEISCHMAN: Yes. What are the -- is it ICD-based, it is DRG-based that will put someone into this category? And the reason I ask this is because there is significant gaming ongoing with labeling patients as sepsis. And this is public knowledge, but the hospital that bills the most sepsis cases in the country is a tiny hospital out, you know, in the middle of nowhere because they call every UTI sepsis. And I can imagine their costs are -- well, very low because it doesn't cost very much to take care of a UTI. So that's one thing.

And just globally ethically, this raises hackles for me because on the one hand, we want CMS and everyone is asking physicians to go all out for sepsis and here we are potentially saying go full out, but keep in mind you don't want to spend too much.

CO-CHAIR FIELDS: Do you want to

comment on that?

DR. CHORADIA: Sure. So of course, one of the -- actually the hospitalist who is the head of the clinical workgroup brought up that exact point. So this is DRG-based. It's specifically looking for certain primary diagnoses within that DRG. That being said, there was a concern of course with people that are overdiagnosing sepsis and also a concern on the reverse of that of people that are underdiagnosing sepsis and basically putting them into other DRGs that aren't paying as much.

With that in mind, the group that developed this episode did create a sepsis episode and tried to put in risk adjustment variables that would assess whether the patient was -- basically to assess the level of sickness of the patient. So it's not just risk adjustment for a patient being very sick, but it's also including variables that identify patients that maybe aren't as sick or maybe shouldn't even be diagnosed as sepsis and including those in there

so that these variables can account for these patients that aren't as sick and maybe -- and if they're billed maybe make the episode, the expected cost of the episode less expensive.

CO-CHAIR FIELDS: So you can risk adjust up or down is what I'm hearing. Is that correct? You could risk adjust downward in other words.

(Simultaneous speaking.)

DR. CHORADIA: That is correct.

MEMBER FLEISCHMAN: So question and caution. Question, so in terms of DRG, is 870, which is non-severe sepsis also included or is just 871, 872? So one question and I'll let you answer in a second.

The caution on that I'll say is the literature shows that if you use -- and CMS obviously doesn't have clinical data -- but the literature shows and there's a JAMA piece in 2017, I think, that showed this pretty well. When you use coding data to decide who has sepsis -- and it might be beyond the actual DRG code --

You might actually use additional ICD codes and so -- the number of sepsis diagnoses has, you know, doubled over the last ten years.

When you look at clinical data, including lactates and blood pressure and everything -- and organ failure and so, the number of sepsis cases has been unchanged, including mortality. So the data that CMS has access to, to be able to do the adjustment is limited compared to the gaming that's going on. And when I say gaming, I don't mean all negative, but just like the labeling of sepsis that's changed dramatically in the last ten years.

CO-CHAIR FIELDS: Helpful context. You can go ahead, Nirmal, if you want to respond. And then we'll move to --

DR. CHORADIA: Oh no, no. I was just -- I was just saying that, yeah, just putting my clinician hat on, I completely agree that with the misdiagnosing and the increasing diagnosing of sepsis. And I did just want to say we include DRGs 870, 871, and 872. Of course, there's a

risk adjuster specifically for the DRGs given that they are increasing level of payments. But it is a good thing to keep in mind.

CO-CHAIR FIELDS: What about the clarifying question on attribution? Sorry, go ahead, Sri. Go ahead.

MR. NAGAVARAPU: Oh, I was just going to add real quickly for the question. As Nirmal mentioned, there are risk adjusters for the separate MS-DRGs. And so given the distinct nature of costs in 870 -- the average cost of that will be picked up. And then there are subgroups, the stratified risk adjustment models for sepsis with septic shock and sepsis without septic shock to allow comparisons within those groups.

So hopefully that helps, but it is the case as you know, to the extent that there's inappropriate coding going on, we're sort of doing whatever we can to deal with that. But there are going to be cases where if something is inappropriately coded, then you may bring in like

a healthier patient to this.

At the same time, like this measure was a priority for CMS and so we worked with the Workgroup to be cognoscenti of that and try and take as many protective measures as possible for it.

CO-CHAIR FIELDS: Can one of you quickly comment on -- I assume hospitalists can be attributed to this measure just given who's proving the care. Can you confirm or deny?

DR. CHORADIA: Yeah, that's correct. Basically it's -- yeah. The attribution for this is the TIN that's billing at least 30 percent of E&M codes. And that's something that basically since we started working on episodes has always been discussed at our TEP. And we included a range of possibilities for them in looking at this. And after looking at all of the data and including their thoughts, believe that 30 percent would strike the appropriate balance between getting enough people -- getting people in the episode while not basically giving providers who

do -- who see a patient once or twice, an episode.

CO-CHAIR FIELDS: Right. Okay, great. I'm actually going to -- oh, go ahead, Sri.

(Simultaneous speaking.)

MR. NAGAVARAPU: Oh, sorry. The last thing I was going to note is someone mentioned the TIN/NPI reliability. An important point related to something Dr. Fleischman brought up last time is as you increase the case minimum, the reliability will go up and we have other results that weren't shown. At 40 and 50 cases for TIN/NPIs, the reliability is 0.606 and 0.651, so substantially higher.

Again -- and we don't -- opinions differ at what we're looking for, but I would just -- want to throw those numbers in there so that people who like this measure and think it's an important measure to be tracking, know that it's possible to increase the case minimum for TIN/NPIs and get substantial reliability.

CO-CHAIR FIELDS: Thank you. Okay, I'm going to -- noting Amy's comment in the chat,

I'd like to move us actually to a vote on the preliminary recommendation for conditional support for rulemaking.

DR. STOLPE: Thanks so much, Rob. And just as a reminder, conditional support is associated with NQF endorsement on this case.

MR. DAWSON: Voting is now open for MUC20-0019, sepsis episode-based cost measure for the MIPS program, do you vote to support the staff recommendation as the Workgroup recommendation of conditional support for rulemaking?

Okay, we're at 19 results -- 19 votes. So voting is closed. The results are 8 yes and 11 no. The Workgroup did not support the staff's recommendation of conditional support for rulemaking for MUC20-0019, sepsis episode-based cost measure for the MIPS Program.

CO-CHAIR FIELDS: All right. All right, well at this point, then we open it back up for discussion. And invite the lead discussants to contribute, Nishant Anan and Julie Stone.

DR. STOLPE: I just want to note here that essentially Scott Fields is representing OCHIN and they we have invited Dr. Helen Burstin to serve as a lead discussant on this..

CO-CHAIR FIELDS: Oh, sorry. Thank you. Okay, great.

MEMBER BURSTIN: I don't have much more to add. I think most of the points have been raised, certainly the issues around attribution, the issues around reliability. Again, at the individual NPI level, it's hard to know what that -- how many -- the realistic numbers that most docs will have. And I think that's a fair question. And you know, back to the point, again we do have quality measures for sepsis here. And it would be really important to understand whether we're actually measuring cost that's associated with lack of care, rather than high quality care. Thank you.

MEMBER FIELDS: I don't have a lot to add either to what's already been described, so I'll just leave it at that.

CO-CHAIR FIELDS: I guess what I'm trying to figure out from the group then is what we vote on next. It sounds like -- is it a do not support with mitigation or just --

MEMBER FIELDS: Yes, yeah.

CO-CHAIR FIELDS: -- or not -- yes.

MEMBER FIELDS: That would be my recommendation.

CO-CHAIR FIELDS: Okay. And the factors for potential mitigation would be --

MEMBER FIELDS: Well, I think that the issues that have been raised around reliability, around coding, around I'll say coding equal diagnosis to some degree.

CO-CHAIR FIELDS: Yeah.

MEMBER FIELDS: But what the definition of the diagnosis is all play a role here.

MEMBER BURSTIN: And just --

(Simultaneous speaking.)

MEMBER BURSTIN: -- correlation to quality.

MEMBER FIELDS: Right, yeah. Thank you.

MEMBER FLEISCHMAN: And the issue with that is the quality measure for sepsis, SEP-1 is actually currently undergoing re-write by --

MEMBER FIELDS: Right.

MEMBER FLEISCHMAN: -- people, by CMS, by others. And the current quality measure is actually very controversial. So it's just -- there's no literature to say that somehow cost reduction or cost containment results in better care. And there's no literature as far as I know correlating SEP-1 in any way with cost. So I'm not sure actually how -- I mean aside from what Nirmal was saying in terms of -- could there be some better adjustment for the differential in coding and labeling? Potentially, but I see these as fatal flaws personally and I don't see how these can be mitigated appropriately.

MEMBER BURSTIN: And just to be -- and there are other quality measures. I mean there is a risk adjusted sepsis mortality measure.

There are other ways to at least, for the next steps in terms of the measure if it moves forward for additional work to be done to better understand whether in fact, lower costs are associated with lower quality. I think that is the concern here is that -- are we actually putting forward a cost measure that in any way is associated with what we hope would be --

(Simultaneous speaking.)

CO-CHAIR FIELDS: Worse care.

MEMBER BURSTIN: And you know, the last thing was is an unintended consequence related to worse care, exactly.

CO-CHAIR FIELDS: Yeah, that makes sense.

MR. NAGAVARAPU: This is Sri from Acumen. It would be useful for us to get some additional guidance on these points. I think on the question of correlation with quality measures, I think the types of doubts that I have about this, that would be useful to discuss. One, the purpose of the cost and quality measures in

MIPS is to have these measures work together and not capture the same things, but instead to work in concert.

So we definitely understand the concern about unintended consequences. What we've tried to make clear is that a lot of what's driving the improvements in cost here are quality outcomes that people do care about like hospital readmissions and ER visits. And so there is a very real incentive to reduce things that we all care about reducing. At the same time, there's going to be other aspects of quality that this measure is not correlated with and is not intended to be correlated with because cost and quality are statutorily required as separate domains that are involved and that are playing their distinct roles in order to measure value.

So I guess that is one question is statutorily, there is a call for having both that requires them not to play duplicative roles, but to work together. And I think what we've tried to show is that these measures do work together

in terms of measuring some aspects of quality, like readmissions. There also is a positive correlation with the acute care readmission measure here for sepsis while other aspects of quality are intended to be picked up by quality measures.

I think the second thing that I would appreciate discussion of is how to go about addressing these sorts of questions about quality measures. And that right now in MIPS, there aren't many groups that are selecting a large set of diverse quality measures. And the ones that do select the quality measures may naturally be ones that are doing the best on those quality measures. And so to have as a pre-condition that the cost measures are correlated with quality measures that are in MIPS would make it very difficult to actually have a cost measure go through because the quality measures just aren't frequently reported by TINs.

And so it would be useful to hear from folks about what are other practical things that

could be done to address this, given that practical limitation. Because otherwise, my fear is that the implication is just that cost measures can't be included. And as Dr. Seidenwurm mentioned before, it's contrary to statute for the MACRA legislation, and cost measures have to be in the program. And so I'd appreciate any discussion to those points.

CO-CHAIR FIELDS: I'd like to comment on a question presented that Amy said in the chat. And please correct me if I'm wrong and if I'm overstepping here. But I can totally appreciate that, Sri -- that comment. But you know, therein lies the problem with statutes that are not governed by clinicians or know how to operate these things, is my comment for that. Like our charge as a workgroup, right, is to recommend measures that get us to the best outcome for patients. And I think what we're trying to describe are the issues with some of these measures that could lead to unintended consequences that could actually harm patients by

avoiding care in particular for this measure, but other measures that have been brought up.

And I think we all sort of appreciate the problem you're addressing in terms of the statutory requirements, but you know, I don't mean to be flippant about it, but that's not really a problem we're going to solve here, nor is it in our purview to solve for it. You know, we can certainly try to be helpful as best we can, but I just don't think that's -- I think what I'm now seeing in the chat, I mean, I think that's right, it's not in the scope of this group.

And William, do you want to go? I think you had your hand up next and then David is next.

MEMBER FLEISCHMAN: So a couple of -- a couple of suggestions that I would say. And I agree with Helen, there are other quality measures, but there's only one that everyone has to report as mandated reporting and that's SEP-1. And what might be helpful is if we see some sort of analysis that looks at the correlation

between cost and SEP-1 performance. As flawed as that measure is, that's one.

On the other issue with labeling, what I would suggest is looking at again, some analysis that looks at IRF control that controls for overall infections. I don't know if this changes the measure drastically. But instead of looking at sepsis, which relies on coding, you look at the entire -- all the infection VRGs.

So when you look at that -- and I actually have looked at that in the past -- so sepsis as I mentioned -- sepsis diagnosis has doubled in the past ten years, but overall infections have not. They're flat. Same goes for mortality. Sepsis mortality has decreased dramatically. Overall infection mortality is flat. So this all goes back to labeling. So if we take the entire group as a whole and look at cost, where you essentially you take labeling out of the picture. So those are two suggestions for mitigating some of these issues.

MR. NAGAVARAPU: Thanks, Will. And I

should just emphasize that this was part of the rationale that the Workgroup used in order to include other infectious disease based on diagnosis coding just as you said. So I mean, for over a year, the Workgroup grappled with this issue that you're talking about and came to a similar conclusion as you, which led to the design of the measure as including not just those sepsis MS-DRGs, but also other hospitalizations indicating other infectious disease and using the diagnosis codes for sepsis on the triggering claim.

At the same time, there was a discussion about going broader than that and going to a broader set of infections even without diagnosis coding for sepsis. And there was concern there about bringing in too heterogeneous of a group. And so I think the Workgroup really grappled with the types of issues you're bringing up for a long time and came to the design for this -- for this measure.

CO-CHAIR FIELDS: David, I'll go to

you next.

MS. SCOTT: Sure, thank you. So again, I participated not in sepsis, but in the overall project of the episodes and the chronic disease management cost measures. So I think the theme that's coming through here -- and none of us really like cost measures. Right? You know, we just find there's something unpleasant about the discussion. But we do have a requirement to do it.

So I think it's within our scope to make the program as good as it can be with respect to the cost metrics and not simply leave the global cost of care in the per capita -- I mean the per-beneficiary spending metrics, which people have complained about, you know, for the opposite reason that you know, it's not close enough to their type of practice. That's it's not close enough to what they have control over.

So just a couple of quick points. One is some discussion was had about outlier facilities that, you know, might game the system.

I believe there are other enforcement mechanisms in CMS that deal with that. There's something called the PEPPER Report that our hospital gets that looks at the proportion of different coding and you know, how that fits into outlier status or within the norms. So I think there are enforcement mechanisms there.

So a recurring theme here is that clinicians might stint on care in order to, you know, save a little bit of money that might impact their cost of care metric. And I'm not so sure that's a big problem. I mean it's hard for me to imagine people making unethical decisions of that sort based upon, you know, a fraction of a percent of their payment from one payer to their group. We heard most people report as groups. So that's an awfully attenuated impact to, you know, commit an ethical breach of that sort. So I'm not sure that should be a major concern.

Regarding the tradeoff of reliability and caseload, that also puts us kind of into a paradoxical position. It's a real tradeoff

because either we have a very reliable measure, but it only affects a very few super specialists who, you know, might perform hundreds or thousands of a particular procedure or you know, dozens and dozens of a rare procedure. We leave other clinicians who participate in the care more broadly and want to be measured on something closer to their practice, we leave them out of these measures. And then -- So I think we have to sort of get a little past the aversion to cost measures and just think about what's possible in that sphere. And that's all.

CO-CHAIR FIELDS: All right, I think at this point where we are is that we have a proposal for a do not support with potential for mitigation as sort of the highest level that I think I'm hearing willingness to support. We already voted down the measure for conditional support, so we're not -- it doesn't seem like we were going to go any higher than that. So I think just for practical reasons, I think we could probably move to a vote based on that unless

anyone had serious objection to that.

Is the proposal we would move forward to a vote for do not support with potential for mitigation. The mitigating factors would be of course NQF endorsement, but also correlation of quality measures and issues of reliability in some of the coding issues that have been summarized that lead to sort of overdiagnosis and for lack of a better word, gamesmanship. I'm sure there's a better word we can put in there.

All right, if there are no objections in moving forward, I think we should move in that direction.

DR. STOLPE: Okay, let's just make sure that we're very clear on what precisely the mitigation points are. The reliability component of that will be captured in the NQF endorsement parts, so we can just leave it as NQF endorsement. However Rob, you mentioned two others. So one is the correlation between quality measures. That those should be --

CO-CHAIR FIELDS: Correct.

DR. STOLPE: And the other being expressing a concern around gamesmanship, namely that there is maybe an underdiagnosis of sepsis.

CO-CHAIR FIELDS: Perhaps an overdiagnosis of sepsis, actually.

DR. STOLPE: Excuse me, yeah. I misspoke. So an overdiagnosis of sepsis that would result in the gaming that you mentioned. But this should be accounted for in the measure developer's plan, that they should perform an analysis around this. Is that what the suggestion is?

CO-CHAIR FIELDS: William, would you care to comment on a potential solution there on the coding piece that we can put in the documentation?

MEMBER FLEISCHMAN: So essentially look at the variability or the -- once you control using whatever controls are built in, look at the variability of the rate of sepsis diagnosis as a proportion of all infection diagnosis across systems and across TINs, NPIs, and so on. That's

how you would look at the labeling variability of sepsis.

CO-CHAIR FIELDS: Wendee, please go ahead before we move to vote.

MEMBER GOZANSKY: Just I also think some analysis examining the fact that we are excluding the sickest folks by excluding those who die with sepsis. That unfortunately is a real outcome. That seems like it would be adding some sort of -- some sort of bias into the measure.

CO-CHAIR FIELDS: Yeah. And before we document that though, I think -- I think there was an attempt to address that earlier by saying because the timing of death is highly variable: it can come up early in an episode or late in an episode, that can have pretty dramatic impacts on cost. So I think that was -- they tried to address that or the team tried to address that already. I just want to make sure do we need to add other documentation in that for the NQF staff to put in --

(Simultaneous speaking.)

DR. STOLPE: -- through NQF endorsement.

CO-CHAIR FIELDS: Sorry, Sam. Say that one more time.

DR. STOLPE: I wanted to ask the Workgroup if they thought this would be something that would be mitigated through NQF endorsement. And if the standing committee for endorsement saw that as an inappropriate exclusion that was a risk to validity, they would vote the measure down based on that.

CO-CHAIR FIELDS: Is that okay, Wendee?

MEMBER GOZANSKY: Yes, that's great. Thank you.

CO-CHAIR FIELDS: All right, great. So I think we're -- Sam, if you're good, I think we're ready to move to a vote. And the vote would be for do not support with potential for mitigation.

DR. STOLPE: Very good. Let's open it

up, Chris.

MR. DAWSON: Okay. And voting is now open for MUC20-0019, sepsis episode-based cost measure for the MIPS Program. Do you vote for do not support with the potential for mitigation?

CO-CHAIR FIELDS: Are we missing folks? Does anyone know? We've got quorum though, I think. All right, let's go ahead and close it.

MR. DAWSON: Okay, voting is closed. The results are 14 yes and 5 no. The Workgroup does not support for rulemaking with potential for mitigation on MUC20-0019, sepsis episode-based cost measure for the MIPS Program.

CO-CHAIR FIELDS: Great, thank you. And that brings us to the end of the cost measures. So I will turn it over to my colleague, Diane, to move on to the quality measures in MIPS.

CO-CHAIR PADDEN: Okay, is everybody all right? Okay, so this is MUC20-0034. And we're going to start with a preliminary analysis. Correct?

DR. STOLPE: Very good. Thanks very much. This is our first of the quality measures. And I do want to recognize that we're significantly behind time. So we'll try to keep our comments succinct and try to move quickly through our process.

So MUC-0034 is the risk standardized acute unplanned cardiovascular-related admission rates for patients with heart failure for the MIPS. The description is this is annual risk-standardized rate of acute unplanned cardiovascular-related admissions among Medicare Fee For Service patients, age 65 years and older with heart failure or cardiomyopathy. This level of analysis is clinician: individual and group practice. The NQF recommendation is conditional support for rulemaking. The condition is NQF endorsement.

Just doing a quick review of the staff preliminary analysis, this measure was noted to address three areas that CMS has identified as high-priority measurement areas: patient

outcomes, communication, and care coordination and cost reduction. It also meets the meaningful measure priority of the hospital admissions and management of chronic conditions. This is an outcomes measures. Therefore the measure developer cited research associated with heart failure costs in the United States exceeding $30 billion per annum.

The measure does address the quality challenge and admissions for patients with heart failure due to acute cardiovascular events is common. And while such rates for heart failure have fallen since the passage of the Affordable Care Act, readmissions still occurred within a month for a fifth of patients hospitalized with heart failure in 2016.

There are currently no outcomes measures in MIPS related to heart failure. A version of this measure with slightly different specifications was implemented in the Shared Savings Program from 2015 to 2019. There is a heart failure readmission measure including the

Hospital Readmissions Reduction Program as well.

This measure uses Medicare claims data, which is noted to be feasibly reported and low burden. I wanted to note that there was a concern that the developer noted cut-off values for greater than 32 or 21 patients for TIN that are needed to achieve provider measures for reliabilities of 0.5 and 0.4 respectfully. And at these thresholds, the median reliability score is 0.7 and 0.6 would be achieved. But the developer also noted some wide variations in the number of patients per TIN with a median of 7 and an interquartile range of 2 to 19, which suggests that over 75 percent of clinicians would not meet the developer's threshold for reliability.

This measure is new and it's not currently being used. The Rural Workgroup noted a high relative priority in that heart failure is a significant problem in rural settings and therefore also relevant. Once again, the conditional support for rulemaking is contingent on NQF endorsement.

Just to quickly summarize the six comments received. There were two supportive comments from University of Colorado and from C-TAC. Also the Society for Cardiovascular Angiography and Interventions expressed their support. There are three expressions of do not support from AMA, from the Heart Failure Society of America, and from the Federation of American Hospitals citing opposition to the measure based on these claims, as well as noting that the measure may be useful to population clinician level, citing a lack of evidence to support applying the measure at its intended level of analysis.

And also some with concerns expressed on the attribution methodology noting concern that cardiologists with two or more visits are accountable to the measure regardless of how many visits a patient may have with their PCP, disincentivizing primary care providers from providing appropriate care. There is also some note that this may be appropriate for ACOs, but

not clinicians. And also noted that it does not include death by heart failure and does not account for STOH appropriately. Other concerns expressed related to reliability and validity. Noting that it had face validity testing, insufficient evidence to support the attribution approach, and no NQF endorsement.

This is the summary of the concerns and the comments and the NQF recommendation. Diane, back to you.

CO-CHAIR PADDEN: All right, so I think I'm going to ask our lead discussants if they would like to share their comments on the measure. Chad?

MEMBER TEETERS: Yeah, hi. Thanks very much. So aside from the concerns that have been raised, I actually have several concerns about this metric. Number one, the mention of heart failure or cardiomyopathy is extraordinarily imprecise and doesn't detail whether it includes heart failure with preserved ejection fraction, whether this is just reduced

ejection fraction heart failure. Those are two very different diseases. Heart failure with reduced EF doesn't have the treatment modalities available to it that heart failure with reduced EF does, number one.

Number two, you know, we know from prior attempts at admission and readmission related heart failure metrics that it actually resulted in increased risk of mortality because there was an increased attempt in managing patients in the outpatient setting.

Number three, it actually, you know, admission, especially in end-stage heart failure is somewhat a natural consequence of the disease process. And so, you know, it doesn't take into account the relative severity or the stage of heart failure that the patient may be in.

The next concern that we have about this is that it could incentivize physicians not to take -- not to be willing to take care of patients who are less adherent to medical therapy or lifestyle management, which could create

greater disparities amongst populations such as ethnic or rural populations who may not be as adherent to recommended therapy. And that could have more adverse outcomes than specialists taking care of appropriate admission populations.

So from my standpoint, I would say the highest I could do would be do not support with conditions.

CO-CHAIR PADDEN: Thank you, Chad. Our other discussant, Wei, do you have anything to add?

MEMBER YING: I just have one more question that, after reading the material, it was still not clear to me how different is this one from the retired ACO version? If that can be expanded a little bit better. And another question is that I think it's part of our mission by someone's comment also that for these chronic condition management, usually the ACO is a better unit of analysis versus, say, an individual physician. So it would be great to hear some thought why that a clinician-based measure is

actually better than an ACO version. That's it.

CO-CHAIR PADDEN: Thank you. Do we have any other questions of clarity from the group? I'm not seeing any hands. Did anybody see any other hands on another page here?

DR. STOLPE: I don't believe so.

CO-CHAIR PADDEN: So in -- pardon me, Sam?

DR. STOLPE: No, there's no other hands.

CO-CHAIR PADDEN: No other hands. So are the developers of the measure here that might be able to speak about some of the concerns, or not?

DR. SCHREIBER: This is Michelle. We should have our team and the developers on the line.

DR. LIPSKA: Yes, this is Kasia Lipska from CORE. I'm happy to address the questions. I noted them down because there were a couple. And just as a start, just to clarify what you had brought up in the beginning about the measure not

applying to over 75 percent of clinicians. Many clinicians who care for patients do not care -- do not take care of a lot of patients with heart failure. So that over 75 percent is out of all clinicians who have at least one heart failure patient.

Clearly we want this measure to be reliable and to reflect a quality signal. And so this measure is really designed to apply to clinicians who do see multiple heart failure patients. And so it's not surprising that many clinicians are not included in the measure. Yet, it's important to note that 90 percent of patients and over 90 percent of the outcomes are included. So just as a clarifying point.

Okay, so the first four points were one, not all patients with heart failure are the same as -- all heart failure patients reduced ejection fraction are not. So this measure does include patients with heart failure or cardiomyopathy, both those with reduced ejection fraction and also those with preserved ejection

fraction. And the measure is adjusted for multiple clinical factors including systolic heart failure, so reduced ejection fraction to account for the fact that those patients have worse outcomes.

Number two, question about increased mortality as an unintended consequence. So we do understand that, you know, admission is a signal of quality. Sicker patients tend to be admitted to the hospital. Clearly we don't want clinicians to not admit patients and allow them to die. We had looked at the mortality in this -- for this measure. The mortality over one year was about 5.8 percent. Those patients who died were much more likely to be admitted, like ten times more likely to be admitted to the hospital during that year.

The measure importantly is designed in such a way -- in such a way that patients who die no longer contribute person time to the measure. Therefore the way that clinicians can really excel at this measure is to keep their patients

alive during the entire time and have them not be admitted to the hospital. Patients who die again, do not contribute that person time to the measure. So we think that mitigates some of these concerns.

Three, admission is a natural consequence of heart failure. True. These are sick patients. These are older patients who have heart failure. They're often admitted to the hospital. The measure is not intended to say that zero admissions is ideal. The measure is intended to pick up a signal that suggests that some clinicians may perform better than others. And that signal is the rate of admissions. We do not expect that rate of admissions to be zero. Patients sometimes really do need to be admitted to the hospital. So we agree with that.

I can't read my own writing here. Okay. Oh, yes. So what about adherence -- patients adherence and the question about whether or not this measure could potentially increase disparities and have clinicians not want to take

care of non-adherent patients? Well I'll just back up. You know, this measure was developed with a lot of input from the TEP and also from a clinician committee, including many cardiologists. And we thought about these issues carefully. It is the role of the clinician to help patients achieve the outcomes that they desire. And part of that is counseling and working on adherence with patients. And helping them access care better. So again, part of that care and avoiding hospitalization is going to be mitigating nonadherence.

I think the last question from other person was how does this differ from the retired version of the ACO measure? So this MIPS heart failure measure is different from the retired ACO measure in that the outcome is much more narrow. This is a cardiovascular-related hospital admission rate as opposed to an acute unplanned all-cause admission rate. This measure is aligned together with a very similar measure that's also being submitted to NQF for the MSSP

Program. And those two are very similar in terms of their scope, cohort, and risk adjustment.

I probably missed something, so I'm going to ask if the rest of my team wants to chime in?

DR. DRYE: Sure. Thanks, Dr. Lipska. Elizabeth Drye, Yale. Let me just address the last question from Dr. Ying about -- you know, why not at the Medicare Savings Program level? I mean this measure, we specifically developed for CMS, for the MIPS Program with the notion that it could work for cardiologists in the MIPs Program. And so that's why it's tailored to both the outcomes and the cohort patients that they care for.

Although as we were definitely aware of and heard from front line clinicians in rural areas in underserved areas -- a lot of heart failure patients are cared for by internists, family practitioners, and other clinicians. So it's developed for MIPS because that's a huge -- a huge number of the patients are in MIPS, not in

the Shared Savings Program. And it is now -- it will be fully aligned with an updated version that as Dr. Lipska mentioned is going towards the Medicare Shared Savings to NQF for endorsement.

So it's really programmatic and policy need to measure in this area with input from those clinicians in those programs. And should fit better with the MIPS Value Pathways that CMS is developing for specialist groups within MIPS.

CO-CHAIR PADDEN: Thank you very much. I do not see any other hands or anything in the chat box. So if we could go to a vote. And it was conditional support.

DR. STOLPE: Very good. Chris, if you don't mind opening up the vote. As a reminder, the conditional support is based on NQF endorsement.

MR. DAWSON: Okay, voting is now open for MUC20-0034, risk standardized acute unplanned cardiovascular-related admission rates for patients with heart failure for the MIPS Program. Do you vote to support the staff recommendation

as the workgroup recommendation, which is conditional support for rulemaking?

CO-CHAIR PADDEN: Okay. It looks like we have 19.

MR. DAWSON: The voting is closed. The results are 12 yes and 8 no.

DR. STOLPE: Basic math tells us that's 60 percent, so greater than or equal to. So that is a -- that is a pass by the narrowest of margins. Okay.

CO-CHAIR PADDEN: Okay. All right, the next measure we're going to talk about is intervention for pre-diabetes. And so I believe Sam is going to share with us the preliminary analysis.

DR. STOLPE: Very good. Thank you so much. Now this is the measure developed by the American Medical Association, intervention for pre-diabetes. The description is that the patient's age is 18 years and older with identified abnormal lab results in the range of pre-diabetes during the 12th month measurement

period were provided an intervention. The level analysis is clinician -- individual and group practice levels. And the initial entry of recommendation is do not support with potential for mitigation.

Now I did want to point out a couple of things related to that. The first is that this measure has been through the NQF endorsement and it was not recommended by the Primary Care and Chronic Illness Committee. Specifically because the committee felt that the interventions that were available to meet the numerator were not adequate. Mainly that the options included either the prescribing of metformin or the referral of the patient out to another service. The committee felt that this was not representative of the range of interventions that are available to primary care clinicians in the treatment of pre-diabetes in addressing the burden associated with it. It was a primary concern of this particular group. But they felt that this was mitigative.

Just a couple of other notes. This measure was noted to address a critical quality objective. And there was evidence that individualized medical nutrition therapy provided by a registered dietician is successful in deterring the progression of pre-diabetes to Type 2 diabetes. And that current evidence supports a role of metformin in diabetes prevention when coupled with lifestyle interventions.

The measure is not duplicative of other measures currently in the MIPS Program. There are no pre-diabetes measures. It is also noted that this is a eCQM, and electronic clinical quality measure that draws on EHR data documented as part of routine delivery of care.

A couple of notes on the nine comments that were received. APTA once again asked that physical therapists be included. The University of Colorado suggested that it was unclear whether metformin or a referral was required or just one. But just for clarity, it's any of those will meet

the numerator. And also that the data source is unclear. This is an EHR-based measure in eCQM. FAH, The Federation for American Hospitals do not support with potential for mitigation. And then there were a total of six other organizations and individuals that expressed their support for the measure. This is the staff's summary. Diane, back over to you.

CO-CHAIR PADDEN: Okay. I'm going to acknowledge that Peter has his hand up, but I'm going to let Amy, our lead discussant and Karen begin. And then I'll come back to you, Peter.

MEMBER MULLINS: Thanks, Diane. Yes, so I just had a couple of comments. I agree with the workgroup from NQF that talked about the interventions not being representative of full scope, primary care family medicine, and also wanted to call out that two of the interventions, well, all of the interventions are going to cost the patient money.

If you're going to refer them to a registered dietician or a CDC-approved plan, that

could potentially cost them 20 percent, a 20 percent co-pay, and I would rather them spend that money on the food that I want them to eat to control their blood sugar instead of a program that I may or may not need to refer them to just to make this measure.

This could also disadvantage rural underserved or disadvantaged communities if those services are not available or if the patients can't afford to go to them. And then, you know, this is something that, you know, I don't want to open a can of worms, but, you know, I'm going to peek under the lid here.

The AASP, in general, doesn't support prediabetes as a thing. We're all pre-something. And if we just -- I'm just going to leave it at that.

CO-CHAIR PADDEN: Thank you, Amy.

Karen, do you have anything to add?

MEMBER ROTH: Well, I just wanted to say that our organization represents about 50 or 60 employers, and this particular area is

extremely important to them. Obesity is the highest risk factor for diabetes and given the very, very serious, you know, complications of the disease and trying to, you know, maybe get upstream to help people, you know, so that they do not develop the disease, I think, is extremely important and our employers think so to.

In their wellness programs, they offer, you know, many different interventions. One that's become very important recently is the one that's offered by Virta Health, which not only helps patients who are prediabetic but also people who have type 2 diabetes reverse their disease.

And so I don't know, I would really like to see this be a measure because of the, you know, the issue around the complications of the disease and how serious those things are, and also, in our community at least, we have many, many, many programs available, some of which are very little or no cost. And so these things, you know, really factor into our belief that, you

know, there is help available for people and that this measure would be very important. So I'll leave it at that.

CO-CHAIR PADDEN: Thank you, Karen.

Peter?

DR. BRISS: Hello everybody. This is Peter Briss. I said before, I'll say again that CDC supports the National Diabetes Prevention Program, so take that into account as you listen to me talk.

So in the reviews and in the comments, there was lots of agreement about the importance of the problem, the effectiveness of the intervention, based on reviews by the U.S. Preventive Services Task Force and others and a substantial quality gap.

A lot of the disagreement related is largely to the questions about feasibility of the interventions, and so I wanted to point out that the interventions seem to us to be more feasibility than have been reflected.

So as you've just heard, in-person DPP

interventions are available in lots of communities. In addition to that, these days there are online versions that are available every place in the United States. So, and the last year has shown us that a lot of health care can be delivered virtually.

So, and to the deliverance and virtually is likely to be, as Dr. Schreiber said this morning, is likely to be a direction going forward. And so the truth is, this one, there's a lot of agreement on the evidence front, and the feasibility front could have been sort of seen more positively. Over.

CO-CHAIR PADDEN: Thank you, Peter.

Any other questions?

In terms of the developers, the measure itself, could answer any of the questions regarding the possibility of other interventions or how we might make this measure a little bit more feasible?

DR. KIRLEY: Hi, this is Kate Kirley. I'm happy to chime in here. I'm a family

physician with the AMA. Appreciate that comment. So we did develop this measure, of course, with convening of a technical expert panel that was very multi stakeholder and major, including a number of primary care physicians who have a lot of expertise in diabetes prevention as well as a lot of hands-on experience.

And, ultimately, the group felt that this set of interventions was the best set of interventions that reflected what was available to them that reflected a strong evidence base, that would be feasible to measure and report on using structured data within an EHR, and that ultimately would be reasonable to hold clinicians accountable for.

And they've provided these multiple intervention options, really, to give patients and clinicians a choice and flexibility here. I think if we were to look at the evidence base for a brief counseling for lifestyle change, we would not find that the evidence base is really supportive here. That's definitely what the

technical expert panel felt, so, ultimately, this was really their set of interventions that they recommended.

You know, we will continue to sort of reexamine the evidence, reexamine the clinical guidelines as they change, but at this point, this was really the set of interventions that was planted on.

Can I also make a quick response to that note about interventions costing patients money? I want to point out that the Medicare Diabetes Prevention Program is a covered benefit for Medicare beneficiaries without cost sharing. So this is available to Medicare beneficiaries for free.

CO-CHAIR PADDEN: Okay, thank you. And there is one more comment, and I think this was brought up when Sam spoke about it, concerns about the limited interventions offered specifically in this measure, which was really counseling and then metformin.

Any other questions before we go to

the vote?

Okay. So, Chris, I believe the vote would go, the NQF recommendations do not support with potential for mitigation. And I guess the question I have is, do we need to specifically state that right now, or are we going to vote first?

DR. STOLPE: Yes, we do. So we also need to explicitly state what the mitigation points. They included respecifying the measure to include an adequate range of interventions for prediabetes available to a clinician beyond the prescription metformin.

We're referring to patients who had external service as well as NQF endorsement.

CO-CHAIR PADDEN: So we're asking is there anything else, or specifically those two would that be sufficient?

DR. BRISS: This is Peter again. As has been said already that the currently evidence-based interventions according to the U.S. Preventive Services Task Force and others

are the ones that are currently included in the AMA measure as specified.

So a broader range of interventions would likely make the interventions less evidence-based. Over.

DR. STOLPE: Thank you for that, Peter.

Nonetheless, this was the conclusion of the primary care and chronic illness standing committee and this is the starting point for the vote. So this is where we are going to start with our vote. If you don't agree with it, you can vote it down. All right. So, but --

CO-CHAIR PADDEN: Okay.

DR. STOLPE: -- I'd start there.

CO-CHAIR PADDEN: All right. Okay, Chris, we're ready.

MR. DAWSON: Okay, voting is now open for MUC20-0040, Intervention for Prediabetes for the MIPS Program. Do you vote to support the staff recommendation as the workgroup recommendation or do not support for rulemaking

with potential for mitigation?

CO-CHAIR PADDEN: Okay, 20, we'll call it.

MR. DAWSON: Voting is closed. The results are 13 yes and 7 no. The workgroup does not support the rulemaking with the potential for mitigation, MUC20-0400, Intervention for Prediabetes for the MIPS Program.

CO-CHAIR PADDEN: Okay, thank you.

I believe at this point, I'm going to toss it over to Rob for the next measures since I disclosed that I worked on these, that particular one.

CO-CHAIR FIELDS: Got it. And just confirming that we're, for purpose of the time since we're running almost an hour behind, we're skipping break. Just confirming that.

DR. STOLPE: I think we should plow ahead.

CO-CHAIR FIELDS: Yes, understood. All right, so we are moving on to the next set of quality measures for MIPS.

Sam, turn it over to you.

DR. STOLPE: All right, very good. We're now going to consider MUC20-0042, the Person-Centered Primary Care Measure. This is a PRO-PM. The Person-Centered Primary Care Measure uses a set of 11 patient-reported items to assess the broad scope of primary care.

The measure developer notes in their description that unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on the patient's relationship with the provider or a practice.

The items within the measure are based on stakeholder engagement and comprehensive reviews of the literature. Level of analysis is at the clinician individual and group practice level.

Now the staff recommendation for this measure is conditional support and an NQF endorsement. The sort of this measure does address critical quality objectives not currently

addressed in this measure set, namely it's the meaningful measurement area of care is personalized and aligned with patient's goals, and the MIPS high-priority measurement area of a person and centered, and caregiver-centered experience outcomes. Capturing the voice of the patient is clearly an important component of delivering high-value primary care.

This is an outcome measure related to patient experience of care, and this measure has been submitted to the NQF Primary Care and Chronic Illness Standing Committee as NQF 3568, which will be reviewed during the Fall 2020 cycle with our measure evaluation meeting occurring in early February.

The measure does address a quality challenge, namely that the assessment of patient experience being a critical element in care delivery. MIPS currently has an experience of care measure, which is the MIPS CAHPS survey, and there are no other primary care experience measures inside the program or inside of the CMS

programs -- related to patient-reported outcomes, excuse me.

So this measure was noted at multiple formats including option of electronic administration. The measure is not in current use.

The Rural Workgroup Input was fairly strong, noting that while it's similar to the CAHPS instrument, but it was relevant and meaningful to rural patients and providers. Once again, conditional support for rulemaking conditional on NQF endorsement.

We had a number of comments, four to be precise. Both AMA and the University of Colorado expressed support and no concerns, but encouraged the use of low-burden PRO-PMs in MIPS.

Blue Cross Blue Shield of Massachusetts opposed, citing a need for a case mix adjustment. That it's plausible that PCPCM scores which include items that implicitly assume a need for care from multiple places and a long enough relationship to "have been through a lot

together," and so these could vary substantially according to patient age, health status or tenure with the index price practice.

The Federation for American Hospitals notes that specifically it's critical to understand whether there is a potential for individuals to prioritize the completion of one survey over another and therefore lead to negative unintended consequences and response rates for other PRO-PMs such as CAHPS.

And this is the summary of the comments. Handing it back to Rob.

CO-CHAIR FIELDS: Great, thank you. And if we can get either the measure developers and/or the lead discussants, and I'm just going to emphasize that if we can keep it as to the point as possible that would be ideal. And I'll have some other comments when I get time for proper discussion.

But I'm going to let the discussants and the developers -- no, I'm sorry. Sorry, I had that wrong. We need to get clarifying

questions first. I apologize.

Go ahead, Rachel.

MEMBER BRODIE: Well, I was a lead discussant, so should I go now?

CO-CHAIR FIELDS: No, that's fine. No, go ahead. Yes, just go ahead if you have --

MEMBER BRODIE: Okay, thanks. So I just wanted to start by saying that I like the measure concept and I would really like to see something like this be successfully implemented.

But I did have a couple of concerns, the primary one being that it doesn't look like the measure development considered case-mix adjustment, you know, variables for potential risk adjustment models, so I didn't see any empirical analysis about this.

I think that without risk adjustment you're not going to know if the performance, you know, whether the performance was good or bad, was due to the provider providing person-centered care, or whether it was a younger-older population or, you know, a practice that has more

established patient panels, that type of thing. So that was a concern.

And then just a smaller concern, it did seem that this measure was more appropriate for a chronic care population or, you know, a patient with, patients with high needs rather than the full primary care. Most of the questions in the instrument, many of them are very relationship focused so I felt like, you know, is this measure going to distinguish whether the patient, you know, if a patient says no, not at all, is that because the provider didn't provide or it just wasn't relevant to the patient, if it was just a quick checkup, you know, so the provider didn't need to stand up for the patient and didn't need to coordinate across multiple, you know, different providers.

So anyway, those are my comments. I feel like it needs mitigation. More work.

CO-CHAIR FIELDS: Thank you. Okay.

And just as a matter of procedure here, we need to quickly determine if we can move

to a vote for conditional support for rulemaking or not and then we can move on to broader discussion, so just trying to assess that relatively quickly here.

So either of the measure developers might have any comments that address anything Rachel just commented on that might be directly related to that.

MEMBER STEVENS: If you can give me guidance as to where I might insert some comment about it as a discussant, appreciate it.

DR. ETZ: I'm happy to let the discussants go first. This is Rebecca, the measure developer. But I would love to hear the comments first.

CO-CHAIR FIELDS: All right, go ahead, Kathleen.

MEMBER STEVENS: Thank you.

I'll also underscore, certainly, the high importance and need for patient-reported outcome measures. I think that even conceptually this field needs further definition. And,

certainly, as it drills down to this particular metric of 11 patient-reported items, there needs to be much more extensive development and identification of the validity across multiple groups.

I think that a concern may not be so much on the metric, but the opportunity to reconceptualize and place into some of the original constructs, this morning, of race, ethnicity, language, but overall leading to the outcome of health equity in terms of personalized care, certainly including social determinants of health and cultural responsiveness. And this is the opportunity of did I have, you know, a fine time in my physician office visit or was there something bigger with this connection.

And I just think it's premature. A very important measure, but yet premature.

CO-CHAIR FIELDS: Thank you for that.

Rebecca, go ahead.

DR. ETZ: Thank you. And thank you for the comments, everybody. We really

appreciate it.

So I think I've kept an accurate list here. It looks like there are seven or eight issues raised. If I missed anything, please let me know. My interest is in addressing them fully because we feel pretty strongly about this particular measure.

So one of the first questions that came up was about whether or not practices would be, or clinicians would be disadvantaged by the question of we've been through a lot together and whether or not a case -mix adjustment would make a difference for that.

We do often get that question about this particular item. It was actually first created ten years ago. It's been used quite a bit. It's one of the only items in our measure that actually has a significant, a years-long backing behind it.

I would remind you that the measures are meant for benchmarking against others, so the target is not to get a perfect score of 4.0. In

fact, this particular item, we wouldn't find that to be appropriate. I would worry about a practice that got a 4.0 in this category.

It's benchmarked against other practices in order to understand whether their performance is actually appropriate or not, and the benchmark that we have on 9,000 clinicians, 9,000 surveys that we've received so far, show that the benchmark for this one is around 2.4.

So that would be appropriate and that's what we would expect. It has been tried in practices that are new and old. It's been tested in practices that are all pediatrics, all Medicaid patients. It's been tested in hospital-owned practices as well as privately-owned practices.

It's currently being piloted with Anthem and across the state of Colorado. It's currently being used at the University of Missouri in pediatrics, family medicine and internal medicine. It's been used for a couple of years in Toronto across family medicine health

teams, and yet it continues to hold and maintain its relatively high levels of validity and reliability, so we don't feel that that's a real issue.

Now whether or not the measure needs a case-mix adjustment is an interesting question and one that we are pursuing right now. We have published on the fact that there is no correlation between this measure and race, ethnicity, gender -- what was the other -- or language.

And, actually, we offer this measure and we have it validated in 28 languages and we have our publication was just accepted to Annals demonstrating that so we actually feel that it addresses a fairly broad community.

The variables for risk adjustment were considered, and again they were included in our publication. We tested along the usual categories and none of them actually had a significant impact, let alone a statistical impact on the validity or reliability. We did

find a rank ordering around age when the measure was applied, but this did not disadvantage any clinician or group.

The question about whether or this measure is relationship focused, it absolutely is. Primary care is a relational field and the interactions with primary care offices are relationship based. In fact, it is part of the definition of the field and what we usually consider to be most important.

Not paying attention to that relationship, which we find can be established in a single visit as well as long-term visits, is one of the biggest weaknesses of measures applied to primary care and one of the largest critiques offered by most of the people who do measurement in primary care.

This is what people want. This is what the clinicians want. We surveyed thousands of clinicians for this measure. This is what patients want. We've surveyed thousands of patients for this measure. We used 10,000

patient comments to create the wording of this measure.

So the relationship is extremely important and is something that happens in a checkup. It is the four Cs--continuity, comprehensiveness, coordination and first contact. And all of those things, if you're doing primary care well, are things that you address in every visit so we don't feel that's a weakness.

Yes?

CO-CHAIR FIELDS: I'm sorry to interrupt, but could you please specifically comment on any cultural implications in terms of how it's tested among various cultural groups and educational groups?

DR. ETZ: Sure.

CO-CHAIR FIELDS: There are a couple things in the chat and I'm just trying to get to those as quickly as possible.

DR. ETZ: Sure. No, I appreciate that. So we fielded this measure in 28 languages and we did that in the 35 OECD countries, and

that's the article that we just got accepted to Annals and it was validated in all the language and in those cultural contexts.

In addition, we have actually had teams in Japan, in Hong Kong, in The Netherlands, in Canada and in the U.K., who have been testing the measure on the ground to see if the difference, if there's any difference in local application than from what we were able to do through the traditional and accepted back translations, forward translations, subject matter, experts in the different cultural categories, and it continued the whole, it was not an issue.

We did do fielding specifically in Canada in a practice that had a high number of Quebecois. We had another practice that had a high number in California of Inuit. We had practices that had a high number of South American immigrants. In all cases the measure held.

Cultural difference was not an issue.

They seemed to understand these very basic concepts that were raised, and I think that's because we spent three years really developing it based on patient and clinician feedback.

Oh, the last piece, somebody said, you know, how it relates to a specific visit, and this is a measure of primary care which is not specific to a visit. The specifications ask that a patient fill it out once a year as long as they've had contact with their practice within the last year. We do that on purpose to not make it specific to an individual encounter.

CO-CHAIR FIELDS: That's helpful, thank you. And then two remaining general questions and then I know we have a hand up also, is any relation to, or correlation to CAHPS that you've seen in terms of its performance and then the CAHPS surveys.

And then I think if you can specifically comment on education, I think you mentioned about it performing well across cultures, but any, again any brief comments on

how it performed on education as well.

DR. ETZ: Yes. We have not noticed any variation based on education. Our patient sample included ten percent that had PhDs or higher, and it included 18 percent that did not have a high school degree. Education was not a factor.

These questions are written such that anyone can really understand them. The first question that you had was about -- lost it. Sorry, can you --

CO-CHAIR FIELDS: I'm sorry. About CAHPS.

DR. ETZ: Right.

CO-CHAIR FIELDS: If there's any correlation to CAHPS.

DR. ETZ: Yes, so the fielding that Anthem is testing right now in Colorado, they are actually fielding it alongside CAHPS and they found it to perform as well as CAHPS. They also found that it offered a wider understanding of primary care than CAHPS did.

CAHPS is really a patient experience survey and this is a patient assessment of primary care, so it includes some experiential questions but it also includes domains of primary care that have 30 or 40 years of research behind them and their importance to this particular field.

CO-CHAIR FIELDS: Very helpful, thank you.

DR. ETZ: I'm sorry. There's one last thing in addition to what Anthem is doing. The group that's been fielding this for a couple of years in Toronto has been fielding it alongside of a patient experience survey that they have in Canada that is equivalent to CAHPS and they have determined the same thing, that this correlated well with that but also offered a broader scope and seemed to be of more meaning to the patients and the clinicians.

CO-CHAIR FIELDS: Perfect, thank you.

Helen, do you still have your hand up?

MEMBER BURSTIN: No, Rebecca answered

all my questions. Thanks. So great, thanks.

CO-CHAIR FIELDS: Yes.

DR. ETZ: Sure.

CO-CHAIR FIELDS: That was great, Rebecca. Thank you. Very thorough and precise. Thank you.

DR. ETZ: Sure.

CO-CHAIR FIELDS: Okay, Wei Ying, please comment. And then we're going to move to a vote because, right after that.

MEMBER YING: Sure. Just a question. I know this, I think this measure is right in the process of NQF endorsements and review, this, the sort of risk adjustment, the need of a risk adjustment, the supporting information that has just been discussed being shared with NQF.

DR. ETZ: It has been.

MEMBER YING: For example, the sort of concordance with the CAHPS and the age and the sort of severity of the disease, whether it's a new patient or older patient, you didn't observe any meaningful difference. Those information NQF

does have?

DR. ETZ: NQF does have that. And it's not there's not a meaningful difference. There is a rank order difference and we are investigating whether we need to do a case-mix adjustment.

But NQF does -- Sam was present at the meeting that took place only about a month ago. We did discuss all these things with the NQF methods panel and it did pass endorsement from the methods panel, although their final meeting as you know is next month.

MEMBER YING: So if I'm reading it correctly, what you're saying is that you are actively looking at a version that potentially will have case-mix adjustment and you're right in the process of doing that; is that correct?

DR. ETZ: No. What I'm saying is that we have not found a need to do case-mix adjustment in any of the data that we've had thus far; however, we did note a rank order association with severity of illness and we are curious, and

therefore investigating whether or not a case-mix adjustment would be useful.

We're doing that work right now. I don't know whether that will prove yes or no. We haven't changed the instrument at all. We're simply testing that as a methodology and we're doing that in conjunction with Anthem right now in Colorado.

CO-CHAIR FIELDS: All right, I'm going to step in and actually move us to a vote, because if we're going to have further discussion, I'd like to do that based on the need to actually have this vote.

So if we can move to the vote, the first vote, which is to accept the preliminary --

DR. ETZ: I'm sorry. If I may, there was one remaining open question in the chat about whether this impacts patients cared for by PAs or NPs. Ten thousand comments from patients, not a single one of them referred to anything but their doctor or their practice.

We have found even nurse practitioners who get their treatment from nurse practitioners talk about going to see their doctor. So we adopted the language that was most meaningful to the patients. It did not confuse them at all that it applied to whatever clinician type they were getting their care from.

CO-CHAIR FIELDS: Great, thank you.

DR. ETZ: Sure.

CO-CHAIR FIELDS: We're for sure moving to a vote now for the preliminary recommendation to conditional support for rulemaking, if we can move to that at this point.

DR. STOLPE: Great. And just as a reminder that the condition is NQF, of course.

MR. DAWSON: Voting is now open for MUC20-0042, Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure for the MIPS Program. Do you vote to support the staff recommendation as the workgroup recommendation of conditional support for rulemaking?

CO-CHAIR FIELDS: All right, we can go ahead and close at this point.

MR. DAWSON: The voting is closed. Results are 14 yes and 5 no. So the workgroup conditionally supports the rulemaking MUC20-0042, Person-centered Primary Care Measure Patient Reported Outcome Performance Measure for the MIPS Program.

CO-CHAIR FIELDS: Great, thank you.

All right. Now we're moving to MUC20-0043, Preventive Care and Wellness. Sam?

DR. STOLPE: Sure. And just as a reminder, this one's going back to Diane. I think she was just loaning you the floor.

CO-CHAIR FIELDS: Okay. Sorry, my bad. That's right.

DR. STOLPE: Just as a quick review of the measure description, once again we're talking about the preventive care and wellness composite. This is the percentage of patients who received age- and sex-appropriate preventive screenings and wellness services.

The measure's a composite of seven component measures that are based on recommendations for preventive care from the U.S. Preventive Service Task Force, USPSTF; the Advisory Committee on Immunization Practices; and American Association of Clinical Endocrinologists and American College of Endocrinology.

The level of analysis is a clinician individual and group practice levels, and the NQF recommendation is conditional support for rulemaking based on receipt of NQF endorsement.

A couple of points related to the measure, this measure aligns with a number of CMS meaningful measure priorities as well as MIPS priorities and is based on seven measures that are currently inside of the MIPS program.

As CMS has pointed out that these seven measures would be removed if this measure is indeed moved into MIPS, so just wanted to meet that question off at the pass.

So the measure is evidence based and

is made of singular process measures which meets clinical guidelines for various preventive components. The measure is, are all currently used inside of MIPS as well as Part C and D Star Ratings programs and are duplicative only if the component measures are kept.

So this measure uses clinician-level quality payment program clinical quality measure registry data that can be feasibly reported and that is considered a low-burden source. The measure is not currently in use as a composite but, as noted, the seven components are. The Rural Health Workgroup input was basically that it was noted to be low burden, that it represented a good report card for rural providers and patients.

This is a summary of the comments received. There were five in total. University of Colorado opposed due to many reasons. The patient might not be up to date, suggesting that the composite measures may not be especially useful for quality improvement.

Pfizer provided general support and suggested that the exclusions of patients over 66 in screenings if they have a claim for frailty may be discriminatory. There are a couple of do not supports too with potential for mitigation from AMA and the Federation of American Hospitals, supported the components but concerned for the measure's complexity.

The AAMC suggested that this measure is premature, and the American Academy of Neurology did not support due to the burden of data collection. Now that's a summary of the comments. Back over to Diane.

CO-CHAIR PADDEN: Thank you, Sam. I will go to our lead discussant and I believe we had, Lisa was here from the Patient Safety Action Network earlier this morning, or is she still there or as --

DR. YU: Actually, I'm here. Can you hear me? I'm Yanling Yu.

CO-CHAIR PADDEN: Yes.

DR. YU: Okay.

CO-CHAIR PADDEN: Okay, so you can -- all right, thank you.

DR. YU: Yes, thanks.

CO-CHAIR PADDEN: All right, so we'll start with you. What kind of comments?

DR. YU: Okay. I have a couple of clarifications, clarifying questions. Should I ask them now and add other comments at the same time or should I wait later?

CO-CHAIR PADDEN: You can, if you would just give us kind of your overview or your initial impressions about the measure and then we'll continue from there.

DR. YU: Okay. Well, you know, as patient and consumers recognizing importance of preventive care, improving patients' overall health and quality of life and the reducing long-term health crisis risk and cutting overall healthcare costs and to improve population health for patients and consumers, we do need it to focus on upstream of health care.

So, in general, we do support measures

that improve, you know, this type of care, but we do have several concerns on this particular measure. Number one, and to make this measure more meaningful, we think it would be good to have this measure be linked to some outcome indicators that are care quality and patient health improvement, and otherwise they can't just document seven components and made recommendations and it becomes a simply a checking box measure. And that's number one of our concerns.

And the second one that is also a clarification question, on the -- there are seven components for this composite. This is a process measure. There's three individual measures like Quality ID 128, preventive care and the screening for body mass, and then the screening for Quality ID 226, preventive care and screening for tobacco use, and then Quality Measure 317 for screening for high blood pressure, and we seem to, if I understand correctly, all those three measures have been topped out in 2020.

So even if that's true we have concerns. It doesn't seem to make sense to include topped-out measures in this composite so, and also none of the seven measures are in high priority.

And the last thing that is clarification is the -- on the page 160, in the first paragraph it lists this measure is, it says that among the services references are screening for breast cancer, colon cancer, blood pressure, diabetes, and when I look at all seven components, there's nothing really explicitly say diabetes. It only has one BMI.

So I'm just curious, you know, where does this diabetes component brought in, in this composite? So that's basically our concerns and in particularly about this topped out the three measures. So that's it for now.

CO-CHAIR PADDEN: Okay, thank you.

I'm going to ask David if you have any other comments to add to those initial comments and then there's one in the chat, and we'll kind

of get them all together to discuss. David?

MEMBER SEIDENWURM: Sure. Thank you.

You know, I think this measure is a good step in the right direction. It is complicated. You know, there's seven different ages and different reporting periods, but I think those are all specified in reliable, within the MIPS construct already.

So I think that's okay. I think it promotes a systemness and a whole-patient approach which I think has long been our goal. It promotes practice integration. Some of the objections were quite legitimate in terms of, you know, ophthalmology or mammography or colorectal cancer screening services being provided outside of the practice and hard to document, but I think this would tend to promote systemness. It does promote parsimony if the other measures are retired, so it gets us down to a smaller number of measures.

With respect to the issue that was raised regarding the topped-out measures, I don't

necessarily regard that as a problem because the topped out definition, you know, is based a lot on voluntary reporting.

So those who are successful at the service report that measure, you know, in order to enhance their MIPS score, but since this would be presumably a whole-patient calculated by CMS type of measure, that criticism I don't think would be relevant.

One concern I did have, and I'm not sure that this is necessarily solvable and I'm not sure how big of a problem it really is, but because they use a linear weighting for each of the measures, there's really, you know, prioritization.

And, you know, it's difficult to know exactly what increment of improvement in which measure has the greatest impact here, but I think in the future some effort at that might be considered, although I think that for the moment I think we should adopt this staff recommendation and give conditional support for rulemaking and

bring it forward for endorsement.

CO-CHAIR PADDEN: Thank you, David.

And there's a question in the chat. Helen, do you want to speak or do you want me to lead it? I'm not seeing you, Helen.

MEMBER BURSTIN: I'm here. I'm happy to do it. I just was a little surprised by Sam's comment which I hadn't noticed that the individual measures were being removed from the program (audio interference) all the measures made (audio interference).

And then just these measures are pretty (audio interference) that whatever gets put in here that those changes will be reflected in the measures over time.

CO-CHAIR PADDEN: Okay. I had a little trouble hearing you, Helen. I don't know if everybody else did or if it was just my phone. So I'm going to read what you -- as people had said.

Would the individual measures be removed, and that's my understanding that if we

should pass this for conditional support for rulemaking then and it went forward, those individual measures would be removed. That's my understanding.

All components may not be applicable to all clinicians. I think that's kind of a good question as well depending on maybe a patient population. And then we have one more question.

If it wasn't asked previously, numerator 5 would require chart abstraction, I would think. I don't know exactly which numerator 5 that one is, specific, so do we have a measure steward here that might be able to answer that question?

DR. ANDRESS: Good afternoon. This is Joel Andress from CMS. I'm the measure lead for the development of the PCW, so I'll take a crack at answering these. I think there's one particular, the question about diabetes, and actually the other one that's asking about the topped-out nature of the components, but I think I may turn to the developer, the measure

developer Mathematica, to respond to.

Right, so I think to the first question about linking these to outcome indicators as opposed to simply checking off that particular screening action or intervention has been taken, personally, I think that's an excellent point.

We limit ourselves in the development of this measure to existing measures in part because we're attempting to undertake an effort to bring some increased parsimony to the assessment, but also to eliminate a situation where you might have documentation of a single kind of intervention on a single issue as opposed to getting a more complete and full assessment of the degrees to which we're providing preventive care in general. And to use that we took advantage of the measures that were available to us at the time.

I think that we would very much like to be incorporating measures that have the kind of follow-on action and outcome results that you

mentioned. Unfortunately, that's not something that we had available to us to hand but, certainly, as such measures become available, I think we would be very interested in considering their incorporation in the programs specifically, but potentially in a composite measure like this should we be able to.

So I just wanted to touch on that. I think that's dead on. I think with regard to the question about linear weighting and the fact that no one particular action is prioritized over the others, I think part of this is that we don't have an agreed-on way of prioritizing one particular action over another.

I think they're all important for clinicians to the covering. And so in terms of deciding which one is important, we simply lack a meaningful prioritization method of it.

I will note that we are considering the pursuits of additional data at the patient level that we think will allow us to potentially consider alternate composite methods that can

look at, for instance, the potential for weighting measures, the impact of a given measure based upon the numbers of patients that are incorporated within the given measure or performance, you know, or an embodiment of performance for each individual patient.

So these are things that we certainly want to consider for the future of the measure and we're pursuing data available, data for that, but those data aren't available to us, currently.

So I think we had to make some decisions about whether or not we wanted to try to wait to have the perfect set of data available for us and the perfect measure set to us, or if we wanted to make an effort to build the composite here with the intention of modifying it in the future as the opportunity becomes available.

And I think, you know, the latter is a better approach because preventive care, you know, clearly, is even now and isn't going to wait for us to have a perfect measure set, I think, in terms of the individual measures being

removed.

So, first of all, I'll put in a note here that we can't, you know, actually guarantee that that's going to occur, the rulemaking process being what it is, I'm sure you're all aware. But we developed this measure with the intent of being able to remove those measures, because as you know there's a limitation on how many measures are incorporated within the program for a given clinician.

And that means that if you're selecting, you know, the influence organizational measure as an example, then that's going to, you know, limit the extent to which you can cover the other issues that are addressed within the composite.

So I think the composite gives us a broader reach into the concept of preventive care for patients. And from a patient perspective, I think that that's quite important for the program to be able to address as broadly as possible.

To the issue of whether or not the

measure is applicable for everyone or the individual components are applicable to all patients, I think that's true. And in fact, you know, we take that into account and that if there are no patients within the measure, within an individual component measure, then that's simply not going to account toward the weighting of the measure.

There will be a zero denominator and so it will not contribute to the overarching score, and instead the weighting will be accounted for among the individual components.

All right, so I don't recall off the top of my head what the results were for the testing for the individual components with regard to the topped-out status. I can tell you that our testing for the performance gap in the individual measure, or in the composite measure indicated quite a substantial gap in performance overall.

I'll turn that over to my colleague at Mathematica and see if they can respond to that.

DR. GREEN: Hey, Joel. Joel?

DR. ANDRESS: Yes.

DR. GREEN: Yes, sorry. Hey, this is Dan Green. Good to be here and talk to all of you all, albeit, unfortunately, it's virtual and not in person. We'll look forward to next year.

Helen, I can't believe I have to see you virtually instead of in person. I'm disappointed. But anyway, thanks for the opportunity to speak. I'll be brief because I know folks have things to do.

You know, this is consistent. Combining this into a composite measure is consistent with the administrator's Meaningful Measures initiative, and also what Dr. Schreiber, you know, spoke on this morning.

You know, early on the program and I was, been with PQRS, actually PQRI when it first started, you know, some of these measures have been around really since that time. So we're really, you know, trying to mature as a program, get more meaningful, clinically useful

information to caregivers.

You know, me, if I'm in my office and I'm seeing patients and I'm documenting that they had a flu shot either given at Walmart or Walgreens or whatever, or maybe given at their primary care doc, that's great and it's certainly, I'm sure we would all agree it's important to make sure our patients receive flu shots, but it's hardly an assessment of preventive care in and of itself.

This measure in a composite form as you guys can see, you know, allows clinicians and patients to see how well a particular clinician or practice is doing at meeting overall preventive care.

I think, Helen, I think you asked, you know, why retire the other measures, and it's a tricky question. I mean it's a good point you bring up for sure, but, you know, unfortunately, within the confines of the program you can also imagine somebody reporting, let's say, this measure and then going back to report the

individual components as individual measures and now they've met the requirements of the program.

I know, but believe it or not we've seen all sorts of crazy things over the years. So, you know, but still and all, having a composite and reducing the overall number of measures, I think again is in alignment with the administrator and our goal to have more meaningful measures.

Last thing I just want to say about some of the topped-out measures, there are some components, certainly, that have higher performance rates. I'm not sure that smoking is one of them when we look at the percentage of patients who actually smoke who are counseled to not smoke, not the -- as opposed to combining those that smoke and those that don't smoke.

When we combine those, you know, the numbers are inflated inasmuch as 99 percent of your practice may not be cigarette smokers. The other one percent who do smoke, you may never counsel.

But if we look at that particular performance rate, it would look like your number's 99 percent when, in reality, those that really needed the intervention, aka the counseling to stop smoking, weren't in fact receiving it.

And I'll pause there because that's about all the questions I remembered.

CO-CHAIR PADDEN: Thank you, Dan. I appreciate it.

And Joel, I'm going to just ask, do you have anything different to add to this conversation, otherwise we'll move to the vote.

Okay, you're good? Okay, great.

Chris, can you prepare the polling for us? And the recommendation is conditional support for rulemaking pending endorsement, I believe.

MR. DAWSON: The voting is now open for MUC20-0043, Preventive Care and Wellness Composite for the MIPS Program. Do you vote to support the staff recommendation as the workgroup

recommendation of conditional support for rulemaking?

Okay, it looks like we have 19 votes. So voting is closed. The results are 15 yes and 4 no. The workgroup conditionally supports for rulemaking MUC20-0043. Excuse me. Preventive Care and Wellness Composite for the MIPS Program. Thank you.

DR. STOLPE: Diane, why don't we turn it over to Sheri Winsper for some remarks related to our COVID measure?

MS. WINSPER: All right, Sam. Can you hear me?

DR. STOLPE: Yes, we can. Thank you, Sheri.

MS. WINSPER: Okay, great. I'll be brief, but thank you. I know our next measures are the COVID-19 measures and two vaccination measures. As far as representing NQF, we just wanted, I just wanted to make one clarifying comment that while the NQF preliminary analysis recommendations do not support with potential

mitigation, this does not in any way mean that NQF as an organization does not support COVID vaccine measures and, I'm sorry, COVID vaccination.

So we definitely do support the efforts with vaccine administration, but we just follow our process and the MAP process in evaluating the collection criteria, and so this really relates to measure specification versus support of vaccination. And I'll turn it back to you.

DR. STOLPE: Very good. Thank you.

At this time, we will have a presentation from our colleagues at CMS related to the measures just to add some clarification and to frame the discussion, so I'll turn it over to the CMS.

DR. SCHREIBER: Thanks, Sam. This is Michelle. I'll kick it off and then I'm going to turn it over to Joel Andress.

Yesterday, at the Hospital and Post-Acute Care MAP, we brought forward, actually, a

number of measures. They don't pertain to this group, but I just wanted to set the stage there because CMS is trying to be proactive when it comes to developing quality measurement about receiving the COVID vaccine.

We recognize full well and actually recognize the way that the vote went from NQF that we don't have all of the information in order to have a robust measure that all of you would be used to. We don't have measure specifications. We don't have the testing because it doesn't exist, you know.

There's obviously a great deal of unknowns so far with COVID vaccination including will it have to be an annual vaccine? Is it, God willing, and again, you know, we vaccinate everybody and it's the end of the pandemic and we don't have to think about it again. Wouldn't that be nice?

CMS, I'm sure, as well as everybody wishes that that were true. But we're thinking forward that we believe that vaccination will

likely have to be ongoing. Just as we measure flu vaccination on an annual basis, we may very well have to measure COVID vaccination on an annual basis and we're trying to gear up for that now.

We have been working in concert with the CDC looking at how to gather data and for the most part we're going to be gathering data through NHSN, although that is not the case for clinicians because that would mean registering every clinician in the United States with NHSN, and I don't think that there's interest on either end on either the clinicians or the CDC's part to do that.

So the collection source here will be different. The measures that were brought forward yesterday include measures for vaccination of healthcare personnel and it was on a wide range of sites from post-acute care settings to hospital settings to ESRD settings to others, and so that's one direction of measures.

We are not bringing forward a measure of individual provider vaccination, although if we get to a point where that is collected that's certainly a consideration. We also brought forward measures on patient vaccination specifically for end-stage renal disease patients in dialysis facilities. We are not bringing forward any recommendations for vaccinating patients in hospitals because it's not clear right now what the recommendations will be about whether or not hospitalized patients should be vaccinated because of questions of immunogenesis.

We are continuing to discuss whether or not we can bring forward a recommended measure for nursing home patients. So we already did for healthcare personnel, but for nursing home patients.

And you might say, well, that's one of the highest priority areas, why isn't CMS doing that? And it's not because it's not important, it's because there's some underlying issues of the authority of collecting the data.

What we're bringing forward to you today is one measure on COVID vaccination by clinicians. This is a patient measure, so whether or not the clinician has evaluated and ensured that the patient in their practices receive a COVID vaccine. Again, we recognize and frankly apologize, but I think all of you do understand that we just don't have all of the information yet.

But we bring these measures to the MAP, one, so that you can conceptually understand where CMS is going and trying to go with it, and two, because if we didn't bring it to the MAP, we would delay by an entire year any ability to bring a measure like this forward even as we continue to develop it, in many cases, with the CDC or measure developers.

And so with that, Joel, let me turn this over to you for a discussion of the one measure that we're bringing forward to the clinicians.

DR. ANDRESS: Thank you, Michelle.

Good afternoon again, everyone. It's still me. I want to take an opportunity to thank my colleagues at Mathematica and NCQA for the work that they did on this measure. It was quite a fantastic effort that they made for us to be able to have this here today to discuss.

I also want to thank our partners at NQF for helping us discuss how do we format this measure and bring it to you in a way that we can ensure that we have a meaningful conversation about the measure moving forward, particularly within the context of the MIPS program. And so if we can go to the next slide please. I'll go ahead and get started.

So I think one of things that we started off realizing about this measure is that, you know, we're essentially using a process that really isn't designed to respond to emergent pandemics with a measure that is precisely designed to respond to an emergent pandemic. And that's caused kind of a disconnect in sort of, in what we're able to present to you and what we're

asking for you from this meeting.

So as Michelle has noted, we don't have testing data available on this measure. We do have a set of specifications that we have had the opportunity to carry forward to an expert workgroup that we have thought about very carefully before bringing you here.

The focus of this presentation is to kind of lay out what our thinking is for that and then make available to you some time to have a discussion with us about how we should best proceed with next steps.

I think there's probably not much point to point it out that we don't have testing data. And the real value for the discussion that we're looking for is: what do we need to think about as we consider moving forward with a COVID vaccination measure, what the implications are, what are the potential unintended consequences, and how best might we act to mitigate those.

So to lay out very quickly on the screen, we have our specifications for the

measure laid out for you. The measure is addressed to a patient base 18 years and older who are seen for a patient visit during the measurement period or for the year.

We have one exclusion for this population, including patients who have received hospice services at any time during the measurement period, and three exceptions. Those exceptions include patient contraindication, patient refusal of the vaccine, or the vaccine being unavailable around some of the sort of thinking behind these.

We left the exception of contraindication fairly broad because we didn't want it to be specific to a given vaccination, and because frankly at the time we were putting this together, we didn't necessarily know what all the contraindications might be for a potential vaccine, particularly a year from now.

Patient refusal is included here primarily because, as we've been monitoring the, let's say political environment around vaccines

in general and this vaccine in particular, I think this is a cause for concern.

And yet we want to be capturing data on patient refusal, because we think this will give us the opportunity to understand where our needs are for education, outreach, and pushing for additional information to drive our policy decisions in the future.

And then finally we've included vaccine availability as a potential issue, although I think our hope is that because this measure couldn't be implemented before 2022 anyway, that of course the vaccination availability will be substantially greater than it currently is.

And finally, for the numerator, the way we laid this out is to try to get as much information as we possibly can about the distribution of vaccines among patients.

And so in order for a patient to be counted with an enumerator, it requires either that a patient has received from the clinician,

or reported having received, at least one vaccination dose or has received or reported having received a full course of the vaccination. Now any of these will incorporate you -- will be included within the enumerator.

Helen, I see your question there. I think the answer to that is that we want to get a sense of what the gap is between patients who are receiving a single dose versus a full course.

And so that was one reason that we decided to depart from the measures that are being based upon the CDC's NHSN reporting data. Because, of course, this measure isn't being captured in the same system.

That was one thing that we had available to us. Of course, if there are concerns around that I think that would be, of course, be back, but I think we'd be very interested in hearing.

So Lisa, I think the answer to that is that the full course will be assessed from the clinician having either asked the patient and the

patient has attested to having received the full course, defined by whatever vaccination is being received, or the clinician has in fact provided, you know, the full course, in this case I think two doses for the two approved vaccines available at present.

Our intent is that there's enough flexibility here to reflect, for instance, another vaccine that receives approval but is at a different requirement for the full course. But it can still potentially be reflected within the measure. Can we go to the next slide please? Thank you.

So as I've noted, you know, this is very much intended as a way to gather information to be able to drive policy decision making. And the decisions that we made in developing the measure have reflected that, which I'll go into in a moment.

We were able to convene an internal expert workgroup to inform the development and specifications around the measures. And that's

in fact, one of the reasons that I think we had some distinction, some differences from the other COVID measures that are being discussed by the MAP this year.

Because there are, I think, different challenges in capturing the data at the clinician level but also some opportunities for receiving additional data. And then we wanted to take advantage of that. And the expert workgroup was quite helpful in doing so.

You'll note, of course, the measure is not seeking NQF endorsement prior to submitting the measure here. Part of that is because we don't have testing data. And as we're all aware, NQF takes a dim view typically of quality measures that are submitted without testing data.

On the other hand, as Michelle has noted, you know, this is a public health emergency. The NQF endorsement process, I think is not really designed to try to churn out measures rapidly in response to a health crisis of this type. Indeed, the MAP isn't designed for

that, and our own MMS blueprint process is not really designed for it.

And so what we're really doing at this point, I think, is trying to shoehorn in what processes we have available into the need, which is the ability to assess the distribution of vaccinations across the patient population but also to encourage efforts to vaccinate those patients among the clinician populations. Next slide please. Thank you.

So I think, with that in mind, we've carried the measure forward as quickly as we can within the current process. As I've already noted, the measure cannot be implemented any earlier than 2022 which is I think in some respects unfortunate. But by acting now, we have the opportunity to ensure that there is a capacity to track and capture vaccine deployment among providers.

I think we had carried the advantage of basing the measure in part off of existing vaccination measures in other areas. We're just

talking about influenza and pneumococcal vaccinations in the PCW discussion.

But it will, of course, because of that, we have I think a good sense of what kind of information needs to be captured for vaccines. And that gives us a step up in thinking about how to get it implemented.

DR. SCHREIBER: This is Michelle. Can I just interrupt you for a moment? Because I'm looking at Helen's question. So it's clear --

DR. ANDRESS: Sure, no problem.

DR. SCHREIBER: -- that COVID vaccination data is going to be collected across the country in frankly many different ways. But to your question, Helen, this is ultimately intended for not surveillance but quality assessment, whether or not a provider is ensuring that patients have had a COVID vaccine.

And I think that probably the best parallel is to think of this as how important it is to get patients influenza vaccine, how important it is to get patients pneumococcal

vaccine. And we think COVID will fall into something similar so that it is ultimately intended for quality assessment in the surveillance information.

And frankly the selection of COVID vaccine administration will be starting now, well before this measure takes place. I hope that answered your question. Sorry, Joel.

DR. ANDRESS: No, of course, Michelle. And then I think finally, as we discussed the specifications, we've tried to design the measure to be as flexible as possible. And there are a couple or reasons for that.

First of all, of course, there is the --- simply the unknown related to what vaccines may become available between now and 2022. We wanted this measure to be able to encapsulate those as readily as possible.

I think the other issue is because of the lack of information available to us, including testing, including published standards or guidelines of usage, you know, it was

important to us that the measure had the flexibility to avoid incurring unintended consequences with its implementation. And so the flexibility is intended to give us sort of a characteristic of the measure that will avoid that as much as possible. Can you go to the next slide please?

So then we come to the question of how the measure can be best utilized. The measure can earliest be proposed in this coming year's rule for performance year 2022. We haven't decided, on the CMS end, how best to incorporate the measure into MIPS.

And I think there are a lot of things that we want to take into consideration. For instance, is the same measure that is best applicable as broadly as possible, or should it be implemented under the same rules as the existing quality measure set?

You know, what are the potential implications for burden and imbalance in those decisions, and what is the best way to report the

information, you know, what are the implications of incorporating the measure for payment and so forth?

So we are very much open to accepting feedback on the implications of measure implementation. And that is, in fact, the primary purpose of the MAP.

But I think it's most especially here, because we have, usually when we're bringing a measure here, we have a pretty strong idea of how it fits within the program. Because we have templates, and we have past usage of measures that have been tested and are being fitted in, in much the way that other quality measures are.

This measure is something of a special case. And so we want to get your thoughts on what the boundaries are, the boundaries should be, and to make sure that we're taking into account all of the potential concerns you would have of us going forward with a measure that is in this current state. Because that is very much what we are in the process of considering. Next

slide.

So the measure is designed to be flexible with regard to the implementation. That's one of the reasons why we allow it to assess either at least one dose or a full course of the vaccine.

We wanted to be able to access at least one dose, because we know that there may be implementation burdens implicated with trying to track the provision of the second dose or trying to track potentially provision of individual doses of multiple vaccines. And so we want the measure to be able to capture that.

At the same time, we want to be able to get a sense of the extent to which clinicians are able to distribute one dose versus a full course of vaccinations. Because that has healthcare implications for us.

The measure is intended to allow for self-report or for the provision of the vaccination, again to allow for as much intake of data as we can possibly have and to ensure that

there is as much opportunity for assessing the appropriate action taken.

And then finally, the exceptions we put into place for contraindication here specifically is intended to allow clinicians the flexibility to assess what contraindications are appropriate for a given vaccine that is available at the time the patient is being vaccinated, and to be able to reflect whether or not one of those contraindications is present, and then to make the appropriate clinical decision to provide the vaccine or not based upon that.

And as such, we avoid the potential unintended consequence of patients receiving vaccines that they should not be receiving that could be potentially harmful for them.

And then finally, I just want to note, we built this measure to be revised. We expect this measure to require revision early on its life, because we expect there to be more data available, frankly, as data are being collected.

And of course, any revisions to the

measure should reflect that, incorporating additional testing data, well any testing data at this point, but also incorporating our experience with the vaccines, the guidelines associated with those, and the potential implications for implementation.

And then I think the other modification we want to consider in the future is the development of an ECQM-based analog that would reflect this.

One of the barriers we encountered early on in this is that the process for developing ECQMs requires existing standards that were not available for us. So we didn't have that option which is why we presented this a CQM. But of course, we want to be mindful of that, that avenue for assessment in the future as well.

So thank you for giving me the opportunity to present this. I turn it back to you if you have any questions for us. Then we are certainly open to responses and would appreciate hearing your thoughts.

DR. SCHREIBER: Joel, thank you, this is Michelle. Well Sam, let me ask you, I don't know if you want to vote or not. I mean we certainly understand the vote of do not support with mitigation. So I don't know if you want to vote on that or not.

We're seeing some very helpful comments already in the chat. What we would very much appreciate is the ability to hear some of that feedback. And so I guess I'll ask you what you want the best course to be here.

DR. STOLPE: Thanks very much, Michelle. What we had planned is for Rob Fields to facilitate the discussion after the presentation. And so if you're prepared to answer a couple of questions from our committee members at this time, that would be the appropriate course.

And then we are required by statute to vote on measures under consideration. So we will still have a vote, so ---

CO-CHAIR FIELDS: Can we vote first

then? Do you mind if -- I mean if we're going to have to vote anyway, I'd rather not have the discussion twice. So is it unreasonable to go ahead and vote, and then do the discussion as we normally do? Or is that not the way you want to go?

DR. SCHREIBER: I mean frankly that's kind of what I was thinking.

CO-CHAIR FIELDS: Yes.

MEMBER BURSTIN: Just a quick point of order, if I could. This is Helen. In the old days we used to have, for measures like this that were early in development, that the MAP could support the direction.

I hate to actually put this forward with a negative connotation for something this important. I don't know that that's even possible, but this just feels wrong to sort of tell CMS, oh, don't do this in the middle of this crisis.

And if there is a way to just maybe, if CMS would allow it, not to necessarily have a

formal vote but to allow us to sort of support direction, since it's not even a fully baked measure yet. We would, it's hard to even truly vote on it.

DR. SCHREIBER: Oh, and I think CMS would be very supportive of that. We really didn't know that was an option. If NQF is fine with that, so are we.

DR. STOLPE: We would prefer not to do that. We're essentially supposed to go through our process and still continue to vote on measures and to provide a recommendation. That's just part of the statutory requirements associated with measures under considerations that are brought forward.

DR. ANDRESS: If I can note, in the past when we've been looking at the feedback from the MAP while we're going through rulemaking, something that is very helpful to us, or has been in the past and I think would be very helpful here, is that I think the vote is fine whenever, you know, you have to carry through regarding

your requirements. And we understand that, as Michelle has said.

But if there is the possibility for a clarifying statement or language that can be incorporated within the body of the report that kind of lays out the thinking of the panel around the measure, then that would be something that I think would be useful for us as we're thinking about implementation of the measure in the future. So I was just going to point out that kind of language can be very useful.

CO-CHAIR FIELDS: In that case, we should probably discuss it before we vote on it so we can summarize that. How's that sound?

DR. STOLPE: Yes, that sounds great.

CO-CHAIR FIELDS: All right. So I was trying to keep track of hands in chat. So Peter, you've had your hand up actually since before we even started the COVID conversation. So I'll call on you first.

DR. BRISS: I knew I was going to have something to say. So anyway, just three quick

things that I think CMS is to be complimented for. For being proactive about this really important topic is point one. Point two is thank you for being collaborative with other agencies and other groups like NQF and this committee.

And then, well the one and two dosing thing is complicated. And so as a -- we favor, CDC generally favors being able to distinguish people that are partially immunized versus people that are fully immunized.

You might do wording to that effect, that counting doses could get you into trouble later. There are vaccines in the pipeline now, like the AstraZeneca vaccine, in which a full course might be one dose. And so you might pick language like partially and fully immunized. But the general direction is really terrific. Thank you.

DR. SCHREIBER: Thanks, Peter.

CO-CHAIR FIELDS: Great. I think Scott, you were next.

MEMBER FIELDS: Thanks. Michelle, it

went by fast, and I didn't catch it. And so it's a question about, you were talking about registering, and it was going to be too complex. And I missed it. It was about clinicians.

DR. SCHREIBER: It was about NHSN, Scott. And Peter may want to comment on this.

So the reason that we are doing the other measures through NHSN is because facilities, hospitals, now nursing homes, others that actually registered with NHSN to be able to submit data to them, okay.

In order to collect this through NHSN, which is the CDC, you know, registry for infections, vaccinations, and the like, in order to do that every clinician would have to register with NHSN.

I think that we might break their system, quite honestly, if we had to register over a million clinicians. And I don't think every clinician would like to have to do that. So we're thinking of other ways to collect data. And that's really what I was alluding to.

MEMBER FIELDS: Thank you. I appreciate the clarification.

I would, if I were to push the vision a little bit, we need a methodology that would enable that sort of following and documentation.

So much as the country is having a conversation about a unique patient identifier, as an example, we have that for physicians with NPIs, having an ability to actually track in that way, I think would have a national type approach to it that, quite honestly, we're missing in the public health arena. At least I think we're missing in the public health arena. That's an opinion, I guess, as opposed to a fact. But I'll throw that on the table.

The other thing, I'll pick up a little bit on Peter's comments. And I guess I'm really looking at this from, I'll say, a clinician perspective. You know, being half-immunized may be a little bit like being half pregnant. There's no such thing.

And so I would just throw out that,

you know, I appreciate that maybe some immunizations may require two, even three doses, who knows, to get it. But the key thing is defining what being immunized means and documenting that.

So I hope that we do that, again, for the purposes of healthcare as opposed to just documentation purposes. So I throw that on the table for people to consider.

DR. SCHREIBER: No, thank you, your point is well taken. And I'm seeing a lot of comments in the chat that, as we think through this measure, we may want to really focus on what others have called fully immunized.

Because really, what is it that we want to know? We actually want to know if patients are fully immunized. And we want providers to ensure that patients are fully immunized. I think that's the goal here.

CO-CHAIR FIELDS: So I would point out, I guess there's likely to be future vaccines that only require one dose. So that would be the

tricky part.

All right. Wendee, I'm going to -- oh actually no, Helen, you had your hand up earlier, but I don't know if we've covered everything you asked, because your hand is now down.

MEMBER BURSTIN: Just a few points. I think most of them have been made. I do think, you know, the process points notwithstanding, I think the key thing is CMS is hearing this. And I kind of think there's clear support for the direction that you're going. And it's really important that you continue to proceed.

I do think there is a nice model here of being able to replicate in many ways what's done with the flu vaccine rather than creating something from scratch. We exhaustively spent so much time trying to figure out patient refusals, et cetera, that using that as the mousetrap may just make the most sense here going forward.

And I'll just say that it is, in a conversation we had with CDC on Friday with 15 of our societies who take care of high risk

patients, there's actually a fair number of our societies who are using their registries to capture vaccination as well, especially to understand the issues around vaccine hesitancy.

So while the couch here is really helpful, it's also going be really important to understand what is leading to some of the refusals and really address those over time. But, you know, kudos to you for bringing this forward in this fast pace.

And it needs to be done. If there's a way for us to support the direction, obviously there's a lot of work to be done. And I hope, to Scott's point, you can find a method that's easy to collect these data, but happy to chat with you more about the registry piece.

DR. SCHREIBER: Yes, thank you, Helen. We may take that offline and do that. I think you're right though, the hope is that this parallels the flu vaccination.

I do have a question for the group though, because we've had a lot of conversation

about patient refusals and whether or not it should, quote, count, unquote, through a clinicians performance. So if the patient refused, does that count for the physician?

You know, at a time of the pandemic, from a public health point of view, you have to have the vaccine. Does refusal actually count, or should it not? And I'm just curious what the group thinks.

MEMBER BURSTIN: I'll just make one more comment there. You know, this is exactly what we went through with flu. And I think the idea is that by having a two-part measure that includes offered but not taken, as well as offered, you get the full sense of the data rather than trying to make an assumption that, you know, I can usually, as the attending, walk in and get almost anybody to take a vaccine after they refuse my resident. But it's still important to, I think, capture those data.

DR. SCHREIBER: Thanks.

CO-CHAIR FIELDS: In terms of

procedure, so I'm being told that we're going to, we have a risk of losing quorum in one minute. So I'm going to ask you --

DR. SCHREIBER: You want to go ahead and vote?

CO-CHAIR FIELDS: -- for some guidance here. Should we go ahead and vote and then come back to comments so we don't lose quorum? Is that okay?

DR. SCHREIBER: I think we should go ahead and vote, because I am reminded by my own team that you are correct. We have to have a vote.

CO-CHAIR FIELDS: All right. So let's go ahead and vote so we don't lose quorum, and we can come back for additional comments so we'll have some guidance.

MR. DAWSON: Okay. And Sam, did you want to say anything before we vote?

DR. STOLPE: Yes, it was just to Helen's point. But we struggled with this as well at NQF when we were reviewing this measure.

We understand the nature of the public health emergency and that the algorithm that we have is intended as a guide. It's not a strict set of rules, but it's intended to help the staff as they set the starting point for where these discussions are going to occur.

Now in light of a public health emergency like this, MAP can recommend the course that you think is appropriate for CMS to take. If it's not, if your choice here is do not support with potential for mitigation, then you should vote that down. And there's nothing wrong with that.

And if you think that there should be a different approach, then you can voice what that approach should be. So just want to keep in mind that there is some flexibility in our overall approach. And Helen, thank you for the sentiments that you expressed.

So please keep in mind that if you want to stipulate some other approach such as conditional support, or full support, those are

within your purview. And I'll leave it at that. And we can go ahead and open up the vote.

Now I just wanted to note that the current NQF recommendation is do not support with potential for mitigation and that the mitigation for this measure that, prior to implementation, that the evidence associated with the vaccines should be, and the measure, excuse me, should be well documented. The measure's specifications should be finalized, followed by testing and NQF endorsement.

DR. YU: Could I ask a question, Sam?

DR. STOLPE: Yes.

DR. YU: You mean the potential mitigation, do you have any timeline for this potential mitigation? Because this is a national crisis right now.

DR. STOLPE: It's a point well taken. So we did not define that. We just said that prior to implementation that the evidence should well documented. The measure specifications should be finalized and that should be followed

by testing and NQF endorsement.

MR. DAWSON: Great. Thank you, Sam. So the voting is now open for MUC20-0045 SARS-CoV-2 Vaccination by Clinicians for the MIPS Program. Do you support the staff recommendation as the workgroup recommendation of do not support for rulemaking with potential for mitigation?

We have 17 votes so far, 18, okay, 19. I believe that is everyone. Rob, should I go ahead and --

CO-CHAIR FIELDS: Yes, go ahead.

(Simultaneous speaking.)

MR. DAWSON: -- responses there?

CO-CHAIR FIELDS: Yes. Let's do it.

MR. DAWSON: Okay. So voting is closed. The results are 17 yes and two no. The workgroup does not support for rulemaking with potential for mitigation, MUC20-0045 SARS-CoV-2 Vaccination by Clinicians for the MIPS Program. Thank you.

MEMBER FIELDS: Thanks. I would like to, David, go to you just because I'd like to

have the comments in the minutes, if at all possible, to help CMS.

MEMBER GOZANSKY: Sure, thanks. So, you know, my comments were really around the question of the patient refusal. And I actually think that, you know, we have seen a lot of silver linings within COVID. And I think perhaps one of the silver linings here would be the question of how do we capture when we really have patients, after shared decision making with patient preference, not to go through with something that we consider to be evidence-based.

I think this is something that we should really be looking at. I totally get it's an EUA. We don't even have, you know, FDA approved it is a pandemic.

We want people to uptake this vaccine. And I think if we're going to go down this path, the more information we can garner around understanding refusal, so that we can get people to start uptaking, you know, it's probably not only going to apply to COVID. It'll improve our

influenza vaccines and what not. I just think that this could be critically important.

So I think it's interesting. I'm interested to see how you're going to do that. And I think it opens for shared decision making around mammography and other things as well.

CO-CHAIR FIELDS: Thank you for that. And I want to make sure we covered everything else.

DR. SCHREIBER: Do you mind if I ask --

CO-CHAIR FIELDS: Yes.

DR. SCHREIBER: -- the group, and I don't want to take a lot time, because we still have another measure. But would you make this a mandatory measure in MIPS? I know that would be controversial in and of itself, but obviously everybody understands the importance of wanting to do this. So I am just curious what the group thinks. And by the way, I don't even know that we can. I'm just asking.

CO-CHAIR FIELDS: Others want to

comment?

We have a yes in the chat. Go ahead, Trudy.

MEMBER MALLINSON: I can let Scott go first, I just couldn't find where the hands up sign was, sorry.

CO-CHAIR FIELDS: I think Scott says yes in the chat, is what I see.

MEMBER MALLINSON: Oh.

CO-CHAIR FIELDS: So go ahead.

MEMBER MALLINSON: Okay, so just a couple of questions for clarification. One was around the actual availability, which well given that this is going to roll out probably 2022 or later, one would hope that availability issues from a production issue have been eliminated by then.

Right now though, we have no national strategy for delivering vaccines. It's very much at a state and even more local level. And so whether someone gets a vaccine or not is, in a large part, as much about the locale in which they reside as the quality of care. So I wonder

about that availability question going forward.

Another question I had was just about the age of 18 that was considered. And I know that right now there has not been a lot of study done about immunizing children with the vaccines. But as potential spreaders of the disease, is there a consideration for expanding that age group in the future?

Others have made a comment about the dosage, and that's changing as we speak, fortunately, today. And I think there's been enough of a conversation about that.

The last question I had was about the use of the word ever, if people have ever received a vaccine. And the idea that we don't fully know right now whether once will be enough, or whether this will be something that people have to do on an ongoing basis, and ever sort of precludes that. So I would just raise those comments.

DR. SCHREIBER: Yes, thank you for that and certainly the comment about ever. You're right, we're hoping that by the time this

measure would be actually used that the issues of supply would be well behind us.

And as Joel pointed out, we fully expect this measure to completely -- not completely but to change. And likely we'll see this as another proposal but with, you know, significant modifications. So you're right, and thank you for that. I've seen ---

DR. ANDRESS: I'm sorry.

DR. SCHREIBER: -- a few things in the chat about mandatory reporting but not tied to payment. And that is something that we need to investigate. The statute doesn't necessarily allow for that. But it is something that we're looking at.

And Joel, I'm sorry. I didn't mean to interrupt you.

DR. ANDRESS: Oh no, not at all. So just one question. I think Trudy, that was, you were recommending a question about the language saying ever, having received the course. Just a question, would it be possible to include that

and other recommendations in the summary that follows the vote?

Since we're talking about things that we need to consider, or make changes to in a measure, or make sure that we're following up on, is it possible to include that in a summary of the conversation, and this may actually be more of a question to Sam, so that that information is available in the report when the vote is provided?

DR. STOLPE: Yes. And Joel, I think that that's appropriate. At this time we should probably move forward. We only have 30 minutes before ---

DR. SCHREIBER: Yes.

DR. ANDRESS: Okay. Thank you very much.

(Simultaneous speaking.)

DR. SCHREIBER: I want to thank everybody really for your feedback. It's been very important, so thank you.

DR. STOLPE: And what I would invite

the committee to do as we're, excuse me, the workgroup, as we move forward into this next area, if you have additional comments, please feel free to enter into the chat. The staff will capture them and include those inside of the final report that we issue for public comment.

CO-CHAIR FIELDS: Okay. Great, so we're going to have a discussion here. I guess we're skipping the gap discussion at this point, right?

DR. STOLPE: We can circle back to it is if there's time at the end.

CO-CHAIR FIELDS: Yes.

DR. STOLPE: All right, let's move forward.

CO-CHAIR FIELDS: Yes, that's fine. Let's start with the MSSP, and I will I guess turn that over to you, Sam.

DR. STOLPE: All right, very good. I think the first thing we're going to do is open it for public comment. So at this time, if there's any comments from the public related to

the measure under consideration for SSP, you may provide your comment to the group.

(No response.)

DR. STOLPE: All right, hearing none, let's move forward with our discussion of the next ---

DR. SCHREIBER: Sam, we have a raised hand.

DR. STOLPE: Oh, okay. Sorry, Don Casey. Don, please keep your comment brief, since we're a little short on time.

DR. CASEY: Thank you. I apologize. Is this comment period for the MSSP measure and not the others?

DR. STOLPE: It's just for SSP. Yes, you're correct, Don.

DR. CASEY: Will there be public comment for the other measures or not? Is that over with?

DR. STOLPE: No, there will be a public comment available at the end of the day.

DR. CASEY: Okay, great, I'll wait.

Thanks.

DR. STOLPE: All right, thanks, Don. Moving forward, we're going to be discussing MUC20-0033, the ACO-Level Days at Home for Patients with Complex, Chronic Conditions. And this is a measure of days at home or in community settings, that is to say not un-planned acute or emergent care settings, for patients with complex, chronic conditions in SSP ACOs.

The measure includes risk adjustment for differences in patient mix across ACOs with an additional adjustment based on the mortality risk at each ACO. The level of analysis is, of course, the Accountable Care Organization level. And the NQF recommendation is conditional support for rulemaking pending NQF endorsement.

Now just a quick summary of the staff analysis here. Just one minute, sorry. I've got about 40 things open on my desktop.

So this measure addresses meaningful measurement areas associated with the management of chronic conditions and preventive care. The

measure is an outcome measure. The remaining at home is generally considered as preferred by patients associated with other important outcomes including increased social activity and reduced depression.

The developer indicated that the time spent at home differs substantially between older patients, which suggests there is potential for improving the quality of care and resulting days at home for the elderly population.

The measure is not duplicative of other measures currently in the SSP program, though some comments drew attention to the fact that there are other inverse measures that are currently inside of SSP that may be somewhat duplicative by the commenter's view.

The measure use of Medicare claims data which can be easily reported and is specified at the ACO level which aligns with the appropriateness of the SSP reporting categories.

The measure is not in current use. And the Rural Health Group, excuse me, the Rural

Health Workgroup suggested that their rural providers could perform well on this measure, and it was shared that rural providers may not have necessary needs in place to provide sufficient home health services which may render the measures challenging in some rural environments.

So once again, this is conditional support for rulemaking contingent on NQF endorsement. The public comments were supported from the National Association of Home Care and Hospice.

The University of Colorado expressed concern that patients who end up in nursing homes after hospitalization, with or without SNF stay in between, and usually from a medical condition which there is loss of activities of daily living, would count against them in the measure.

CTAC expressed concern that days at home may not be possible for all patients with chronic conditions and better to track days out of the hospital specifically.

The American Medical Association

expressed concerns whether differences in performance on this measure could reliably be attributed to services delivered by ACOs and whether this measure could be used to truly distinguish the quality of care ACO participants received.

This concern that preliminary performance scores confirmed concerns that the measure will not produce sufficient variation to enable anyone to distinguish high versus low performers.

AMA further cautions CMS that this measure may be attributed at a level where the outcome can be meaningfully influenced and is closely linked to structures and processes that are actionable by ACOs, feasible to implement without unnecessary burden, and demonstrably reliable and valid with appropriate risk adjustment, including social risk factors.

Premier noted that they did not support the measure, as it is not a true outcomes measure by their estimation, that other measures

already addressed the measures' intended consequences.

AMT noted that they do not support because the measure should not be added to SSP and echoed Premier's concerns.

FAH also had concern for duplication with the existing SSP measures around admissions and re-admissions and to assess the removal of those measures that this was going on.

That's the summary of the comments of the NQF staff recommendations. Back to you, us. I believe it's Diane who is leading this measure.

CO-CHAIR PADDEN: Okay. Thanks, Sam. In the interest of time, we do have a NQF recommendation, but I am going to ask our subject matter expert, William, if you would like to provide a comment or two to see where we're kind of sitting with this measure. Dr. Fleischman?

MEMBER FLEISCHMAN: Sorry, I actually don't think I was aware that I was assigned to this. So ---

CO-CHAIR PADDEN: No, okay. Well do

you have any comments? I have your name down here, so ---

MEMBER FLEISCHMAN: Oh, I might have in a minute.

CO-CHAIR PADDEN: Okay. Any other comments? I see a hand. Jennifer?

DR. STOLPE: I just wanted to note that Jennifer isn't a member of the workgroup. So Jennifer, if you could please ---

(Simultaneous speaking.)

DR. STOLPE: -- public comment, that would appreciated.

CO-CHAIR PADDEN: Okay. So we'll catch that later. All right, so shall we go to a vote, seeing no comments or hands? Chris?

MR. DAWSON: Okay, just a moment.

CO-CHAIR FIELDS: Is Susan Knudson not on, I guess? I believe this -- I mean I have several comments, but not for the purposes of clarifying the measure. But I just wanted to make sure the --

CO-CHAIR PADDEN: Do you want to make

those?

CO-CHAIR FIELDS: -- I guess in terms of procedure. Well I mean in terms of procedure, I think we should probably vote in terms of clarifying the measure the way that it's supposed to work. But I didn't know if the discussants had -- if Susan's still on. I guess not.

DR. STOLPE: We'll make comments, and express concerns, or raise questions for the developer if you wish, Rob, prior to the vote.

CO-CHAIR FIELDS: Okay. I mean I think we have a few concerns or I guess questions for the developer, I guess more specifically in terms of there are several ACOs, for example, that care for a density of long-term care patients.

And it's a little curious in terms of how the measure is calculated in terms of if you're already in long-term care, and you go in and out of the hospital, and you go back to skilled nursing for some time before you go into long-term health, how those things are calculated

in terms of the episode. Like where does the episode start in particular?

CO-CHAIR PADDEN: Okay, I think that ---

(Simultaneous speaking.)

CO-CHAIR FIELDS: -- care, but how does it count?

DR. BERNHEIM: This is Susannah Bernheim.

CO-CHAIR PADDEN: Susannah's on. Thank you, Susannah.

DR. BERNHEIM: Hi, this is Susannah. I realize it is 5:30, so I'm going to try and be brief and specific. The two things we thought a lot about developing this measure, based on what had happened with prior versions, were nursing home residents, you know, folks who were there residential, and how to handle mortality. The question was about folks who are in nursing homes.

So this measure is designed to primarily focus on acute care usage. So days in

care are emergency room observation stay, admissions, follow-up, SNF care. Nursing home days are not strictly counted as days in care. However, from a policy perspective, it was important to not encourage over use of nursing care.

So residents who are resident at the beginning of the performance year, we're only assessing days in care if they then go from their nursing home into the hospital.

But each ACO's result is adjusted slightly based on their expected rate of new transitions to nursing homes as a policy adjustment to ensure that we're not rewarding over use of nursing homes. It's a little bit complicated, but that's the goal. I'm happy to explain more, but I'm trying to respect your time.

CO-CHAIR FIELDS: No, that makes total sense. Can you address the mortality, because we were going to go there, and that was actually another question of mine.

DR. BERNHEIM: Yes.

CO-CHAIR FIELDS: Hopefully that'll be quick.

DR. BERNHEIM: So the days in care are -- so the measure ultimately is a combination of three separate models. I'm over-simplifying slightly, but essentially we build the days in care looking at your predicted versus expected days in care.

That result is then adjusted for higher than expected mortality rates, again with the same purpose of trying to avoid the unintended consequence of looking like you do well on this measure because of a higher than expected mortality rate. So the nursing home and mortality, they're weighted slightly differently, but they are functioning similarly as an adjustment to the score.

CO-CHAIR FIELDS: Okay. And just a general question from, I guess, from the CMS standpoint is how this measure sort of fits into the APP for ACOs and MIPS APMs. Is there a plan

or a sense for that?

DR. BERNHEIM: I don't know who from the Shared Savings Program is on.

MR. JOHNSON: Steven Johnson's on the line. The idea would be, what we would want to see, what is the -- how this fits across all of the various ways and metrics on the quality side for the ACO program.

So in looking at the days at home, just as Susannah explained, we're just trying to get a better idea of the patient population and things of that nature to see how long they're actually there in the community versus how long they're at home. So any feedback on how we can improve that or things of that nature, we'll definitely appreciate it.

CO-CHAIR PADDEN: Rob, do you have any other questions?

CO-CHAIR FIELDS: One quick one is that are COVID days going to be excluded since they were excluded from MSSP costs? Is there a plan or any plan around COVID?

MR. JOHNSON: That's something we'll take back up. I am not quite sure at this time.

MEMBER FLEISCHMAN: Question, so I guess a more proper name would be days not in acute care as opposed to days at home, would be a better description of the numerator.

But I see hospice is excluded based on the concern that it might -- that it would be a negative driver of potentially withholding care. Does that include inpatient hospice as well?

DR. BERNHEIM: Yes. We made a decision that once they have the hospice benefit we essentially ignore that location.

CO-CHAIR FIELDS: Thank you. All right, that's it, Diane, sorry. That was all my questions.

CO-CHAIR PADDEN: That's okay. I had the chat box over your name. I didn't see you. Yes, I don't see any other hands. And I don't see anything else in the chat box. So now we're ready for the vote, Chris.

MR. DAWSON: Okay. And there were a

few votes already cast before we backtracked the conversation. So I did clear those out. So we'll be starting over here. Give me just a moment.

DR. STOLPE: Thanks, Chris. And as reminder, this is a conditional support for rulemaking contingent on NQF endorsement.

MR. DAWSON: Thank you. Voting is now open for MUC20-0033 ACO Level Days at Home for Patients with Complex, Chronic Conditions for the SSP Program, the vote to support the staff recommendation as the workgroup recommendation of conditional support for rulemaking.

Okay, we have 18 votes. I believe that is all of them, right?

CO-CHAIR PADDEN: Yes.

MR. DAWSON: So voting is now closed. The results are 16 yes and two no. The workgroup conditionally supports the rulemaking MUC20-0033 ACO Level Days at Home for Patients with Complex, Chronic Conditions for the SSP Program.

CO-CHAIR FIELDS: Excellent. Okay, well congratulations everybody, we got through

all of our measures. I know we were all sweating bullets for a little bit and that we skipped portions of our agenda in order to move forward with those, including breaks. So thank you to everybody for hanging in there and getting this through our very busy agenda.

We're not going to quite move into public comment yet, because we did skip a couple of parts, so mainly the gap discussion. So if it's possible, and I'll defer to our co-chairs, we do have about 15 minutes left. And I do want to leave some time definitely for, minimally for Don's comments and for others.

But do you think we could have a brief gap discussion where we could proffer measures, concepts, and ideas that we think would need to be included inside of SSP or MIPS before we move on?

CO-CHAIR FIELDS: I'll just comment just briefly on the SSP. You know, I think some of this has played out publicly in comment letters but to just take the opportunity, I do

think that I have concerns, as do many of my colleagues in this space, that the radical shift in quality measures in the SSP program is devaluing, honestly, at least this element of the value-based care movement, frankly in terms of the very small number of measures and the choice of measures, as well as the choice to move to ECQMs.

But specifically in terms of the, you know, I am all about trying to ease the burden on docs on reporting measures. But I'm kind of failing to understand how ultimately in 2022 or three ECQMs can adequately evaluate the quality of tens of thousands of Medicare beneficiaries along with some CAHPS surveys. I'm missing it.

While I totally appreciate the sense of trying to ease the burden, I just feel like it shot too far. And you know, just to reiterate, there has to be a lot more work done on ECQMs for all these programs moving forward, whether it's a true gap. It was certainly a gap in development, I would say.

As much as anything else, I think we're going to have some really significant unintended negative consequences about really moving forward with ECQMs before they're ready from the operating side, and especially as it relates to rural NCQA providers. I think it's going to particularly hit them hard.

CO-CHAIR PADDEN: Anyone else have any comments?

MEMBER BURSTIN: This is Helen. I'll just make one comment that I feel like I made about 25 hours ago. But I think at the start of this discussion about the need to consider measures that actually reflect racism and equity rather than just stratifying existing measures.

CO-CHAIR PADDEN: Thank you. Anyone else? Anything in the chat? Nothing in the chat. Okay, Sam, nothing in the chat and I don't see any more hands.

DR. STOLPE: Great. Now Helen, was your comment intended for both MIPS and SSP or just generally? Okay.

MEMBER BURSTIN: Yes, generally I think.

DR. STOLPE: Are there any comments related to the gaps in MIPS that we should consider as well?

DR. YU: Yes, this is Yanling Yu. I just want to comment, I really encourage CMS and NQF more think about outcome measures. And we have a lot of process measures. And I think that, you know, the outcome measure would tie it more meaningfully to, you know, the overall informing quality and, you know, the patients' quality of life and healthcare improvement.

DR. STOLPE: Thanks, Yanling. Any other comments about the MIPS measure sets and gaps?

(No response.)

DR. STOLPE: Okay, if not, we can go forward and open it up for the public comment period. Don, you've been patiently waiting. Dr. Casey?

DR. CASEY: Yes, can you hear me?

Sorry.

DR. STOLPE: Great, thank you.

DR. CASEY: Can you hear me okay?

DR. STOLPE: Yes.

DR. CASEY: Oh, great, thanks. So four quick points. First of all, congratulations to the group for getting through a complex agenda.

And Don Casey, American College of Medical Quality, speaking as an individual, four quick points relative to the first sepsis, 0019, understanding that the group did not support this measure, but highlighting a point that wasn't made regarding the difference between sepsis coded as present on admission and not present on admission.

If this continues to be used, I think that's important we documented a high degree of variability between 200 teaching hospitals in terms of those two categories which are separate.

Secondly, on 0034, I want to echo and add to Dr. Teeter's comments from ACC regarding

the lack of the ability of ICD-10 to keep up with the modern classification and staging of severity of heart failure which is not captured in ICD-10 codes. And so I would caution using the current ICD-10 set alone.

Third point, 0043, appreciate the intent of having the person-centered primary care measure set as a composite, but a fair warning, having been sitting on an e-quality measure TEP, that there's been a lot of pushback.

And given that these were developed with AACE and ACE as opposed to the primary care groups, I'm cautioning CMS that, when this gets to an e-quality measure set, there's going to be a different conversation.

And then lastly, relative to the COVID -19 measure which I support and think is good, there is a high degree of variability in a very rich research base that shows geodemographic variation, for example, but also even within countries of origin within a certain ethnic group.

And so Dr. Burstin will remember that we used to, in the old days, spend a lot more time worrying about field testing. And I think that field testing would be a good way for Dr. Schreiber and others to consider getting this into play. Because we don't want to create the perception that we're disadvantaging providers who care for these diverse populations. Thank you.

DR. STOLPE: I'd also note that Jennifer Gasparini had her hand raised previously. Jennifer, did you want to make a comment?

CO-CHAIR FIELDS: I know Jennifer, and she had to unfortunately jump off for an emergent issue. But her comments are in the chat. In my other hat as Board chair of NAACOS, I'm fairly familiar with the comments she placed in the chat and commented on earlier.

I would also just add, based on extending what Don just said, that from a constituency point of view CMS can be a great

place in terms of testing measures that may be reporting only perhaps on large scale, and certainly equity measures or things of that nature, if there's a great degree of interest among our constituents, to test those measures out. So we'd very open to that.

DR. STOLPE: Very good, thank you, Rob. And just for the sake of the record, I will go ahead and read portions of the comment that Jennifer submitted.

So first, she notes that for the days at home measure the National Association of ACOs echoes many of the concerns raised in today's discussions and would like to know if this measure is in addition to the existing APP measures or in place of a measure currently used, and a question on what data will be shared with ACOs in quarterly reports in regards to this measure.

She says that NAACOS would support the concept of the measure but has some concerns with the exceptions for the measure and risk

adjustment issues with the measure, so do not support addition of the measure at this time.

As for measure gaps, National Association of ACOs continues to urge CMS to think differently about APM quality measurement, including ACOs, where something like health equity could be a very good measurement area and also, at the same time, not as well suited to evaluate the individual clinician level.

Okay, any further public comments at this time?

(No response.)

DR. STOLPE: Okay, hearing none, we can go ahead and move to a summary of today. I'll turn it back to Rob and Diane.

CO-CHAIR FIELDS: I'll keep my comments really brief, just to thank you all again for all your time, and your energy, and perseverance working through breaks and a short lunch. I feel like we tackled some pretty complex issues in terms of cost and quality today, certainly prompting more robust discussion down

the road.

I hope it was helpful for the CMS team and the measure developers, and I will turn it over to Diane.

CO-CHAIR PADDEN: I would echo my thanks to the group and for your stamina. I can attest that I'm exhausted. It's hard to sit for a long period of time when we're used to maybe moving around.

But in terms of kind of some general comments, I thought it was a really good discussion on having, about cost and quality measures and how they're complementary or how they work together so that we can really provide that quality of care while keeping the cost down. So I think that -- I'm hopeful that CMS and everyone got some really good take-home points there.

I also thought it was a good discussion about how sometimes we think that these measures might decrease clinician burden. But at the same time, we know that we need to

have the measures there. And so it's a fine dance to make a decision on where the measures are and how that will impact the workload and clinician burnout. And with that, I will close it out and thank you all very much.

DR. STOLPE: Thanks very much, Rob and Diane, we very much appreciate your leadership through a very challenging agenda today.

I wanted to see if there are any further thoughts from our colleagues at CMS before we adjourn.

DR. SCHREIBER: So thanks, Sam, I appreciate it. To our co-chairs, thank you so much. You did a great job at facilitating this. And to NQF, thank you also.

On behalf of CMS, I just want to say thank you to everybody for really very thoughtful discussion and feedback.

The cost measures is something that I think, Sam, we're going to need to take offline and maybe even have a subgroup around it. Because I think we have some issues where I don't have an

easy answer to some of the mitigations that people want, quite honestly. And then it's going to require further discussion. So again, to all of the group, thank you so very much. And be safe and be well.

DR. STOLPE: Thank you, Dr. Schreiber. And lastly, before we adjourn, I just wanted to offer NQF leadership an opportunity say any closing remarks.

MS. HAYNIE: This is Michael Haynie. I would like to echo everyone's thanks. I know it has been a long day. We are greatly appreciative for all of your time here, all of your thoughtfulness. And you're very good natured as we've pushed through some breaks, and issues, short lunch. Your comments are truly helpful and very informative. And again, we just end with gratitude here.

DR. STOLPE: All right, thanks so much, everyone. We'll adjourn for the day. And really appreciate all the hard work that went into this. Thank you, and have a good night.

(Whereupon, the above-entitled matter went off the record at 5:55 p.m.)