NATIONAL QUALITY FORUM

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MEETING OF THE
MEASURE APPLICATIONS PARTNERSHIP
HOSPITAL WORKGROUP

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MONDAY
JANUARY 11, 2021

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The Workgroup met via Video Teleconference, at 1:00 p.m. EST, Akin Demehin and Sean Morrison, Co-Chairs, presiding.

WORKGROUP MEMBERS:
AKIN DEMEHIN, MPH, American Hospital Association, Chair
R. SEAN MORRISON, MD, National Coalition for Hospice and Palliative Care
AMY CHIN, MS, Greater New York Hospital Association
JAN DONIS, RN UPMC Health Plan
TEJAL GANDHI, MD, MPH, CPPS, Press Ganey
FRANK GHINASSI, PhD, ABPP, National Association for Behavioral Healthcare
KELLY GIBSON, MD, Society for Maternal-Fetal Medicine
KAYCEE GLAVICH, Press Ganey
MARYELLEN GUINAN, JD, America's Essential Hospitals
MARTY HATLIE, JD, Project Patient Care
VILMA JOSEPH, MD, American Society of Anesthesiologists
ANNA LEGREID DOPP, Pharm.D., American Society of Health-System Pharmacists
JENNIFER LUNDBLAD, PhD, MBA Stratis Health
LISA McGIFFERT, Mothers Against Medical Error

ELIZABETH McKNIGHT, MS, Intermountain Health Care
DENISE MORSE, MBA, City of Hope
SANTOSH MUDIRAJ, MPH, Henry Ford Health System
SARAH NOLAN, PhD, MPA, Service Employees International Union
JANIS ORLOWSKI, MD, MACP, Association of American Medical Colleges
AISHA PITTMAN, MPH Premier Healthcare Alliance
KAREN SHEHADE, MBA, Medtronic
CRISTIE UPSHAW TRAVIS, MS, Memphis Business Group on Health
DEBBIE WHEELER, Molina Healthcare
JACKSON WILLIAMS, JD, MPA, Dialysis Patient Citizens
MIKE WOODRUFF, MD, Intermountain Health Care

INDIVIDUAL SUBJECT MATTER EXPERTS:
ANDREEA BALAN-COHEN, PhD
LINDSEY WISHAM, MBA

LIAISON FROM THE RURAL HEALTH WORKGROUP
JESSE SPENCER, MD, Intermountain Healthcare

FEDERAL LIAISONS PRESENT:
MICHELLE SCHREIBER, MD, CMS
MIA DeSOTO, PhD, MHA, AHRQ
JESSE ROACH, MD, CMS
DANIEL POLLOCK, MD, CDC

NQF STAFF:
MATTHEW PICKERING, Pharm.D., Rph, Senior Director, Quality Measurement
UDARA PERERA, DrPH, MPH, Senior Manager, Quality Measurement
CHRIS DAWSON, MHA, CPHQ, CPPS, LSSBB, Project Manager
BECKY PAYNE, MPH, Senior Analyst

ALSO PRESENT:
ELIZABETH DRYE, Yale CORE
SHARON McCAULEY, American Dietetic Association
COLLEEN McKIERNAN, Lewin Group
KARTHIK MURUJIAH, Yale CORE
LISA SUTER, Yale CORE
ANGEL VALLADARES, Avalere Health

A-G-E-N-D-A

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

1:00 p.m.

DR. PICKERING: So, I will go ahead and kick this off since it's 1:00 p.m. here on the eastern side and to kick start this. So, welcome back. Thank you all.

For those folks, again this is the Hospital Workgroup Room, so if you're in here from the PAC/LTC, that was a different link, so this is the Hospital Workgroup Room. We'll be going over the measures for the Hospital Quality Improvement Programs.

You can see again some housekeeping reminders similar to what was listed previously this morning, just keeping yourself on mute. This is a Zoom meeting, so we encourage you to use the video feature once you're chatting. You're not obligated to, but we encourage it just so we can see your faces as you're talking.

We also encourage you to use the raise hand feature as well during the discussion if you'd like to. We would then call on you and

monitor your participation that way or through the chat box. We'll keep an eye out for that.

For those members of the public, there will be public commenting portions of the meeting, and so during those portions, you're more than welcome to submit your comments through the chat, and we'll try to leave some space as well for those who are dialing in.

And also as another reminder for the workgroup meeting folks, the Poll Everywhere link, so again, that is the link that we'll be using to vote on the measures for consideration. That is a separate link from the Zoom meeting. It is a Poll Everywhere link. It was sent via email earlier this morning.

So, for those of you who have it opened up and tested, thank you very much, but for those of you that maybe haven't tested it yet, please go into it just so you can pull it up and get it running and test it.

We have, I think, a few folks that still need to open it up and test it. Again, we

need to use that feature for voting and also to help us monitor for quorum.

Becky, if you could flip back to the team slide, that would be great. I just wanted to recognize that staff has been very much instrumental in the background in supporting these efforts to date. We both have the MAP Hospital and also the MAC PAC/LTC that were also on the meeting this morning.

But as you can see listed here, we have quite a few folks that have been supporting the efforts of this cycle, and on the MAP Hospital side, myself, Matthew Pickering, Senior Director.

We also have Samuel Stolpe. Dr. Stolpe has been with NQF and MAP previously. He has been supporting and also leading the clinician side as well, Udara, who all of you have heard from earlier today, who is our senior manager.

Katie Berryman is our project manager, and Chris Dawson, another manager on the MAP

Hospital as well that will be helping with our voting procedures today, and Carolee, who is also a manager from the Coordinating Committee and definitely has been integral in making sure to keep things moving and leading up to the Coordinating Committee.

Becky Payne, who is our analyst, who has been very supportive with making sure you all get all of your materials so that you can review them and getting you ready for today's meeting. And then we heard from Michael Haynie who is our managing director here at NQF, and also Taroon Amin who is our consultant.

I just wanted to recognize these individuals as well and thank them for all of their time and effort leading up to the meeting today and moving forward.

I'm just going to check in again. Sean, are you able to -- were you able to join?

CHAIR MORRISON: Yep, I'm here. Sorry, Matt. I was just finishing lunch, so I didn't want everybody to see me eating.

DR. PICKERING: No worries. I was trying to do the same quickly, very quickly. So, yes, thank you all for coming back. So, I will also mention as we go into the COVID-19 measures, before I turn it over to you, Sean, you heard a presentation this morning from CDC and CMS.

One measure in particular that we will be looking at, which is MUC-0044, which is the vaccination coverage among healthcare personnel, it spans a series of programs within the Hospital Workgroup.

So, one thing that the Rural Health Workgroup did last week, and according to NQF policies, there may be some similar feedback across all of these different programs, and there may not be a need for the workgroup to revote again.

So, if there are no objections after we vote on the first measure, excuse me, the first program with this measure and we go to the next program, if there's no objections, if there's a unanimous decision, we can carry over

those votes from program to program.

Again, that's only because it's for the same measures across multiple programs. So, there has to be a unanimous decision, and that means no objections.

So, if you object, then we will have a separate vote for that specific measure in that specific program, and that objection does not require a vote. It's just saying I would wish to vote on this separately or I do not want to carry over the votes. All we need is just one.

Again, it has to be a unanimous decision to carry over. So, I want to mention that before we get into the COVID-19 discussion as there is that one measure across all of the programs.

Secondly, you'll see that as well with the global malnutrition measure. That's MUC-0032. That's used across two different programs. Again, if there is no need for the committee to feel like they want to revote unanimously, we can carry over that decision to the different

programs since it's the same measure in two different programs.

Any questions there before we get started and turning it over to Sean to sort of kick us off with COVID-19 measures?

MEMBER HATLIE: This is Marty Hatlie. I can't find the raise my hand button. Sean tried to help me, but I can't find it. The public comments on the MUC list today, I don't remember seeing a link to those. Is there one that was distributed that I just missed?

DR. PICKERING: The public comments, so they're within the PAs.

MEMBER HATLIE: Okay.

DR. PICKERING: So, at the very bottom of the PAs, there's sort of a green portion. That's where the public comments are in.

MEMBER HATLIE: Okay, I got it. I've got that. Okay, I just wondered if there was something more recent than that, okay. Okay, thank you.

DR. PICKERING: Yep, sure, and we can

also resend some of them momentarily if that's helpful. And, hi, Sarah. Did you have a question?

MEMBER NOLAN: Yeah, I did. So, to -- I mean, I like the process that you laid out because it seems more efficient, and I guess so that sort of means that any -- that it wouldn't make sense to sort of have a robust discussion on the first program, you know, rather that people can sort of air their views on the concept of the vaccine requirement measure generally. Do you get what I'm saying?

DR. PICKERING: So, yes, I believe I do.

MEMBER NOLAN: And, you know, so for example, the public comment gets pretty much repeated for each measure. I didn't notice any comments that were specific to one program. There may have been a few, but I don't want to assume, but I sort of anticipate that people's opinions are going to be their opinions no matter what the program.

CHAIR MORRISON: Yeah, Sarah, yeah, it's Sean. We anticipate that, and so what I anticipate is that there's going to be a rich discussion around the first one, and then hopefully a very streamlined discussion around all of the other, the same measure within the different programs. And obviously, you know, if something comes up unique or somebody forgot something, we will get to that.

DR. PICKERING: And then I just wanted to also remind folks about how this will go. So, NQF staff and myself will be introducing the measure going through the PA, and then our co-chairs, in this case Sean for COVID-19, will be asking for any clarifying questions which can then be sort of triaged either to the developer or to NQF staff, and then after those clarifying questions are resolved, there will an open for vote, and the vote is to whether or not you want to accept the PA recommendation as listed in there.

If we have 60 percent or more that

accepts it, it will stand as-is, and we move forward to the next program. If we do not attain that 60 percent or more, then we will need to open it up for further discussion in which our lead discussants will then go through the PAs, as well as provide any concerns that they may have, and engage the rest of the workgroup in that way, and then as Sean and Akin sort of summarize some of those viewpoints, we will then open it up for a vote based on one of the decision categories.

And again, we need to have 60 percent or more on one of those decision categories for it to move forward. If we do not, then sort of by default, it would accept the PA recommendation.

MEMBER McGIFFERT: I had a question. I don't see any public comments in the preliminary analysis documents I have. Was there one sent earlier and then another later?

DR. PICKERING: There was one sent earlier, yes, and then we did send one late last week on Friday.

MEMBER McGIFFERT: I think that's the one I have, but --

DR. PICKERING: We can certainly resend that out. So, there were two different PAs sent out as PDFs. One was sent prior to the public comments getting put in, and the other was sent out on Friday, and the public comments would be I the green portions.

MEMBER McGIFFERT: Yeah.

DR. PICKERING: Yeah.

MEMBER McGIFFERT: I see where they're supposed to be, but I'm not seeing anything.

DR. PICKERING: So, maybe --

MEMBER McGIFFERT: Friday, what date was Friday?

MEMBER HATLIE: Lisa, I couldn't find them either and --

MEMBER McGIFFERT: The 11th or the 9th? No, would it be the 8th?

DR. PICKERING: It would be -- yeah, so we can resend those out. So, the team right now will resend those out.

MEMBER McGIFFERT: That would be great. Thank you so much.

DR. PICKERING: It was -- yep, and just to confirm, it was sent around 6:15 p.m. Eastern on Friday. So, those will be resent out. Are there any other questions before I turn it over to Sean?

MEMBER LUNDBLAD: Hi, this is Jennifer. I have a question about the voting. Can you hear me?

DR. PICKERING: Yes, yes, I can.

MEMBER LUNDBLAD: Okay, thanks. So, I did my test poll earlier, and so which region of the U.S. do you call home, and that's, my response is still what's on my screen. Will I need to navigate to some other point on that website or will, when the time comes, will that just refresh and it will direct me where to go?

DR. PICKERING: Yes, when that time comes, it will refresh. When we get to that specific question, it will refresh for you and then we'll be able to vote accordingly.

MEMBER LUNDBLAD: Great, thank you.

DR. PICKERING: Thank you.

MEMBER McGIFFERT: And I'm sorry, should we go ahead and sign in on the voting already?

DR. PICKERING: Yes, if you are -- if you have not done a test, we just encourage you to open up the link, put your name in there, and do a test just to make sure you have it up and running.

MEMBER GHINASSI: This is Frank Ghinassi here. Others may have experienced the same thing. I don't know, but on the letter that you sent just an hour or so ago, there's a link under language number one and a link under number two, and a link that says here's a test.

I did the same thing that the other individual did. I went right to the test and said what part of the country I'm in, but just to try it, I tried the other link and it says sort of uh-oh, page not found. So, the test link will work, right, the one that we pulled up?

DR. PICKERING: Yes, it should work.

MEMBER GHINASSI: Because the other link did not take me to a viable page, just so you know.

DR. PICKERING: Okay, so it should be -- so if you know what -- and what link was not working? It was just the other one, not the test link?

MEMBER GHINASSI: I can tell you exactly because I just had it up. It was -- so when I got the email at 9:15 and it says to capture the level of agreement, we're using this voting link.

It's like the second little paragraph down, and when I clicked on that, it doesn't go anywhere. When I go underneath it, it says number one, under desktop, navigate to. If I click on that, it doesn't go anywhere.

Then a little further down after number three on your letter, it says a test poll is now live, and I clicked on that one and that one worked, and that's how I test voted on that

third one. The other two -- I may be the only one, but the other two did not work for me.

DR. PICKERING: Okay.

MEMBER GHINASSI: Just so you're aware. That's all.

DR. PICKERING: Yeah, thanks, Frank. We will try to get this resolved for you. Is anybody else having issues like Frank is?

MEMBER NOLAN: How do we know if the test worked? I mean, I clicked on my region and a thing popped up saying, telling me I could create a presentation.

(Laughter.)

DR. PICKERING: That means it worked. That means it worked.

MEMBER NOLAN: Okay, okay.

DR. PICKERING: Right.

MEMBER NOLAN: Awesome.

DR. PICKERING: So, I'd like to kind of move a little, move along. Frank, we'll try to get that issue resolved for you.

MEMBER GHINASSI: I'm seeing the same

screen she is now, so if that works, I'm fine.

DR. PICKERING: Okay, okay.

MEMBER GHINASSI: Thank you.

DR. PICKERING: No, thank you, and this is kind of why we try to send these links out a little bit ahead of time so we can try to work out all of the kinks and bugs, but we'll revisit this when we start getting to the voting, but it sounds like others are up and running.

Again, if you haven't accessed it, please go ahead and do so, and we'll continue to move forward with the meeting.

So, Sean, I'm going to turn it over to you to kick us off here with the COVID-19 measures.

CHAIR MORRISON: Thanks, Matt, and good afternoon, everybody. I guess good morning still on the west coast, and thanks, everybody, again for joining on what's going to be, what is a long day on top of what's been a very long week.

So, as they say, let's dive into the

MUC, and we're going to start with the COVID measures, and just a couple of opening remarks.

One is that there are a lot of feelings, passions, decisions around vaccinations, and that's what makes the discussion we're going to have shortly about the measures and the CMS's role in having vaccinations as one of their quality metrics so important.

The other piece that I would say is that as you heard earlier, CMS recognizes how quickly they've had to respond to this pandemic, and they are really looking to us for advice for constructive criticism and for guidance as they move forward, so part of our discussion is going to be focused on that.

Let me start with public comment, not committee comment, and what I would ask for public comment is that please limit your comments to a discussion of the measures and please limit your remarks to two minutes or less, and let me open that up for public comment. Raise your hand

through the chat if you'd like or just put your comment into the chat and we will take it.

DR. PICKERING: Right now, Sean, I don't see any hands raised. Udara, anybody coming through the chat?

MS. PERERA: Nothing that I see.

CHAIR MORRISON: Thanks, thanks, guys, and I'm going to be a little slow, I'm afraid, because given the number of people, it's hard to see everybody's little screen and hands up all at once, so I'm relying on you, Udara and Matt, for some of that.

So, with that being said, we're going to turn to the first measure and --

MEMBER McGIFFERT: Excuse me, is there any way someone could quickly summarize the public comments since some of us didn't see it or were you looking, today, you're looking for different public comments?

CHAIR MORRISON: We're looking for different, yeah --

MEMBER McGIFFERT: Okay.

CHAIR MORRISON: We're looking for different --

MEMBER McGIFFERT: Got it, thank you.

CHAIR MORRISON: -- none that have been on already.

MEMBER McGIFFERT: Okay.

CHAIR MORRISON: So, I think, Matt, are you the one who's reviewing the NQF staff summary of the measure?

DR. PICKERING: Yes, yes, I'll go through the PAs.

CHAIR MORRISON: Could I ask you to do that?

DR. PICKERING: Sure, sure, so --

MEMBER McGIFFERT: I'm sorry to interrupt again. I think I missed the opportunity to ask for one to be separated, and it seems to me that the patient measure might require different kinds of discussions, maybe not, but since there's only one that involves patients and all of the rest are healthcare workers, I think I would like to discuss that

separately.

DR. PICKERING: So, Lisa --

CHAIR MORRISON: Yeah --

DR. PICKERING: Sorry, Sean.

CHAIR MORRISON: Go ahead.

DR. PICKERING: You're referring to MUC-0048 which is for ESRD patients?

MEMBER McGIFFERT: Yes, yes.

DR. PICKERING: Yes, that is currently slated to be discussed separately.

MEMBER McGIFFERT: Great, thank you so much.

DR. PICKERING: Thank you. So, the first measure is MUC-0044, and the first program that we're looking at right now is the Hospital Outpatient Quality Reporting Program.

So, within the PA, we recognize obviously the critical quality issue that lies ahead with COVID-19, and this is a new measure that's not been reviewed by the MAP Workgroup or used within the CMS program.

This vaccination is a national

healthcare priority. The Hospital Outpatient Quality Reporting Program does not include any measures of vaccination for healthcare personnel or patients, which is MUC-0044 for healthcare personnel.

We also recognize that there is a quality challenge. At the time of drafting the preliminary analysis, which was back in November, there really wasn't any SARS, or, excuse me, the COVID-19 vaccines that have been approved by the FDA, and that existing healthcare personnel vaccination measures demonstrate variation in performance across facilities, and since this has been approved, sort of thinking about the opportunity for improvement, which is, you know, it was zero, so there's a large opportunity for improvement with this measure.

However, even recognizing the importance behind the measure and the importance behind the quality challenge, the NQF recognized that even before any vaccine really comes to the FDA for approval or even for emergency use, the

vaccine must be first shown to be safe and effective through clinical trials.

So, there's definitely some evidence to show that when it comes to the FDA, and that early reports of vaccines in development suggest that now they may be more than 90 percent effective in the prevention of transmission of the virus.

However, there really isn't a lot of evidence currently that exists related to how the measure is performing, but also that emergency use authorization is promising, but there needs to be more evidence on actually real world evidence and effectiveness of the vaccine, and then also thinking about the measure as well.

And so with the evidence decision here, the NQF staff rated that as a no just based on the fact that there still is not a lot of underlying evidence outside of just clinical trials to see how the real world effectiveness is.

Moving down, related to efficient use

of this measure across the different types of programs or even resources, this measure provides really important information not currently available in this current setting or the level of analysis, and really is intended for eight federal programs for non-long-term care settings.

And the developer really indicates that this measure will be submitted using COVID-19 modules on the NHSN website. However, this vaccine will be collected across seven different job categories as we saw presented earlier, but also listed within the actual measure submission.

But it really is unclear to what impact a difference in date of reporting could be, and the date of collection of these categories may have on efficiency and alignment, and also just the burden that this may have on providers and also these facilities as well with this measure, so it's unclear.

As far as feasibly reported, again, that's unclear. Facilities currently participating in the Hospital Outpatient Quality

Reporting Program already report on measures, but it's really unclear about the reporting for this measure specifically and the mechanism of that reporting with the Hospital Outpatient Quality Reporting Program.

The same thing with specifications, so if you think about how well this is intended for the care setting and level of analysis in populations, the specifications aren't fully developed, so this is unclear and this results in a preliminary recommendation of do not support with potential for mitigation.

And the mitigation points for this measure prior to implementation are that the evidence should be well documented and that the measure specifications should be finalized following testing and NQF endorsement.

And the proposed measure represents a really promising effort to advance measurement for an evolving national pandemic, and the incomplete specifications require immediate mitigation and further development should

continue.

Again, the program that we're talking about, Hospital Outpatient Reporting, this program and the needs and priorities, the needs and priorities listed there are making care safer, person and family engagement, best practices of healthy living, effective prevention and treatment, making care affordable, and communication and care coordination, of which this measure does align with a few of those priorities.

I will just touch on some of the public comments that came in with this measure as well. So, there was some comments related to do not support for this measure saying that the adoption of this measure was really premature, and more appropriate levers, the chief being the intended goal are sufficient for vaccination coverage of healthcare personnel, and there was some discussion around how this measure really differs within the clinician measure.

So, this is the facility level

measure, MUC-0044, and there are some exclusions listed for the clinician measure and talking about some clarification and alignment with that measure, so that's MUC-0045, of which we're not talking about in our workgroup, but it is within the Clinician Workgroup.

Some comments were received as well around ensuring the data capture is really identical or as close as possible as what's collected with the influenza immunization measure.

So, some of the programs that we are going to be talking about today have the influenza measure, but there is some discussion here around the identical or harmonized type of approach to the data capture with that measure.

And it should be noted or it should not be used for payment decisions or public reporting as there is concern that this measure will undergo substantial changes.

So, that was just a high level review of the PA, as well as some of the comments that

were received, and these comments are very similar across all of the programs for MUC-0044, so I will stop there, and, Sean, I'll turn it back to you.

CHAIR MORRISON: Thanks, Matt. That was extremely helpful. So, at this point in the proceedings, what we're going to do is we're going to ask all of you if you have either clarifying questions for the measure developers or concerns that you'd like to express, and we will compile those and ask CMS to develop, or to answer those, and I am going to try and start going down the list of folks who have hands.

Also, if you could put them in the chat function, that would be also extremely helpful because then I can just, the measure developers and I can just read them off. So, looking at my Brady bunch screen, let me start with Anna at the top.

MEMBER LEGREID DOPP: Thank you. This is exciting. I just want to say thanks for the opportunity to talk about it. Thanks to CDC, and

CMS, and NQF for facilitating the discussion.

At a time where we've been so reactive with decisions because of COVID-19, it's really nice to be thinking about this proactively, and then also nice to know that there is a lot of understanding of the uncertainty and that there is some willingness to accommodate that and be mindful of that moving forward as decisions are made.

You know, Dr. Budnitz said that the nice thing about this is that this is not -- there is precedent for measures about vaccinating healthcare workers, which is true, but he is not precedented and unprecedented.

We've used that word a lot these days as novel virus, brand-new vaccines, the pipeline is changing. We only have two out of the gate so far with another three closely behind. That might change this dynamic a bit.

The question about vaccine durability has come up with the potential for the shift in the strains, the allocation, the EUA

considerations.

I think those are all complexities that will be -- I trust the process will work to work some of these things out, but they're just, they remain unanswered.

From the health system pharmacist perspective, we've asked -- we've been asking our members about this, whether or not their institutions are looking at mandatory vaccination, and everyone has responded with a not yet, although we have surveyed our members and well over 90 percent of them are willing to get the vaccine, will, or have either gotten it or will get the vaccine, and so we're really pleased about that, but from an institution perspective, they're not there yet largely because of some of the legal implications with the EUA versus a full BLA approval.

The comments that we've received from our members related to these measures have been brought up, but I do want to just list them, related to concerns around all of the different

date and information sources, and seeking interoperability, and consistency, and disease of use.

There's inventory information systems. There's state immunization registries. There's VAERS. There's now NHSN. And just thinking about all of these different information sources and how much of a potential burden that might be back on the provider side is something they're looking at closely.

There was some wanting to get some clarity around the definition of healthcare worker, and I see we have that thanks to the analysis and the information that's been provided, but that question came up, and then also how do you account for those multiple locations?

Many of these, at least at this point, are being all administered in the same location, but as we start to see mass vaccination or community pharmacy locations being opened up, how is that accounted for? So, that's the large

summary of my response. Thank you so much.

CHAIR MORRISON: Okay, so, Anna, thank you. And I just, I want to preface this again. There are a lot of concerns, questions, comments about vaccine and vaccine rollout.

The charge, unfortunately, of this committee is not to create those. So, what I'm going to really ask is people to really focus their comments on concerns specifically around the measures that we're focusing on today.

And if there are concerns around the population, around rollout, about what people are doing, then that is a concern about -- that's simply a concern of I don't believe the measure has been specified appropriately yet, because we're not here to design the measure.

Because if we, unfortunately, if we attack everything COVID, we're going to be here until about 9:00 tonight and nobody has planes to catch, so Akin and I can keep you here until Zoom goes dead.

So, Jennifer, I have you next. And I

know there are chats going in and we're -- I'm going to ask our NQF staff just to collect all of those for our developers and we can tackle those all at once if there are questions and concerns. So, Jennifer, Jennifer?

MEMBER LUNDBLAD: Great, thanks so much, Jennifer Lundblad with Stratis Health. I also put my question in chat, so I'll just repeat it here.

So, first of all, I just really commend CMS and NQF for tackling something so emergent and timely. It's really important, and appreciate the opportunity to be able to debate it today.

My question is about timing, and maybe I was just a little confused on what I heard. I think that in our joint session earlier, I understood that this would go for fiscal year 2022, and so I'm trying to understand, as I think out 18 months or so, and think about what comes up in proposed rulemaking then.

And, you know, none of us, of course,

will know the situation, and I'm just trying to understand the timing of, the proposed timing for when it goes into rulemaking even as we know the challenges for where vaccines are available right now.

And so if you could, Sean, just talk a little bit about, however the measure gets specified, what that timing will be for rollout for when it gets included in public reporting and when it will then be a more publicly available measure?

CHAIR MORRISON: I would love to talk about it, but that's not my role, so I'm going to turn it over to CMS and the measure developer --

MEMBER LUNDBLAD: Thanks.

CHAIR MORRISON: -- to ask them to talk about it if we can.

MEMBER LUNDBLAD: Thank you.

CHAIR MORRISON: But thanks for the power there, Jennifer. I appreciate that.

DR. SCHREIBER: Yeah, you got yourself out of it, Sean, right? So, this is Michelle.

In order for anything to go into a 2022 program, it has to be introduced into rule writing in 2021.

So, in this case, it would either be the IPPS or the OPPS rule, which the preliminary, you know, proposals are generally out sometime in the spring.

By then, we would hope to have much more clear both information about the vaccines and measure specifications which will be developed by the CDC.

Then there's always the opportunity after public comment to, the rule will be finalized probably, what, late fall, sometimes early winter.

So, there's actually that entire opportunity of time to finalize the actual measure specifications based on the information that we get before that would be finalized with a collection period then likely starting in 2022.

Now, that does not, however, obviate any collection of COVID vaccination data that may

be happening in the country in either NHSN or other vehicles, okay? So, I'm just talking about how it is treated in any of these programs that we're talking about.

It will be introduced in rule writing in the spring. We'll have the measure specifications as best as we can by then. By the time the rule is finalized, which will be late fall or winter, we will have very clear measure specifications, and then the introduction into the programs would be in 2022.

MEMBER LUNDBLAD: So, Michelle, thank you so much. Is it fair to say that what this does, given the unprecedented circumstances and situation we find ourselves in, by doing this now, even though we saw with the NQF assessment, it essentially gets a foot in the door, which is the only way it can happen for fiscal year 2022?

DR. SCHREIBER: Yes, thank you. That's very well put. Without this, we would have to delay an entire year.

CHAIR MORRISON: Thanks, Michelle, and

thanks, Jennifer, very helpful. Maryellen, I have you next.

MEMBER GUINAN: Great, thanks, Sean. Hi, everyone. I don't want to relitigate the whole specification side. I do agree that more specificity needs to go in there and to finalize those.

But just a broader question because it's been raised numerous times in terms of HHS protect the data that's been going in, that is required and mandated under conditions of participation in order to receive data, and hospitals have been diligently reporting, and we're at --

DR. SCHREIBER: They have.

MEMBER GUINAN: -- 96, 97 percent, which is great, and great partnering with HHS on getting those hospitals to report, so, I guess, a clarifying question or broader intent question of tying this type of data reporting to accountability programs.

I know we're talking about OQR, but

also we're noting it could be an IQR, which, of course, then leads down the path of being available for value-based purchasing, for the STARS program. We pull measures from IQR. And so I'm just wondering the kind of intent behind tying this to kind of the accountability side of the --

DR. SCHREIBER: And Maryellen, you're obviously absolutely correct. The data that gets reported to HHS is, you have numbers' data. You know how -- you know the numbers of vaccination, for example, but you're right. We're looking at performance, and it really is a question of safety and facility safety.

You know, so what is the percentage of healthcare staff within a given facility that are vaccinated? And we see that as a safety issue for patients with healthcare personnel being vaccinated, as well as the staff themselves, so a safety facility, and you're right.

So, this is a performance measure that would be probably publicly reported with time, so

that wouldn't happen until 2023 in all likelihood, or even beyond. We don't envision it in a payment program for quite some time.

And the truth is, as Janice pointed out this morning, you know, look, if God willing, one vaccination were to work and we didn't have COVID at all in the future, we wouldn't use the measure.

But for the foreseeable future, I think all of us certainly believe in the urgency of this and in looking at the performance of organizations in getting certainly their staff vaccinated, and ultimately their patients vaccinated.

MEMBER GUINAN: Thanks, Michelle. Can I just follow up real quickly? I think that's then very important in terms of the exclusions and specifications when we look at the context of kind of surge and if we face this next year.

You know, a new season, then just the construct of healthcare personnel is changing in terms of do we include the volunteer health corps

folks? Do we include the traveling folks that have come in?

And just the surge in terms of someone being party or personnel or in the denominator one week, and then, you know, it's changing quarter to quarter, so to balance that as well, but thank you.

CHAIR MORRISON: Thank you. So, I've got Janis, then I've got Cristie, and then I've got Sarah. And for those who have put questions or concerns in the chat, don't worry. We will target all of those. I know Michelle is anxiously waiting looking at those. Janis?

MEMBER ORLOWSKI: Michelle, you may have answered this already, but, you know, this is a critical issue right now. The question is, is it a critical issue in 2023? And if we look at pandemics, the answer is no. It's not going to be a critical issue in 2023.

And so I wonder, and you said this when you were responding to Maryellen, is it's important to get this approved now so you can use

it next year, but if pandemic follows the course of both what science is expecting and what other pandemics have done, a 2023 reporting may no longer be as sort of eminent and important as it is.

DR. SCHREIBER: Maybe, Janis. I'd like to think that that's true, but let me see. The last pandemic of 1918 was the flu, and we are measuring flu vaccination because every year, it morphs and changes, and we all need to have flu vaccination annually.

We don't know what COVID will look like. It may very well follow that same course that we need COVID vaccination annually. Our hope is perhaps that perhaps that's not true, but if we speak to prior pandemic diseases, all we really have is influenza, and we're still measuring it.

CHAIR MORRISON: Cristie?

MEMBER TRAVIS: Yes, thank you very much. I'm kind of going back to the topic of it being used in these programs, you know, that the

measure is being proposed for.

And it seems that it is very important in these programs, especially public reporting, but also in pay for performance obviously, that we're looking at how hospitals, in this particular case, how hospital outpatient programs compare to one another.

And so I certainly can appreciate the specification issue, but there is another issue here, which is a testing issue for reliability and validity, and the ability for these measures to actually identify appropriate variation across institutions and facilities.

Can you, Michelle, or others talk about what type of testing -- I can't imagine that too much testing has gone on since it's only been up and running for a couple of weeks, but to me, that's another really important part of putting these in a public reporting program is that the consumers need to be able to trust that they really are seeing the variation that may be evident in the reports, so testing would be

something I'd be curious about.

DR. SCHREIBER: Yeah, I don't know who's on the phone from CDC. I saw that Dan Pollock is on. I don't know if Dan Budnitz is, and I will let them speak to testing.

But really what we have is the experience of the testing from the healthcare personnel flu vaccination, and I think that we have seen that it's very valid and very reliable across multiple settings, and that's really kind of the empiric evidence that we're going with.

Yes, we have to test this particular measure also. I certainly understand that, but we do have a history of staff vaccination measures.

CHAIR MORRISON: Sarah?

MEMBER NOLAN: Thanks. So, I wanted to, I guess, echo Maryellen's concern that she raised about this sort of morphing it, I guess, into a value-based, to you get the sort of performance measure. I have a question and a related comment, actually maybe two related

comments.

So, the question is whether there's any consideration of other measures that would address safety, and particularly safety among health personnel, and that comment is that it seems to be that if this is the measure, there's a risk of it becoming the thing, and sort of obviating the need for other, for other things to happen in healthcare facilities.

And I would point, you know, especially to the need to provide healthcare workers, particularly frontline workers, with PPE, with paid time off, to ensure that there are infection control protocols.

So, SEIU represents frontline workers. We have members who have died because they did not get PPE. We represent -- I'm turning to my second point.

I also think that we're -- this is a process measure for sure, but the number of people who get vaccines is to some extent also an outcome measure, and it's an outcome of the

processes employers put in place to make the vaccination happen.

We, as a union, have launched a massive attempt and campaign to educate our members about the need to get vaccines, but we have also adopted as a principle that vaccines should not be mandatorily required.

A lot of our members are people of color. Some of them have relatives who were in the Tuskegee Experiment. They have -- there's a lot of good reasons for vaccine hesitancy, and if the --

If this is the measure and there is a need to put good numbers on the board by making vaccines mandatory or pressuring workers rather than educating them, and rather than educating them in a way that is particularly responsive to the past that some people have experienced, that would be a problem.

CHAIR MORRISON: Thanks, Sarah. Marty, you found your hand.

MEMBER HATLIE: I did, Sean. Thank

you to the village of people that gave me suggestions in the box, and I'm going to ask a deja vu question. If we want to support this measure as much as we can, is there a timing difference between conditional and do not support with potential for mitigation?

Do we somehow expedite the timing of doing whatever modifications need to be done if we go with conditional versus do not support with mitigation? I just can't remember from year to year.

CHAIR MORRISON: Neither can I, so I'm going to ask Matt.

DR. PICKERING: So, Marty, just to clarify here, you're saying is there a timing constraint or a timing consideration for conditional versus do not support?

I would have to turn to maybe the CMS on this as even if it was conditional, with certain conditions being, say, NQF endorsement, I think the timing would be trying to submit it to some sort of a cycle for that endorsement.

If there are do not support with potential for mitigation, what are those mitigation points? And those mitigation points could also be, you know, NQF endorsement, which would then lend itself to be following the right cycle.

But I'll see if Michelle, Dr. Schreiber, if you have any comments relating to timing related to either one of those decision categories?

DR. SCHREIBER: No, Matt, I completely agree with what you said. Thank you.

CHAIR MORRISON: So, folks, I don't see any more hands up, so what I'm going to quickly do is just run through the questions in the chat for Dr. Schreiber and try and target the ones that haven't been answered in the chat.

So, let me just quickly, let me try and do that. Michelle, why are long-term care workers not included?

DR. SCHREIBER: I'm sorry, which long-term care workers? Because there are some long-

term care workers, but they're over on the post-acute side.

CHAIR MORRISON: Right, I think that's what I was -- I think that's the -- I was going to answer it for you, but I think this is the Hospital Workgroup, so these are the hospital measures.

DR. SCHREIBER: Yes, correct.

CHAIR MORRISON: So, we're not focusing on the long-term care.

DR. SCHREIBER: Correct.

CHAIR MORRISON: Denise Morse, I think all of your questions were answered subsequently down by CDC, and Jennifer, we tackled that one, sorry.

Frank asked is the underlying assumption that the hospital or program have substantial control/influence over the decision making of HCP and/or healthcare professionals and/or patients?

DR. SCHREIBER: My answer to that is yes because, you know, let's just begin and look

at the analogy of flu vaccination, and it went through a period of years actually where, you know, hospitals encouraged flu vaccination, had campaigns to encourage flu vaccination. Then that kind of got stricter and stricter.

For a while, it was, well, if you don't get a flu vaccine, you're going to have to wear a mask while you're at work all of the time, and then there's frankly a large majority of organizations now that mandate flu vaccination in order to work there, and so I think that facilities absolutely have influence over their healthcare personnel.

Now, that being said, to Sarah's and others' points before, I don't know that that's an expectation right now. Of course, there's a sensitivity about people who have all kinds of reasons to be wary of vaccines, but I think we need to put that in light of the pandemic.

What's best for the health of all of us in this country is to get people vaccinated, and I think transparent information on how

organizations are performing is just something that can shine a spotlight on that.

And that may not be for CMS to incentivize or to pay initially, but it certainly is for the organizations themselves to have the opportunity to look at how they're doing and to take whatever steps they feel are appropriate.

CHAIR MORRISON: Thank you, Michelle. Lindsey and Matt, this is to you and your team. The preliminary analysis indicates no for evidence based or an outcome measure. It is also noted that the FDA is charged with determining the effectiveness. Even though it was under an EUA, I would ask NQF reasoning for classification of this criteria as a no.

DR. PICKERING: Right, thanks, Sean, and appreciate the question as well. You're right. The FDA looks at safety, but also efficacy, right, so efficacy being is it doing what it's supposed to do?

But we're talking about real world evidence with this evaluation of evidence is

seeing how well it's actually performing when it's outside of a clinical trial, right, the clinical trial being the ideal state as opposed to real world settings.

We also want to consider how well the measure may potentially perform as well, and so evidence to support the measure. And that being said, if it's an outcome as for a process measure, is there evidence to show association that a facility or the accountable entity can do to actually impact the outcome or the measure itself, the measure score?

So, these are other additional elements that we're looking at with evidence, and right now, since it's so new, recognizing that there are clinical trial data to show that there may be some efficacy and safety with this, there really isn't enough for us to make the conclusion firmly that there's evidence to support the actual measure associating facility level interventions that can be shown to improve vaccination rates for healthcare personnel, and

likewise for the patients' measure as we get into that.

So, that's really where we have to say no for that evidence just because there's none that currently exist.

CHAIR MORRISON: Thanks, Matt, very helpful. I'm just quickly -- I think the questions around multiple sites of vaccines were answered.

There is a couple of questions that have come up again around whether if we vote do not support with potential mitigation, is the door still open for inclusion in 2020 rulemaking once the measure specs are finalized? And it's just a clarifying question both to NQF staff and to CMS.

DR. SCHREIBER: I'll comment on that one, Sean. The answer is yes. It is still open for rulemaking even if it's do not support. Although CMS doesn't ever like to do this, I think all of us recognize that this is a recommending body and the government does have

the final say.

CHAIR MORRISON: The questions around vaccine supply have been really nicely answered. Thank you, Suchita, sorry, it's been a long day, Suchita.

And then I think the last one that Elizabeth McKnight raised was the burden of simultaneously reporting on COVID and influenza vaccines and the burden of that. I think that's probably more of a comment than a question.

DR. SCHREIBER: Well, actually, I will comment on that one because the influenza vaccine for the most part has been removed out of the public reporting for most programs.

CHAIR MORRISON: Thanks, Michelle. That's very helpful. And then last, let's see, Sarah has a question. Oh, there it is. Sorry, Sarah. Is it possible to say something more about what the mitigation would look like? And then Aisha, I have you as well.

DR. PICKERING: I'll start about the mitigation. So, as we've indicated in the

mitigation, it would be -- and again, when we think about putting mitigations in place or even conditional support, we're trying to really state what the conditions are.

In this case, the mitigation here would be around evidence, further developing the evidence, and well as the measure specifications being finalized, and ultimately moving forward for testing and endorsement is the areas of mitigation here.

So, that's what we have indicated in the PA, and if the group agrees to that through the vote, that's where we'll stand, but if there's other types of mitigation, we'll have the vote separately on what that would be.

CHAIR MORRISON: Thanks, Matt. Aisha, unless something happens, you have the privilege of having the last question or comment.

MEMBER PITTMAN: Thanks. So, my question was around, you know, if the specifications evolve during a performance year, has CMS thought about that, noting that the

specifications aren't done yet and, you know, indicating that it will sort of evolve as the science evolves?

That has challenges when you're constantly changing specifications within a performance year. So, how have you thought about mitigating that or what would the process for that be in calculating a rate for the full year?

DR. SCHREIBER: I mean, you're absolutely correct about that. I think that we would end up having to go forward with the measure with the specifications that get finalized, and then if there were changes, I would think that for the most part, they would be on an annual basis through rule writing.

If something really were to be necessary, as we did during the COVID pandemic in several instances, you can do interim final rules with comment, but I think all of us like to avoid that and all of us like to avoid constant specification changes. We would write this in a way that we hope it would be as broad as possible

and as easy to do.

CHAIR MORRISON: Thank you, Michelle. And Frank, there's a great issue brief to your question from the Kaiser Health Foundation around influenza vaccine. Frank asked is there an update around regional and state variability?

Obviously, or maybe not obviously, we don't have this yet for COVID, but there's some really nice work that's been done around influenza and the chat is there. Cristie, I see you have your hand up.

MEMBER TRAVIS: Yes, I was -- I have a question kind of going back to the timing issue.

And certainly taking Michelle's comment to heart and the reality of it that, you know, we're an advisory body and, you know, CMS could put this measure in the program even if we did say do no support with opportunity for mitigation, it does seem to me that conditional support really to a certain extent says you don't have to come back to the MAP, where do no

support, if CMS did not put it in the program, it would almost seem to me like it would need to come back to the MAP the next year, which could mean that there would be a timing difference potentially.

And I guess, Matt and Michelle, I'm just trying to clarify in my own mind because conditional support is if you meet the conditions, you know, it's support, where do not support with mitigation still carries the do not support with it.

So, it would seem to me it would need to come back here unless CMS, you know, opts for going on and putting it in the program, which they certainly can do. So, I'm just trying to be sure we parse those differences, and Matt, I don't know if that's a question to you or if that's a question to CMS.

DR. SCHREIBER: Cristie, I suspect this measure's going to come back in the following year no matter what, I mean, unless we --

MEMBER TRAVIS: Okay.

DR. SCHREIBER: -- absolutely are through the pandemic and don't need it, because remember, we also bring any measure with substantive changes back to the MAP.

MEMBER TRAVIS: Okay, okay.

CHAIR MORRISON: So, folks, I'm going to --

MEMBER TRAVIS: Thank you.

CHAIR MORRISON: I think we've had a really fantastic discussion and I really thank everybody for being so focused and helpful to CMS. This is really a challenge.

I'm going to suggest now we move to our vote, and the first vote is on the acceptance of the preliminary analysis by the NQF staff, correct, Matt? I'm getting the process right? I always hate doing that.

DR. PICKERING: That's correct. That's correct. So, the first vote again is going to accept the preliminary analysis recommendation, so that is do not support with

the potential for mitigation.

And again, the mitigation for this measure is prior to implementation, there would be evidence that would be well documented and that the measure specifications should be finalized, as well as testing and NQF endorsement is what is listed within the preliminary analysis.

So, you are voting just yes, accept the preliminary recommendation, or no, not accept, and that Poll Everywhere link should be functioning now, and so, Chris, I'll turn it to you to sort of open this up.

MR. DAWSON: Thank you, Matt, just a sound check. Can you hear me okay?

DR. PICKERING: Yes.

MR. DAWSON: Great, so voting is now open for MUC --

(Audio interference.)

MR. DAWSON: -- 0044, SARS-CoV-2 vote to support the staff recommendation as the workgroup recommendation of do not support with

potential for mitigation, yes or no.

PARTICIPANT: So, I have a logistical question. Mine was up on the screen a moment ago. I didn't yet vote, and now it says it's waiting for the polling presentation to being.

PARTICIPANT: Yeah, mine as well.

(Simultaneous speaking.)

MR. DAWSON: Okay, Carolee or Becky, do you recommend I just deactivate this, clear the responses, and start over?

MS. PAYNE: Hi, Chris, this is Becky. Yes, let's clear the responses and I will click the activation button once you have done that, so please just let me know when you have cleared the responses.

DR. PICKERING: So, while we're waiting for that, I know Linda -- Linda Van Allen, are you on the call? Okay, I think I saw her. Linda will be calling in, I believe, and she may be providing her vote over the phone, but I don't see her on the call just yet.

MR. DAWSON: Okay, thank you. So I did

clear the responses and then I got five more in immediately after that so let me clear the resp-, they're still going now so.

DR. SCHREIBER: So vote again.

MR. DAWSON: Responses are coming in.

MEMBER ORLOWSKI: So are you going to tell us when to re-vote, or are we doing that now?

MR. DAWSON: Yeah, so the votes continue to tick up here. So let me, I'm going to deactivate this. Let me clear the responses and we will try this again. I'm clicking deactivate this, so let's try it again. So voting is now open for MCU20-0044, SARS-CoV-2 vaccination coverage among healthcare personnel for the Hospital OQR program. Do you vote to support the staff recommendation as the workgroup recommendation, which is do not support for potential for mitigation?

PARTICIPANT: I'm still having difficulty.

DR. SCHREIBER: Yeah, it still keeps

flashing away once the --

PARTICIPANT: Yes.

DR. SCHREIBER: It goes up and then goes away.

MEMBER ORLOWSKI: I just voted, not sure, maybe I was quick.

DR. SCHREIBER: It is showing to me now.

DR. PICKERING: It's like the gopher arcade game, right? You have to hit the gopher really quick before it goes back --

MR. DAWSON: And do I need to check if Linda Van Allen is on the phone for providing a verbal vote at this point? Or are we still expecting her later?

DR. PICKERING: She may be coming in a little bit.

MR. DAWSON: Looks like we have 24 results. Let me show the responses here. Voting is closed. The results are 20 yes and four no. The workgroup confirms a do not support for potential for mitigation for MUC20-0044, SARS-

CoV-2 vaccination coverage among healthcare personnel for the Hospital OQR program.

CHAIR MORRISON: Thank you, folks, and even I'm math-challenged and know that that gets above a 60 percent. Matt, my understanding is now that we can ask that that vote continue down all the MUC-44 measures. Is that right?

DR. PICKERING: No, we'll at least open it up for some discussion and questions for the programs, but if there aren't -- I would encourage if there's nothing new that we move right along. If there is an objection then we'll hold a vote for that specific program. If there's no objection, it's a unanimous decision, we will carry over the votes for each one of the programs. That's just specifically for MUC0044.

CHAIR MORRISON: So we're down into the Hospital IQR program, the Hospital Inpatient Quality Reporting program. Just ask if there are new specific comments or objections to moving forward. Let me just start with new comments.

DR. PICKERING: And as you're waiting

for those, Sean, I'll just state, as well, that for this measure within this program, it also has a do not support with potential for mitigation just so we have that on record. The mitigation points for this measure prior to implementation are that the evidence should be well documented, that the measure's specifications should be finalized and followed by testing and then NQF endorsement.

CHAIR MORRISON: Matt, can we move to the next program then?

DR. PICKERING: So no objections?

CHAIR MORRISON: Didn't see any, yeah.

DR. PICKERING: Okay.

CHAIR MORRISON: So this is going to ambulatory surgery. Again let me just ask if there are specific comments, questions that have not come again and again?

DR. PICKERING: And also for this measure within this program, it's also do not support with potential mitigation and mitigation points for this measure prior to implementation

are that the evidence and specifications should be finalized followed by testing and NQF endorsement.

CHAIR MORRISON: Any objections to moving on? Matt, can we go to the inpatient psychiatric facility? I think that one's next, right?

DR. PICKERING: That is next.

CHAIR MORRISON: New comments, questions, concerns?

DR. PICKERING: And for this measure in this program, again do not support with potential for mitigation. Mitigation points are prior to implementation that the evidence shall be documented, but the measure's specifications should be finalized followed by testing and NQF endorsement.

CHAIR MORRISON: Any objections? Matt, the TPS exempt cancer hospitals? Again, new comments, questions, concerns?

DR. PICKERING: The preliminary recommendation for this, do not support with

potential for mitigation. The mitigation points for this measure prior to implementation, that the evidence should be well documented, that the measure's specifications should be finalized followed by testing and NQF endorsement.

CHAIR MORRISON: Any objections? Okay. This is where I get to turn things over to Akin, right Matt?

DR. PICKERING: Not just yet. We still have two more COVID measures.

CHAIR MORRISON: Oh, not quite.

DR. PICKERING: Not quite, getting a little excited. Sean, so the next measure was the same measure, it's 0044 for the ESRD QIP program. Again, similar situation with our review and preliminary recommendation was do not support with potential for mitigation. The mitigation points for this measure prior to implementation is that the evidence should be well documented and that the measure's specifications should be finalized, followed by testing and NQF endorsement. I just want to

confirm, I got a message from my team that I was coming in and out. Do I sound okay? Am I still coming in and out?

CHAIR MORRISON: You sound pretty good, Matt.

DR. PICKERING: Okay, thank you.

CHAIR MORRISON: Again new questions, concerns? Any objections? Okay, next?

DR. PICKERING: So now it's a different measure, so the voting won't carry over since it is a new measure. It is MUC0048. So with this measure, this is for the ESRD QIP program. This is the vaccination coverage for patients in end-stage renal disease. Previous was vaccination coverage for healthcare workers. With MUC0048, this is a new measure that has not been reviewed by the MAP previously, nor have they seen this program.

We again recognize that this is a national healthcare priority. I think there is no measures addressing vaccination coverage within the ESRD QIP set. We also recognize that

there is a quality gap here, a quality challenge, as essentially the performance on this measure as it stands is essentially zero, so there is opportunity for improvement.

However, again similar to the evidence on previous measures and what has been explained previously around how NQF has evaluated evidence, indicating that while early evidence has been submitted to the FDA for emergency use authorization and it's promising, a full range of evidence is still emerging, again thinking about the evidence to support the measure itself.

And then the other areas around feasibility, still unclear related to how this would be reported if it would actually cause any additional burden to report on or collect and report on, so that is still unclear, as was stated previously for MUC0044. The preliminary recommendation on MUC0048 is do not support with potential for mitigation. The mitigation points for this measure prior to implementation, the specifications should be specified and well

documented, and the measure should be specified and finalized followed by testing of NQF endorsement.

CHAIR MORRISON: Thank you, Matt. Other questions related to this measure?

MEMBER MCGIFFERT: I have a question how it will be implemented. So the facility would simply ask the patients if they've gotten vaccinated? Are they going to be offering vaccinations to patients? It's sort of hard -- is it just like a count of who already is vaccinated? I'm not clear on that.

DR. SCHREIBER: This is Michelle. So yes, the facility would just be asking patients if they were vaccinated. Jesse Roach, Dr. Roach is on the phone, who is the actually acting chief medical officer for the quality measures group and is also a nephrologist and physician lead of many of the ESRD programs. I'll ask Jesse to comment in a moment. But this is really just asking patients if they've been vaccinated. There isn't a plan at the moment, although there

certainly could become one of dialysis facilities actually giving vaccination on site. This is merely to ask patients. Jesse, did you want to comment?

DR. ROACH: Yeah. Actually, I don't have anything to really add other than what you have said. I don't have anything specific to add.

DR. SCHREIBER: Thanks.

MEMBER MCGIFFERT: I think my follow-up would be how does it actually reflect the quality of the facility if there isn't really anything they have to do other than ask? If you get my question? It just seems very perfunctory and not necessarily a reflection of quality.

DR. SCHREIBER: I certainly understand your question, and again Jesse can comment on this again. But we know that providers have a great deal of influence on their patients, and when they recommend, for example, certain things like vaccination we know that not every patient is going to want to comply, but we know that it

certainly does help.

Otherwise, why do we do smoking cessation and counseling and things like that? So we know that it does help. In the dialysis community in particular, I think that dialysis patients are seen on a very routine, regular basis several times a week within a facility, so I think that a facility does have some influence, shall we say, on what the patient decisions are. I suspect that it may happen in the future that dialysis facilities will actually be able to give vaccine. I'd also like to point out how important we think it is to give patients in a dialysis facility the vaccine. They are some of the highest risk population that we have. Their mortality rates have actually been quite high, and I know Jesse does have the data on that and can certainly comment.

MEMBER MCGIFFERT: So just as a follow-up, the assumption is that they might ask once and find that 50 percent of the people are not vaccinated, just say. And then they ask in the

next quarter again and find that 40 percent or 60 percent are vaccinated. Is that a theory, that you'll see a change in what the patients do based on what the facility has asked them?

DR. SCHREIBER: We think that that's true and actually we see that in measures all the time. They start well, something happens, an intervention and you're encouraging people, you're counseling people or what have you, then it improves.

DR. ROACH: And I do think this will also change significantly as the facilities start getting vaccines, which they're in discussions with the CDC. This is something I think that's evolving right now.

DR. SCHREIBER: Hey Jesse, there's a question on the chat. Does this include home dialysis patients, as well, or just the facility?

DR. ROACH: Home, everyone.

CHAIR MORRISON: Everyone. Thanks, Jesse. Is everybody okay if we close and move to a vote? I don't want to cut off discussion, but

also am conscious of keeping us on our timeline, as well.

DR. SCHREIBER: Sean, it's Michelle. Can I just make one other comment because there have been a few questions? For example, why are you doing patients in end-stage renal disease and you're not doing them in the nursing home or we don't have it in the hospital or something like that. The reason is that number one, these are very high-risk patients. It is felt that this is a reasonable circumstance. They're still ambulatory.

In the hospital there was FDA discussion about whether or not we actually want to give vaccination to hospitalized patients because of their immune level and the immunogenesis of this, so we specifically did not do hospitals. Quite frankly, we would have done nursing home facilities except there's an underlying issue of the authority to get that data. So it was looking at specific settings, determining the highest risk of the patients and

then the authority that we have for data collection and whether or not we actually could influence the patients.

CHAIR MORRISON: Jackson, I see you have a comment on -- Lisa, I'm just going to respond to yours in the chat.

DR. PICKERING: Yeah, just real briefly, I agree with Dr. Roach and Dr. Schreiber on this one. But I do have a concern about the numbers on the flu vaccination. They were exactly what I predicted they would be for dialysis facilities, meaning highest in New England and the Upper Midwest. That is a pattern that we just see across CMS quality measures, across quality programs. That's a pattern that you almost always see. I don't think we need to measure regional cultures and regional subcultures any more than we already do. I'm wondering if it would make more sense to have a structural measure to the effect of did the dialysis facility offer on-site vaccinations.

CHAIR MORRISON: Thank you. Are we

okay if we move to a vote? Matt?

DR. PICKERING: Yeah, Sean, that sounds good. That sounds good. Thank you all for your comments and questions. Chris, I'm going to turn it to you to open up the voting platform.

MR. DAWSON: Okay, voting is now open for MUC20-0048, SARS-CoV-2 vaccination coverage for patients in end-stage renal disease in SRD facility. Do you vote to support the staff recommendation as the workgroup recommendation of do not support with potential for mitigation? I also want to ask if Linda Van Allen is on the phone with us right now? We've got 23 responses in, so I will show the responses. Voting is closed. The results are 20 yes and three no. The workgroup does not support recommendation with potential for mitigation MUC20-0048, SARS-CoV-2 vaccination coverage for patients in end-stage renal disease, ESRD facilities for the ESRD QIP program. Thank you.

CHAIR MORRISON: Thank you. I think with that I now -- sorry, I'm just looking at my

notes. It is now time for last comments or suggestions to CMS, and then we will close out this section. Did I get that right, Matt? Please tell me yes. Supply us this feedback.

DR. PICKERING: Right, so thank you, Sean. Recognizing that there's a series of same measures across all these programs, we really wanted to engage this group on thinking about recommendations to CMS related to how to ensure that these measures are implementable within the programs that have been considered. So with that framing, are there any other additional comments or feedback that the group has around how to ensure that these measures are implementable within the programs that they're being submitted for, or any additional feedback you have?

CHAIR MORRISON: Maryellen, I see a hand up.

MEMBER GUINAN: Yeah. Just going back on a point that was raised earlier this morning in terms of -- I believe Michelle mentioned the concept of stratification on these measures, and

it came with the ESRD in terms of stratifying by the facility type or if it's at home or whatnot. I also have a consideration just in terms of stratification for the patient population for these measures, particularly given the vaccines that we currently have as being two doses.

Particularly for the patients that our essential hospitals treat, we're looking at social determinants of health and specifically transportation, in terms of getting to that second dose and completing the course as being something that is out of the control in many cases of the provider. So I just wanted to flag in terms of going beyond the usual stratification for duals, something to consider.

CHAIR MORRISON: Thank you. Jennifer, I think your hand is up, too, yes?

MEMBER LUNDBLAD: Yes, thank you. I just wanted to note that I think everyone on this call is aware that critical access hospitals are not required to participate in the IQR program, and so we have 1,300-plus facilities across the

country. We are serving really important needs in rural, and none of these programs will be required for them.

I just wanted to make sure that as CMS moves forward in contemplating how to coordinate with the Federal Office of Rural Health Policy and the MD QIP program to make sure that when we think about a measure like this, when it does get finally specified and it goes through those next stages, that we try to reach across as much as we can the hospital programs. That would include critical access hospitals.

I don't know, Jesse, if on the Rural Workgroup, you discussed that at all and certainly would welcome any additional insight. I just want to note that important group that's missing because it's not a requirement for them.

CHAIR MORRISON: Thank you, Jennifer. Anybody else? I know there's been some chat and answers in the chat box. Going once, going twice? Three times.

DR. SCHREIBER: Sean, Michelle. Can I

just make a last comment from CMS point of view.

CHAIR MORRISON: Michelle, of course you can.

DR. SCHREIBER: Thank you. Thank you for everybody's great thoughts and deliberations. We certainly understand that people are supportive of vaccination across the country, as NQF pointed out before. This isn't a reflection of lack of support for vaccination. But frankly, we offer apologies but couldn't really do much about it that we don't have a measure that has specifications in the way that NQF is used to seeing it or certainly testing data.

We know that, we understand that. We understand the rationale and we understand the vote. Hopefully we will be able to bring you a measure in the future that does have specifications and that does have testing to it, but I hope that all of you understand that we were really doing this out of a sense of urgency and being proactive, that without bringing this to the MAP this year it would have delayed us

from doing anything for at least another year. So really thank you for everybody's very important feedback. We actually apologize we couldn't have brought you something with more testing and more specifications, but I think everybody understands the reason why not.

CHAIR MORRISON: Yes, I think speaking for all of us, Michelle, yes. I'm going to turn things over to Matt and Akin then and rest my voice.

CHAIR DEMEHIN: Good plan. Thanks, Sean. So this conversation may end up being a bit shorter than the prior conversation. We're going to shift gears and talk about the end-stage renal disease quality incentive program and one other measure that is up for discussion with that program. Let me turn it over to Matt to talk about the program and talk about the measure.

DR. PICKERING: Thank you, Akin. So this program is pay-for-performance and public reporting program. As you can see, listed here the incentive structures as of 2012, payments for

dialysis facilities were reduced. The facilities fees did not meet or exceed the required total on the score. Payment reductions will be on a sliding scale, which could amount to a maximum of two percent per year.

The goal is really to improve quality of care, and specifically dialysis care, to produce better outcomes for these beneficiaries. So I'll just talk about the measure, which is on the next slide here. I'm sorry, just missed the public comment period here, so I'll just open it up, as well, to see if there's any comments from the public.

Again, you can use the chat feature as well as the phone. If there's any comments from the public related to this program, as well as the measure under consideration, which will be MUC0039 standardized hospitalization ratio for dialysis facilities. Udara, I'm going to ask you if you see any hands raised.

MS. PERERA: I currently do not.

DR. PICKERING: I don't see anything in

chat. We'll talk about the measure, we'll go to the next slide if there are no public comments. Standardized hospitalization ratio for dialysis facilities, this is defined as the ratio of the number of hospital admissions that occur for Medicare ESRD dialysis patients treated in a particular facility to the number of hospitalizations that would be expected given characteristics of the patients seen at the dialysis facilities and the national norm for dialysis facilities.

This measure can be calculated as a ratio, but also can be expressed as a rate, it's the facility level of analysis. This is a fully specified measure. It's an updated version. There is a version that's currently being used within the ESRD QIP program, but this is an updated version. The updates to this measure are focused on risk adjustment methods, specifically the inclusion of a preventative comorbidity adjustment, the additional of Medicare Advantage patients and a Medicare Advantage indicator in

the risk adjustment model.

Updates to the paramterization of existing adjustment factors and reevaluation of interactions and an indicator for patients' time spent in a skilled nursing facility. These updates have been reviewed and also endorsed by NQF in the standing committee that it came through. I was passed by CSAC, our Consensus Standards Advisory Committee, for their review this past spring and evaluation cycle, so Spring 2020.

There are no other competing measures for this specific measure. However, there are measures that align with this measure. There's the standardized mortality ratio for dialysis facilities and also the standardized readmission ratio, as well, for dialysis facilities. For the recent spring 2020 evaluation cycle, the developer did cite several studies that provided effective opportunities for dialysis facilities to reduce hospitalizations.

With that, as well as going through

NQF endorsement and passing on the evidence, we rated this as a yes, that there is evidence to support the measure, as well as yes, that there is critical quality objective to this being met, as well as the quality challenge. The measure developer cites that dialysis patients are admitted to the hospital frequently, spending an average of about 11 to 14 days in the hospital per year.

Related to efficient use of measurement resources, this is a facility-level measure as currently implemented in the program as is. In this newer version that's been updated and endorsed, as well, it's sought to be implemented within the program. Again, it's aligned or harmonized with the other two measures I mentioned, standardized mortality ratio and well as standardized readmission ratio for dialysis facilities.

As far as feasibility for reporting, the measure uses data that are derived from an actual ESRD patient database and is primarily

based on their own web facility-reported clinical and administrative data. The renal management information system, or RMIS, and the Medicare enrollment database and claims data, so it uses electronic data sources and data sets, seeing that it is feasible.

The measure is specified and tested at the facility level, so it's appropriate for the level of analysis and the population of interests, so yes. The developer indicates that there is no negative unintended consequences, as well, for this measure. So ultimately the preliminary recommendation for this measure is to support for rule-making, again noting that it has gone through NQF endorsement with its updates to the measure, as we said previously, and a current measure is already used within the ESRD QIP program, but again the updates and going through NQF endorsement bring this measure forward for the workgroup to consider. Akin, I'll stop there and turn it back to you.

CHAIR DEMEHIN: Thanks, Matt. That was

a very comprehensive overview of the preliminary analysis. As we did during the previous section, I'm now going to open it up for clarifying questions or concerns from the workgroup. What questions do folks have? I'll ask Udara to help keep track of anybody who has raised hands. I see Jackson. Go ahead. Jackson, are you on mute?

MEMBER WILLIAMS: I apologize, I think I hit the wrong button. I had a question for Dr. Schreiber. Your slide this morning that you didn't discuss that you flashed up for a while regarding sociodemographic status adjustments, I noticed the citation at the bottom was for the 2016 ASPE report, not last year's ASPE report, which seemed to do an about-face from the 2016 report. I was just wondering if you could clarify, because this to me is a measure that would be appropriate for peer-grouping or something of that nature. What exactly is CMS's policy on this going forward?

DR. SCHREIBER: There is certainly

ongoing discussion across CMS, across HHS actually, regarding the ASPE report because it did seem to change from what had been done in the past and changed to some degree from what NQF had had a consensus around doing. So it's still under consideration and it may yet change again. I think at the moment we haven't made certainly in rule-writing any changes to HRP, which is the one program that we do do stratification for duals.

I think that what we also spoke about this morning, that we start providing confidential feedback information on a more broad scale perspective so that organizations can see how they're doing based on stratification for whatever measures of social determinants that we have still holds true for this case, as well. This isn't one that we're bringing forward that in the program would be stratified. Jesse, correct me if I'm wrong, but it is at this point. An interesting thought, though, so Jackson, thank you.

MEMBER WILLIAMS: I do read those reports, Doctor.

DR. SCHREIBER: Yeah, I know. Thank you. Yeah, the ASPE report has been a subject of intense conversation.

MEMBER WILLIAMS: Thanks.

CHAIR DEMEHIN: Other clarifying questions or concerns from the workgroup?

DR. SCHREIBER: Can I just -- I'm looking at Lisa's question about the ASPE report. So Matt, for NQF, you may want to make that public -- not public, it is public, but you might want to make it available to the members of the group that may not be as familiar with it.

DR. PICKERING: Certainly, thanks Michelle. We'll send that around. Thank you, Lisa, for asking. We'll put that in the chat.

CHAIR DEMEHIN: Not hearing any other questions or seeing any other raised hands at the moment, I do have one clarifying question of my own, if I may. I think I understand the rationale for the inclusion of Medicare Advantage

patients in the measure, just given the growing prevalence of Medicare Advantage. There was one comment that was raised in the public comments about the extent to which the expansion of the measure to include Medicare Advantage was tested with that additional population and the extent to which any regional variation in Medicare Advantage might be accounted for. Would you or Jesse be able to comment on that?

DR. SCHREIBER: I'm sorry, I guess I'm not understanding the question. Can someone clarify it for me? You're looking for regional variation around this?

DR. ROACH: I was double-muted. I was wondering could you repeat the question?

DR. SCHREIBER: Okay, thanks, Jesse.

CHAIR DEMEHIN: Sure. So as I read the public comment, there were some questions about how the expansion of the measure to include Medicare Advantage had been tested and whether there was any analysis of the impact that any regional variation in Medicare Advantage uptick

might have, measure performance, I think that was the crux of it. I think it was Kidney Care Partners who raised the concern.

DR. ROACH: Okay, so they didn't test for regional variation, they just included the MA population in their testing, but they didn't test for regional variation.

CHAIR DEMEHIN: Okay. Other comments or questions? Seeing none, we're going to proceed in a fashion similar to how we did on the last round of measures. We're going to have a vote on whether to accept the preliminary recommendation from NQF staff's preliminary analysis. That recommendation is to support this measure for rule-making. Let me turn it over to Matt to talk about how to do that.

DR. PICKERING: Sure, no worries. Thank you. That's correct, Akin. We're going to have the committee vote in a similar fashion to accept the preliminary recommendation or not to accept it. Chris, I see you have the poll running on screen, so I'll turn it over to you to

make that happen.

MR. DAWSON: Thank you, Matt. Voting is now open for MUC20-0039, standardized hospitalization ratio for dialysis facilities with ESRD QIP. Do you vote to support the staff recommendation as the workgroup recommendation of support for rule-making? Yes or no? I will ask again if Linda Van Allen has joined us yet? We have 22 votes. I'll give it just another couple of seconds here. Voting is closed. The results are 22 yes and zero no. The workgroup supports for rule-making MUC20-0039, standardized hospitalization ratio for dialysis facilities with ESRD QIP.

CHAIR DEMEHIN: That went fairly smoothly. Before we leave the topic of the ESRD QIP, we did want to have an opportunity to talk about any gaps in the program measures set. I believe the subsequent slides include a little more information on what measures are currently in the program. Any thoughts on gaps that ought to be addressed in this program?

DR. ROACH: I don't have any thoughts. I just want to everyone know, I stuck the link to the ASPE report in the chat.

CHAIR DEMEHIN: Thank you, Dr. Roach. Other thoughts on gaps in the current program measures set? I do want to make sure we have an opportunity to advise CMS on what other issues it may want to begin addressing with this program that it isn't already.

DR. PICKERING: Yeah, Akin, I'll chime in, too, just to provide a little bit more of a context for the measure. In the needs and priorities document, just thinking about for future consideration care coordination, safety and patient/caregiver-centric experience of care are priority domains that have been indicated for future measure consideration. If that provides a little bit of assistance there, but thinking about where there could be some gaps along those priority domains or if there are other potential priority domains of interest. Those are the three that are indicated in the needs and

priorities document.

CHAIR DEMEHIN: I don't want to belabor the conversation if folks don't have thoughts here, but let me offer one more opportunity to talk about program measure gaps and other ideas for the agencies as they think about this program going forward. Okay, hearing none, I guess I would say I'm sure Dr. Roach and Dr. Schreiber would welcome additional thoughts on measure gaps outside -- oh I'm sorry, I missed Marty's raised hand. Go ahead, Marty.

MEMBER HATLIE: Akin, I just jumped in because I wanted to do something to fill the silence. I've made this comment before, but I think in general across all programs, but certainly this one, we need to be looking at opportunities there are to measure cultural obstacles to improvement, whether that's at the leadership level or some other level.

When we look back at 25, I'm really speaking to the patient safety priority, 25 years of focus on patient safety, it's a lack of

commitment to transparency and to sharing at the organizational leadership level that gets in the way of so much of the improvement work we want to do. I'm not a measurement person. I don't know how to get to that. There is some really interesting work going on around disclosure and transparency and candor, but I'll reiterate that here. I've said it probably every phone call I've been on in the last three or four years, but I hope it's helpful.

DR. PICKERING: Marty, if I may ask, is that somehow related to the health literacy of the health system or organization, if you're thinking about cultural obstacles, your health organization being health literate to that? Or is it something a little bit different? Help me understand a little bit more about that, because I've not been on previous MAP meetings where you've mentioned this, so I apologize.

MEMBER HATLIE: So Matt, it really gets at the way we implement a systems approach. It's a commitment to having the resources to do

quality improvement, to be sharing your lessons learned beyond your own organization so the same things don't happen elsewhere in Hospital B or Dialysis Center C or D that have happened already in Dialysis Center A.

We just haven't gotten to the point where we are really having a culture of sharing things, for a lot of reasons. A lot of social vectors, liability, reputation, payment, all those things get in the way of us doing more to really improve safety. There's a 25-year look back really happening right now at how much progress we've made on safety in this country, and culture is the obstacle. When I say culture, it's really tied to leadership. I don't know if that's helpful, Matt. I feel like it's a 10,000-foot explanation, but it is a real problem.

DR. PICKERING: Thank you for clarifying that. I see Tejal has also commented on top of yours saying agree to that. Thank you for sharing that.

CHAIR DEMEHIN: Janis?

MEMBER ORLOWSKI: I think that I would make two comments. One is speaking as a nephrologist, I think that there has been incrementalism that has occurred in regards to safety. That might be part of what Marty is saying, as well. I believe that there is hope. In the REMA world there has really been a dramatic new program to take a look at end-stage renal disease care, to take a look at innovation, to take a look at safety.

There are a couple of partnerships, federal, private partnerships going on right now to take a look at this, as well as CMMI programs looking at kidney care. What I would say is that there is a role for incremental process managements in quality, but we also need to take a look and say how do we make the big leaps? I am optimistic with the innovation that CMS has unsupported as we take a look at renal care in the future. The question is how do we look at that in other programs?

CHAIR DEMEHIN: Great comment. Any

other comments on this program and measure gaps and the measure that we just talked about?

DR. ROACH: I just wanted to thank you both for those last two comments and the ones in the chat. Those are very good and we'll be taking those back. I think the one about the culture and the one about us moving forward with bigger jumps are things that we do need to look at. So I appreciate you bringing those to us.

CHAIR DEMEHIN: Wonderful. Well, this has already been a very robust conversation. I think all of us have reached the point of a well-earned break. We are going to take a 10-minute break and plan to reconvene at about, it's 2:47 now, about 2:57 or so. Let's plan to be back on and we will pick back up where we left off. Thank you all.

(Whereupon, the above-entitled matter went off the record at 2:47 p.m. and resumed at 2:57 p.m.)

DR. PICKERING: Let's go ahead and kick it off.

CHAIR MORRISON: So first, I want to thank Akin for getting us back on a timeline, all but two minutes late. Thank you, sir. Very impressive. Well done. So we are now going into our next set of programs and measures. Welcome back everybody and, Matt, I turn it over to you to you at this point, I think, right?

DR. PICKERING: Yes. I'll talk about the program and then --

CHAIR MORRISON: -- yes.

DR. PICKERING: -- right, yes. So right now we are looking at the Medicare and Medicaid Promoting Interoperability Programs for Eligible Hospitals and Critical Access Hospital Measures. Before I talk about this program specifically, we're going to be looking at a measure here, MUC0032, so this is the Global Malnutrition Composite Score. So this measure has been submitted for this program but also for the Hospital Inpatient Quality Reporting program.

So similar like we did with the MUC0044, the COVID-19 measure, if there's no

abstentions, since this measure is very similar -- or it is similar to submit it to two different programs -- if there are no objections -- excuse me -- if there are no objections, we can carry over the vote going into the Hospital Inpatient Quality Reporting Program Measure, or MUC0032, the Global Malnutrition Composite Score.

But first, we'll talk about its submission to this program, which is a pay for reporting and public reporting program. The incentive structure for this is that eligible hospitals that fail to meet the program requirements, including meeting clinical quality measures requirements, receive a 3/4 reduction in the application percentage -- or applicable percentage increase. The goals of this program are really to promote interoperability between EHRs, or electronic health records, and CMS data collection.

And as previously stated at the Rural Health workgroup when there was discussion around its use in this program as well as Hospital

Inpatient Quality Reporting Program, CMS had shared that the reason for its use in this program is just to keep the sets aligned. Seeing that this is an ECQM, again going into this interoperability program, this measure is being submitted as an ECQM for this program, and to keep the sets aligned, it's included in this program as well as being submitted for inclusion into the Inpatient Quality Reporting Program.

Sean, I'll turn it back to you for any public comment.

CHAIR MORRISON: Perfect. So let me at this call for public comment either in the chat or by raising your hand if you're on the Zoom call.

I don't see any public comment, Matt, so if that is the case, can I ask you to introduce the Measure?

DR. PICKERING: Sure. So this Measure is a composite measure consisting of four component measure of optimal malnutrition care focusing on adults 65 years of age and older

admitted to inpatient service to receive care appropriate to their level of malnutrition risk and/or malnutrition diagnosis, if identified. The appropriate care for inpatients includes malnutrition risk screening, nutrition assessment for that at risk -- or for those at risk, and proper malnutrition severity indicated along with a corresponding nutrition care plan that recommends treatment approach. It's a facility-level measure, and this is a composite. It has been submitted NQF for Fall 2020. It addresses an important topic that's not currently used within these interoperability programs.

And the developer suggests the implementation of this measure may lead to improvement in outcomes such as reductions in 30-day readmissions, associated costs, and additional resource utilization.

As mentioned previously, it consists of four components, as you can see listed on the slide there. Thinking about evidence, the developer does cite evidence suggesting its

association with outcomes such as 30-day hospital readmissions compared to those without sort of a care plan in place, a malnutrition care plan. However, submitted to the Fall 2020 NQF endorsement process by the measure developer notes that the screening for malnutrition risk for conducting nutrition assessments was indicated as a grade E or supported by level 4 or level 5 evidence, so those are case reports.

Additionally, the evidence for providing nutrition supporting intervention for patients identified by screening and assessment at-risk -- for those at risk for malnutrition or malnourished was graded a C, or supported by at least one level 3 investigation.

Moving on to the quality challenge, the developer does note that among hospitals that meet a case minimum of 20 patients and at least 3 reportable measures in 2019, 44.7 percent of hospitals were the highest-performing tier, tier 3; 14.9 percent were in tier 2; and 40.4 percent were in tier 1, so you can see there's variation

there across the rates.

The Medicare and Medicaid promoting interoperability programs do not currently include any measures with similar areas of focus for this target population. And all components are required data elements within this composite measure are captured with electronic health records, and therefore the measure can be feasibly reported. The measure is also specified and tested at the hospital and patient acute care facility level analysis, so that is aligned.

And then that leads us to a preliminary analysis recommendation from the NQF staff of conditional support for rulemaking. And the conditional support for rulemaking is recommended pending NQF endorsement. So Sean, I'll stop there and turn it back to you.

CHAIR MORRISON: Thanks. And now I think is the time if there are clarifying questions or concerns for the committee, for the measure developers, or CMS, now is the time. Jennifer.

MEMBER LUNDBLAD: Great, thanks. I think those are a really important pair of measures that we're taking a look at and really addresses something that's not well-attended, so appreciate that they've come forward. I think it's especially true for things like pressure injuries and wound healing, surgery recovery, those kinds of things. And while it's not addressed as part of the measure, there's probably a social determinant or social factor related here if you think about food insecurity.

But my question has to do with time to understand or getting some clarity around how this is a composite measure. It -- I can't tell in the specifications that were included how it comes together as a single composite. It really looks like four separate measures to me. So I'm trying to understand what the denominator is and does that shift as -- so it's screening for everyone, and then screening goes to a full-blown assessment if a patient is at risk; and if they're at risk, then it's about having that care

plan. And so I'm trying to understand what that looks like as a single reportable measure, as a composite. Is it an all or none, or does that denominator shift over time? Is there ability to understand a little bit better what the reporting of that would look like?

CHAIR MORRISON: Thanks, Jennifer. Could I turn that over to -- do we have the measure developers or CMS? Can you answer Jennifer's question?

MR. VALLADARES: So hi, everyone. This is Angel Valladares with Avalere Health. I'm not sure the CMS team wants me to kick it off, or if they'd like to --

DR. SCHREIBER: Yes, Angel, go right ahead. Thank you.

MR. VALLADARES: No problem. Yes. Great, fantastic question. And this is -- may just be depending on the timing of the submission itself, but we have been working with the contractors on the measure -- you know, basically for the MAT. And the actual specification for

the calculation of the score was something that we had -- you know, we had to sort of wait for guidance from the MAT staff, and that was happening during the -- some of the review.

But the long and the short of it is that we have been able to develop a specified version of the calculation to match up with the standards required for MAT and then subsequent Bonnie testing. The way that the calculation algorithm works is the four measures are calculated first independently and then a unadjusted average of the four performance scores provides the final score for the composite. None of the measures are provided, you know, sort of a specific weighting. And when we tested that across, you know, sort of in a number of different ways, we were able to demonstrate the scores sort of reliability. And then also, of course, the other thing that was important for us to understand was that having a specific score was indeed associated, you know, sort of doing well or not doing well on the measure depending

on your population, was still associated with the outcomes that we know malnutrition specifically is used, you know, in terms of association studies like 30-day readmissions as was described in the opening.

So again, just quickly the calculation is the unadjusted average of the four scores. The hospital does have to have at least three scoreable measures for them to get a score on the global composite score. And then it's reported out, you know, basically as a total score for their -- the period that they're reporting.

MEMBER LUNDBLAD: Thank you.

CHAIR MORRISON: Thank you. Other clarifying questions, comments, concerns?

MEMBER McGIFFERT: I had a follow-up to that. Since each measure is sort of conditioned on the one before it, and they have to have at least -- did you say they have to have at least -- did you say they have to have at least three of the four in order to become a measure? So if a hospital screened people and

found that no one was at risk, then they're -- they would not be reported on this measure, right, because that wouldn't trigger the other steps.

MR. VALLADARES: Yes. That is correct in theory. The -- however, one of the things that we've learned over almost 10 years of doing, you know, sort of the malnutrition work -- I haven't been part of that entire 10 year journey, but for the part, at least, that I've been involved, is that there are a number of quality improvement opportunities, so some gaps.

And one of the major gaps, for example, is where physicians, for example, may find a particular patient malnourished but may -- you know, so they may make a diagnosis, but they aren't coordinating with the nutrition care team in a timely enough manner where they can go in, make a, you know, sort of a physical assessment, clinical assessment, and generate the right nutrition, intervention, recommendation. Even if the patient, you know, doesn't get some of those

interventions before they're discharged, they can at least receive that guidance. It could go to their next provider, you know, outside of the hospital, or it could even go with them or their caregiver, and that could be things like modifications to the diet, providing, you know, oral nutrition support, and other nutritional interventions like education that may be recommended in an outpatient setting after the patient is discharged. So that's a major gap, for instance, that we've seen.

And so to that point, the four measures, while thematically related, if you -- you know, looking at the care process itself, what the measures do is they sort of capture the patients that may be missing from one step to the next. So for example, with the screening measure, if patients are, you know, screened and they're found to be at risk, obviously, we want to make sure that the patient is assessed.

But there may be patients who are assessed that were not screened, and that is a

normal part of hospital protocol, because many of these hospitals have a 24 to 48-hour automatic sort of trigger, I you will, in some of their protocols where if a patient is in the hospital for more than a day or two, and they haven't been screened, the dieticians usually come in and do a physical assessment anyway, because if they're there for that long, there's a very high chance that they have some sort of nutritional compromise, so they come in and do an assessment, and those patients end up in measures 3 and 4, right, if they end up diagnosed, which sometimes they are. But they're not in, you know, 1 and 2, for example.

So hopefully that makes sense. I was trying to sort of give you a lay of the land and an understanding of how we've seen in our collaborative of a few hundred hospitals across the country, how they've been implementing this workflow.

MEMBER McGIFFERT: Yes, that makes sense, but I'm wondering -- I remember there was

-- isn't there an exclusion for people who didn't get the initial assessment --

MR. VALLADARES: No, the only exclusions are for patients who were discharged to hospice or left against medical advice. And then the other thing that's built into the measure is we don't look at patients who were screened -- so we don't look at the screening of patients who were screened more than 48 hours before admission as that screening would no longer be clinically valid at that point.

CHAIR MORRISON: Mike Woodruff? Saw your hand.

MEMBER WOODRUFF: Thank you. Just a quick question. This is an important topic, and it's got a great evidence base behind it. My question is it's been in testing for a number of years now through the collaboratives, and I'm just clarifying whether this bundle or this composite measure, when executed well, do we have evidence that this drives improved outcomes, specifically this measure?

MR. VALLADARES: Sure, happy to answer that question as well. So we -- to your point, we've had a phenomenal engagement and excitement around this measure's use in over -- at least the data that we've received has been -- has come from over 100 hospitals. We used around 50 to 60 hospitals to test the measure, and the collaborative that we have itself is of 300 hospitals around the country. They have been implementing and luckily, in that process, one of the things that we've been doing is working with the sites to publish on their own data. And we do have quite a number of papers that have been published, and some are still -- you know, the time we have been aligned, they're still under review, but we have a few that were published in the last year or two.

And the most -- one of the most recent ones was published, and I believe unfortunately it didn't come in on time when we submitted for the MUC, you know, list itself, but it is part of the evidence we submitted to the NQF for

endorsement.

It's a paper that we published based off the -- a group of hospitals that we had all reporting data around the same time. It was about 30 hospitals that work together implementing quality improvement on this very topic at the exact same time. And our findings were that, you know, given the implementation -- from a process perspective, of course, they were able to close a number of gaps, and we were able to show statistical significance there around screening and assessment, around capturing diagnosis, and obviously that ending up with more patients getting the right care they needed.

And then in terms of outcomes, what we were able to showcase was just sort of reinforcing what we already know in the literature, right, which is that patients who are malnourished, patients even who aren't even at that stage or may just be at risk, right, they were just screened, triaged, and found out some kind of diet issue or some obvious weight loss.

Those patients have a much higher likelihood to be readmitted within 30 days and also have two to three times longer length of stay.

When we showcased the patients who were able to be diagnosed and provided a care plan over that period, we showed a significant decrease in readmissions.

The length of stay data is a little bit different, because we didn't look at some factors that you would need to. We didn't have the data, basically, to look at some factors to be able to control for length of stay, because the problem with the length of stay is, right, the sicker patients are obviously going to be there for a longer period of time. And so you're more likely to be in the hospital for longer if you end up being seen by a dietician and receive care, right, and you receive that care plan. So naturally, the patients who had the care plans had a lower readmission rate than those that didn't. But the ones who had the care plan also were in the hospital longer, because they tended

to be sicker than the ones that, you know, were not assessed as malnourished or diagnosed as malnourished.

CHAIR MORRISON: Thanks. Jennifer.

MEMBER LUNDBLAD: Thanks. A different question. So for this one that we're looking at, 0032, is for the interoperability program, and I think what you just described is terrific, and it's going to be really helpful for critical access hospitals who are included in interoperability program, because they don't, quite honestly, have very many rural relevant ECQMs.

MR. VALLADARES: Right.

MEMBER LUNDBLAD: I think only two right now unless they deliver babies, and so this would be a nice addition to that mix. So my question is, as you were just describing the studies you've done, were there any really small rural hospitals that participated, and were they able to sustain their denominator so that they would have enough cases to report so that they

would have this as a reportable measure? Were there any --

MR. VALLADARES: Yes.

MEMBER LUNDBLAD: -- of the really small CAHs in your study?

MR. VALLADARES: Yes. We had -- I'm just looking at my documents here. We had one, two, three, four -- sorry, going through the whole thing, it's a very long list -- five -- we had about five or six critical access community hospitals. So these are very small hospitals with less than 100 beds.

CHAIR MORRISON: Thanks. Lisa.

MEMBER McGIFFERT: I just wanted to clarify that the -- I think this is a terrific measure also, but I'm struggling. Is -- it seems to be more of a measure of helping the hospitals with readmissions and length of stay measures. And so the assumption is that if the patient is not readmitted, then somehow the screening for malnutrition is the reason why. And I understand there were some studies that you have connected

with that. Could you talk about that a little bit more?

MR. VALLADARES: Sure. That's a great question, but just off the bat, I would say that's not the argument we're suggesting, right? So what we're suggesting is that we've done a number of studies which showcase two different things, right? I think one is what you were hinting at at the top, right, of your comment, which was that malnutrition is definitely a way to help hospitals, particularly the providers, right, understand a risk factor that is a significant predictor of adverse, you know, outcomes, right; so increased readmission risk, increased lengths of stay, average lengths of stay at the population level. In terms -- and I will -- you know, you could also say individually. So we were able to showcase that with some of the testing documentation as well, and obviously the evidence is pretty significant, especially internationally, I think the United States unfortunately falls behind significantly

in terms of many of its peers in other countries studying this. There's significant evidence in Europe and Asia and, you know, developed countries showcasing the link.

In terms of what we were able to showcase with improvement, right, is that if you complete the whole process, not the screening because the screening itself, all you're doing is identifying the -- you know, your target population which to focus which admittedly is also a problem in the states, right, which is very limited nutrition personnel. The ratio of sort of nutrition experts, if you will -- if you want to -- including registered dieticians and nutritionists -- is fairly low per patient. You know, the number of patients that are seen by a dietician is rather high. So they have a pretty high ratio there. And I apologize, I have a doorbell ringing at the same time.

But I will I just say that the long and the short of it is that what we showcase was for those who do get that diagnosis and then --

you know, the care plan coordinated with the physician and dietician implemented, that we saw those -- that reduction and readmission. So it's an association. Of course, we're not trying to suggest that it's causal, but the association was very strong in our data, and we think that in the evidence across the board, you will see that nutrition interventions, when applied to the right population, have very significant impacts in terms of helping out patients and reducing adverse outcomes.

MEMBER McGIFFERT: Thank you. That's great. And I'm assuming that that fourth component is actually a very specific plan to that patient that will help that patient get to some community support and things like that?

MR. VALLADARES: So the care plan itself is structured as part of the standard of care that the professional society, the Academy of Nutrition and Dietics, which is the steward of the measure, dictates in its guidelines for standards of practice, and it includes making

specific recommendations around sort of the composition of nutrition support, right? So there are different modalities depending on the diagnosis and the state of the patient. And then also, there is the education and counseling needs and as you said, the referrals to outside. And I think someone had mentioned very early in the commentary around there being an issue on food insecurity and one of the main areas that dieticians are -- especially in our learning collaborative, they are starting to implement more of -- is making connections with community support groups and making referrals so they get -- the patients have access and their caregivers have access to food banks and, you know, other support services like that.

MEMBER McGIFFERT: Thank you.

CHAIR MORRISON: Let me suggest at this point that we go back to Matt to talk about voting. The first we're going to do is a vote to -- whether to accept the NQF recommendation. And depending on that, we'll determine our next

steps. Matt, did I get that right?

DR. PICKERING: Right. So yes, thank you, Sean, for keeping us moving along. I'm just looking at the chat box. It doesn't look like there's anything different. I appreciate Jesse Spencer's comment related to the Rural Health workgroup, felt that these measures could be captured in the rural hospital setting. Thank you, Jesse, for sharing that.

Okay. So, Chris, I will turn it over to you. I'm sorry for that inaudible speech there, Charles. I was just sort of reading the last little bit on the chat, but nothing new there. So Chris, I'll turn it to you.

MR. DAWSON: Okay. Thank you, Matt. The voting is now open for MUC20-0032, Global Malnutrition Composite Score for the Medicare and Medicaid Promoting Interoperability Programs for Eligible Hospitals or Critical Access Hospitals. Do you vote to support the staff recommendations as a workgroup recommendation of conditional support for rulemaking, yes or no?

And I will ask again, do we have Linda Van Allen on the line? Okay. We have 21 results in, 22, 23, we'll give it just another few seconds. Okay. Voting is closed. The results are 22 "yes" and 1 "no." The workgroup conditionally supports for rulemaking MUC20-0032, Global Malnutrition Composite Score for the Medicare and Medicaid Promoting Interoperability Programs for Eligible Hospitals or Critical Access Hospitals.

CHAIR MORRISON: Thank you, Chris. Let me know just open it up for questions, comments -- no, sorry, not questions, comments but identification of gaps in the program and measure gaps that CMS should consider.

DR. PICKERING: While you're doing that, Sean, and waiting for some folks, maybe chime in with this program, which is very similar types of priorities for the inpatient quality, inpatient quality reporting program, the hospital inpatient quality reporting program, which is strengthen person and family engagement as

partners in your care; promote effective communication and care coordination; promote effective prevention and treatment of chronic disease; and make care safer by reducing harm caused due to delivery of care are the priorities for future measure consideration within the measure, at least prior to this document.

MEMBER LUNDBLAD: So can I just ask -- this is Jennifer again -- in the comments, the public comments that were shared in the version release on Friday, a couple of different commenters wrote about the documentation of the four elements being measured, that documentation felt like it had the least evidence and was the least clinically relevant. The other three, the screening, the assessment, and the care plan all felt kind of strong and were supported. But there were a couple different commentors that were about documentation. Is this an appropriate time to ask about that, if there's any -- if there's a reaction to that piece of the public feedback?

CHAIR MORRISON: Jennifer, that would have been a little bit earlier around the questions and comments, but what I would --

MEMBER LUNDBLAD: Okay.

CHAIR MORRISON: -- suggest is since we are going to do this again on the Hospital IQR, why don't you just bring it up then?

MEMBER LUNDBLAD: Got it, thanks.

CHAIR MORRISON: No worries. This is really -- this is the time about gaps. Okay. Let me close that out then and turn that over to Akin who gets the Hospital IQR program.

CHAIR DEMEHIN: Okay. So the first measure on this list is going to look very familiar to all of us, but I think before we launch into talking about the malnutrition composite score again as well as the patient-reported outcome measure around hip and knee replacements, I'm going to kick it over to Matt to talk about the program itself. And then I think we're opening it up for public comment after that, right?

DR. PICKERING: That's correct. Thanks, Akin. So the Hospital Inpatient Quality Reporting program, or Hospital IQR, is a pay for reporting and public reporting program, with the incentive structure that hospitals that do not participate or participate but fail to meet the program requirements receive a 1/4 reduction of the applicable percentage increase in their annual payment update. And really, the program goals are to progress towards paying providers based on the quality rather than the quantity of care they provide to consumers and beneficiaries as well as providing those consumers with information about hospital quality to improve their care decision-making.

Okay. Akin, I'll turn it back to you for opening up for public comment.

CHAIR DEMEHIN: All right. Thanks, Matt. Are there any public comments on the IQR program and the measures we're about to talk about either via chat or on the line?

(No response.)

CHAIR DEMEHIN: I'll ask Udara to help monitor those for me. Okay. I don't see any at this point, so I think I'm kicking it back over to Matt to talk a little bit about the malnutrition measure. Matt, let me ask you, should we talk about the malnutrition measure separately and then launch into the hip and knee measure? They seem pretty different, so I may want to divide up the conversation here.

DR. PICKERING: Yes, Akin. I think that makes sense. We'll talk about them separately. I will say that, you know, we could carry over the votes for the global malnutrition composite from the previous measure since it -- or the previous program. And just to touch on the measure itself, if we could go to that slide, you can see it listed here. It's the same measure that was submitted for the interoperability programs. The preliminary analysis is similar to that as well, recognizing that this is a composite measure, and the evidence to support this, as was stated by the

developer, they've done some studies here to associate some of the components of the measure to outcomes like 30-day hospital readmissions, to length of stay, and also noting that this measure has some gaps, or at least there is a quality challenge here that could potentially be fueled.

There is some other evidence, again, that the developer supports with this measure, specifically within the Fall 2020 evaluation that is happening right now as this measure has been submitted for Fall 2020 NQF endorsement. Or some of the malnutrition risks and some of the nutrition assessments provided some evidence there with grade E supported by level 4 or 5 types of evidence as well as some of the other assessment components and screening components if the measure were grade C were supported by at least a level 3 investigation.

But again, the developer has mentioned that they've done some additional studies and research with other outcomes, as stated previously. It's for the Inpatient Quality

Reporting program, which does not currently include any measures in this area or with a similar focus. It can feasibly be implemented and reported because it relies on electronic health record data or electronic data. And the measure is specified and tested at the hospital inpatient acute care facility level of analysis as well.

So this leading to a conditional support for rulemaking as the preliminary analysis for recommendation, and the condition here is that it's recommended pending NQF endorsement. Back to you, Akin.

CHAIR DEMEHIN: Thanks, Matt. So before I open it up for additional questions from the group, and I do want to get to Jennifer's comment about documentation, I have a couple of things I wanted to get a little bit of clarity on from CMS and perhaps from the measure developer.

The first is there is something unique about how ECQM report requirements are structured in the Hospital IQR program. It is a -- there is

a link between the promoting interoperability and IQR programs, but the way the IQR program works is that hospitals select from a list of ECQMs available to them. And I wanted, number one, to ask CMS whether it had any intention of changing that kind of reporting structure.

The second is that we did see a very similar measure to this one come before the MAP just a few years ago. I am struggling a little bit to understand exactly what is different about this version of the measure which, as I recall, the MAP was not terribly enthusiastic about versus this one. So I wonder if we could have a little more conversation about that.

DR. SCHREIBER: So I'll kick it off a little bit. I don't recall this from the past. I know it's been sort of on the list. I know that it's been on the list for a while and hasn't come forward before, but I don't recall that it's come to either the MAP or NQF, so Angel or some others on the CMS team may know history that predates me.

Regarding your question on the promoting interoperability program, Akin, you are correct. This would become one of the measures that an organization could choose to report, is one of the measures -- you know, there's a slate of measures and organizations get the choice. We don't, at this moment, have any plans of changing that. And of course, unless you tell me the AHA wants us to mandate certain ECQMs, Akin, I'll certainly take that under advisement. But at the moment, I ---

(Simultaneous speaking.)

DR. SCHREIBER: -- yes. At the moment, we plan on continuing choice. I will say though, just so that the group recalls, that we did put into writing this year -- I think it's in IBPS but things got jumbled this year -- that we are going to make public ECQM data. We haven't before. Remember that has not been something that we have posted in like Hospital Compare, and it has not been public, we do plan and we finalize that in rural writing that we will be

bringing ECQM performance public.

And also we are increasing over time the timeframes for reporting. So right now you can -- and you report an ECQM for one quarter. Over the next several years, it will increase by a quarter, so the following year, for two quarters, the following year, for three quarters, and all of this was finalized in rule writing, so CMS is putting more of a focus and spotlight on electronic quality measures.

MR. VALLADARES: And if I may, this is the developer, Angel. I just wanted to add to Michelle's comments around the timing and the history. So you are right. There is a similar measure which I would actually say is a component measure that was brought to the attention of this body several years ago in, I think, about maybe three or four years ago at this point.

Originally, when we had gone to MAP through the MUC list, we had presented the component measures in a slightly -- these are slightly modified. But basically the component

measures were presented as individual measures for hospitals to report individually. And the recommendation, in fact, that we received the committee was to consider a composite measure of the four measures. And we spent about three years or so developing this composite measure based off of those -- that feedback which we received both from this body and also from the endorsement committee, which told us that we should consider a composite considering how they're -- you know, the measures are related to each other. All the processes are important but they're related to each other, and they would strengthen the case for pursuing this area of measurement if we had a more cohesive set that sort of, you know, brought you to a specific quality conclusion, if you will, at the end. So that's the history and, I think, the relationship between the one that you're probably recalling from a few years back.

CHAIR DEMEHIN: Thank you, Matt. That does help. I was trying to kind of string

together the history of this and was having a bit of a challenge doing so. I just want to make sure that Jennifer has the opportunity to raise the issue from the prior discussion, so let me kick it over to you.

MEMBER LUNDBLAD: Right. Thank you and thank you for helping me get my questions placed appropriately in the sequence of things. So I know that in the public comments that were in the written materials that we received on Friday, what I said just a minute ago, that a couple of commentors identified the documentation element, one of the four component parts of the composite measure as not having the similar strength of evidence as the other three. And that maybe explains the history that we just heard, some of the reference, so it coming before the NQF in a previous iteration. So I'm wondering if Angel or anyone else can comment on that documentation component, that one of the four?

MR. VALLADARES: I am happy to speak

on -- and I presume you're speaking about the appropriate diagnosis of malnutrition. So in fact, that measure is a really important piece of the puzzle, and it actually plays quite a number of roles. And what's really, you know, I think interesting about this measure, of course, from my opinion and our opinion as an organization and as a partnership among several stakeholders, is that malnutrition, you know, has a role across, you know, not only many units and departments and sub-populations of a hospital, but also from a thematic perspective, right, its impact on outcomes like readmissions, and length of stay, and costs, and mortality, but also the fact that it is also a really important care coordination piece, because the care provided for malnourished patients does require a number of different, you know, folks from the care team to be involved, whether it's the nursing team that screens the patient and, you know, it's triage at the very beginning at admission, to the experts in nutrition and the, you know, registered

dieticians who come in and provide the recommendations after conducting thorough assessment of the patient to ensure that they're indeed nutritionally compromised, and then the physician who signs off on the diagnosis and ensures that the care plan that was designed and developed by the dietician team moves forward.

And importantly, from a transitions of care perspective, that when that diagnosis is in there and it's documented for that patient, the likelihood of it being part of the patient's discharge planning increases significantly, because now there's a diagnosis to focus on, and many hospitals, you know, are used to implementing problem-focused discharge planning. And so sort of the number of reasons why we have that measure, it's been very important for documenting and understanding the malnutrition rates that hospitals have.

And one other piece I'll just sort of plug in is the data that we've shown that our hospitals and our learning collaborative,

implementation of these measures, including that measure in particular, have been able to sort of identify more evidence-level or evidence-reported levels of malnutrition, which looking at claims data alone, showcase that there is a significantly under-reporting or a significant under-reporting of malnutrition nationally when you look simply just at claims.

So you know, those are the, I would say, the pillars of support for that specific component and its relationship to the rest. Hopefully that helps provide you a bit of context from our perspective.

DR. SCHREIBER: Yes. And Jennifer, it's Michelle. If I could just comment for a moment? First, Angel, I love your passion for this measure, but your underlying point is absolutely correct, that there is less evidence for just documenting whatever, not just this but in anything. You know, did you document x, y, and z. Did you provide education. Those seem to really be measures that have the least amount of

effect, as it were, on outcomes and care. And so it is true, CMS is moving away from those for that reason. They're kind of just like check the box things, and that's why we're moving more towards outcomes. But I believe it's also why in this measure, it has been strengthened by the inclusion of several other elements.

MEMBER LUNDBLAD: Makes sense, thank you.

CHAIR DEMEHIN: Great. I believe I see Janis's and up as well.

MEMBER ORLOWSKI: So my comments actually follow, I think, along with the previous discussion. And first of all, I would say I believe that this is a very important indication for health and something that can -- should be documented and should be worked on.

I always wonder why we do these things in the inpatient setting. And I would tell you that this is an ambulatory -- it really belongs in the ambulatory care. I kind of feel like we capture people in the inpatient, so we slap on

the flu, we slap on, you know, the malnutrition screening, you know, we sort of do all these things. If we really are thinking about how we are going to affect this, I think that it goes into the ambulatory setting so that if we use these same markers prior to someone needing their hip done or prior to someone needing, you know, whatever, that this becomes a place for us to make a broader impact over multiple ambulatory visits.

In addition, I think that what will happen is that in many cases, the process measure will be implemented through some sequence, and it will be documented, and it will increase the cost of care. But it will -- but that plan will not always have legs as the individual leaves the hospital unless we do connect it to the outpatient.

DR. SCHREIBER: So thanks, Janis. Michelle, again. I think that's an important issue, and actually Angel and I have been texting a little bit, so I'm going to tell you what he

said because this actually is correct.

Part of the issue of not having it in the ambulatory side is that we don't have great data standardization around this. We don't, as you all know, have the financial incentives to support nutritional care in the ambulatory side, and so that people felt like they perhaps couldn't do this in an ambulatory side. There is a lack of access to nutritional care on the ambulatory side. And I think those are all critiques of care, quite honestly, and critiques of the payment system. And maybe introducing measures like this actually would shine a spotlight on that in the ambulatory setting.

MEMBER ORLOWSKI: Exactly.

MR. VALLADARES: And if I may, I have just an example just for context, and this has been one of the shining I think stories of the work that we've been doing in this malnutrition learning collaborative. And many of your hospitals who first became members of the collaborative and began implementing the measures

and making changes to care based off of their performance on these measures, they've actually naturally transitioned to actually reinforcing the discharge planning.

So while I certainly understand the concern of sort of like you said -- I love the analogy of "walk away care plan" -- I think one of the great findings that we are hopefully going to be publishing on very soon to reinforce the evidence is the fact that many of these hospitals, after having a really successful time expanding their programs for identifying and treating malnutrition in the hospital, have gone on to implement coordination for discharge and even beginning to do some of the leg work, as you suggested, to have better nutrition care in outpatient settings.

I think the challenge is that at, you know, this time, there really isn't like a center of focus or incentive in the outpatient for these measures to be successful in outpatient without the hospital component which is, unfortunately,

where, you know, it is probably a critique of the health system that many of these patients are first identified with malnutrition.

MEMBER ORLOWSKI: So Angel, I appreciate your comments, and again, let me be very clear. It's not that I -- I believe that it's a very, very, very important measure, and I do believe that it's one of the measures that should be -- you know, food scarcity, the issue of malnutrition, all of these, the fact that it is more applicable in the ambulatory setting, but we don't have a mechanism to take care of it there so we put it on the inpatient is exactly my point. It really doesn't -- it doesn't fit in the inpatient. There will be some benefits. I have no doubt about it, Angel, that you'll be able to, you know, give us examples of some people where there's benefits.

But speaking globally, what we need to do is to take a look at how we identify and make available nutritional support in the outpatient, make these evaluations, because that's where this

measure belongs.

DR. SCHREIBER: Janis, I agree that it belongs there, but I'd hate to go saying that it doesn't belong on the inpatient side, because I think issues of nutrition belong -- I was going to say equally well but perhaps better on the outpatient, but certainly belong on the inpatient side. When we get to issues of wound healing, when we get to issues of, you know, patient recovery, I think that it's equally important, but it is certainly very important and valid on the inpatient side.

MS. McCAULEY: Ms. Schreiber, this is Sharon McCauley. I am from the Academy of Nutrition and Dietetics.

DR. SCHREIBER: Wonderful.

MS. McCAULEY: I am just --

DR. SCHREIBER: Thanks, Sharon.

MS. McCAULEY: Hi. How are you? I'm Senior Director of Strategic and Quality Management, and to answer Janis's questions, you know, the dietician/nutritionist, which I am a

registered dietician licensed in Illinois -- and I've been on this program working over the 10 years that Angel has described as our measure steward working side-by-side with the developer. Our dietician/nutritionists are involved in all the continuum of care prior to the, you know, admissions, into the facility, into the hospital, working through those levels of the pieces and parts of the components of the composite measure, making sure of their transitions of care.

We have, as Angel has indicated, stepped up. These dietician/nutritionists across the country are doing quality improvement in all phases. They are now connecting with our long-term skilled nursing facility dieticians, rehabilitation dieticians, home health, and are doing -- so this program that we've had, this malnutrition quality improvement initiative has really elevated our standards of practice, which I am also in charge of at the Academy. And so every single level of competence to the expert moving forward through every single domain of any

of the other areas, we are there at the forefront.

So this is -- and I understand what you're saying about the ambulatory, but it has to start in the inpatient to move forward and transpire out into a huge learning collaborative and a learning health system. So thank you so much.

DR. PICKERING: Thank you very much as well. I just wanted to confirm, were you with the developer or work -- you worked with them on the measure?

MS. McCAULEY: Oh yes, I worked with the developer since day one, so I'm -- so we're good, yes. So at the Academy of Nutrition Dietetics, we are the steward of this malnutrition composite --

DR. PICKERING: Steward?

MS. McCAULEY: -- measure. Yes, the measure steward. And to Akin's point, we did have the four components separately in prior, and that was in 2016. I can give you my notes if you

need them, but no, we'd like to move forward with this composite measure as we understand that, you know, on the table right now is conditional support for rulemaking. And we appreciate all of your support. Thank you.

CHAIR DEMEHIN: All right. Let me pause one more time and see if there are any other questions by way of clarification or comments on this measure.

(Pause.)

CHAIR DEMEHIN: Then let me ask Matt, should we just do a straight revote on this measure, or should we carry forward with the recommendation that was applied to the promoting interoperability program as is? What do you suggest in terms of process?

DR. PICKERING: So we can just -- are there any objections to carrying over the vote from the interoperability programs? So again, that vote was the same conditional support for rulemaking pending -- or at least the recommendation pending NQF endorsement. We can

carry those votes over, or if there is an objection, we can have a separate vote on this measure for this program. So I'll turn it back to the workgroup if there is an objection, or if there is none we can carry this over.

CHAIR DEMEHIN: You can either say it over the phone or raise your hand in the platform if you want to raise an objection. Right.

(No response.)

CHAIR DEMEHIN: I'll have Udara also monitor as well.

MEMBER ORLOWSKI: I'm not sure what you're asking us. Are you asking us to allow the vote that we did 10-20 minutes ago to carry over for this discussion or to revote?

DR. PICKERING: So to carry over if you feel the vote --

MEMBER ORLOWSKI: I think if you -- if that was the intention, it should have been announced at the prior vote that we were voting. It should have been handled as the COVID questions were -- that a vote would carry

forward. What you're doing is now retrospectively saying your last vote will count. So I do object to that.

DR. PICKERING: Oh, I apologize, Janis. I thought I had mentioned at the beginning with the previous measure. So you object, we can definitely open it up for a vote. So let's do that.

MR. DAWSON: Okay. Give me just a moment here, and I'll pull the question up. Okay. So voting is now open for MUC20-0032, Global Malnutrition Composite Score for the Hospital IQR program. Do you vote to support the staff recommendation as the Workgroup recommendation which is conditional support for rulemaking, "yes" or "no"?

(Pause.)

MR. DAWSON: And I will ask again if we have Linda Van Allen on the line, and if so if she would like to share her vote with us?

(No response.)

MR. DAWSON: Okay. We have 22 results

in. I'll give it just a few more seconds.

Okay. Voting is closed. The results are 20 yes and 3 no. The Workgroup conditionally supports for rulemaking MUC20-0032, Global Malnutrition Composite Score for the Hospital IQR program.

CHAIR DEMEHIN: Okay. Thank you. There is one more measure under consideration for the IQR program. Let me turn it over to Matt to talk about it.

DR. PICKERING: Great. Thank you, Akin. Okay. So now we are MUC-0003, Hospital-Level Risk Standardized Patient-Reported Outcomes following Elective Primary Total Hip and/or Total Knee Arthroplasty. The measure will estimate a hospital-level risk standardized improvement rate for PROs, or patient-reported outcomes following elective primary THA or TKA for Medicare Fee-for-Service patients 65 years of age and older.

Substantial clinical benefit improvement will be measured by the change in score on the joint-specific patient-reported

outcome measure, or PROM, instruments measuring hip or knee pain and functioning from preoperative assessment data collected between 90 to 0 days before surgery to the post-operative assessment data collected 270 to 365 days following surgery. So this is a facility-level measure.

And regarding the preliminary analysis -- actually, Akin, I'll see if there's any public comment for this measure.

CHAIR DEMEHIN: There are actually several comments for this measure I think.

DR. PICKERING: Coming in from the public, Marty?

CHAIR DEMEHIN: I thought so. Maybe not.

DR. PICKERING: Okay.

CHAIR DEMEHIN: There were a couple of comments included in the preliminary analysis guide. I'm not sure that there were any new ones raised today, but can I ask the NQF staff to double-check?

DR. PICKERING: Yes, and confirming. Okay. So moving forward to the preliminary analysis, okay. So the Hospital IQR program currently doesn't have a measure of person and family engagement related to total hip and total knee arthroplasty. However, the program does include a payment measure for hip and/or knee arthroplasty and a complication rate measure following hip or knee arthroplasty.

The measure is an endorsed patient-reported outcome performance measure, or PRO-PM, that passed this past spring, so this past evaluation cycle, spring 2020, and also went through CSAC and is endorsed as it stands currently.

The developer also cites studies with this measure that suggest optimal clinical outcomes can be influenced by the surgeon performing procedure and the team's efforts in the care of the patient, care coordination across provider groups and specialties, and patients' engagement in their own recovery.

Related to the quality challenge, the developer notes that the average in distribution of hospital risk standardized improvement rates range from 6.65 percent to 86.84 percent with a median rate of 66.49 percent. So this was included in the most recent testing information that was submitted and ultimately reviewed by the standing committee, CSAC, for endorsement.

The developer further noted that the interquartile range for this was 54.36 to 72.51 percent representing a difference of 18 percentage points, so a variation that exists currently and we said that this was a quality challenge based on these data.

The measure complements existing outcome measures that are publicly reported in the Hospital Compare. As we mentioned previously there is a risk standardized episode of care payment measures, NQF Measure 2653, which is the average change in functional status following total knee replacement surgery. That's an existing Clinician Group level measure and is

similar to this measure as well. Feasibly reported, this measure does allow hospitals to collect data using paper and electronic formats, so not all required data elements are electronically collected, but it is a patient-reported outcome measure so collection of survey responses may potentially have burden on certain facilities. But this -- again, this measure allows to collect data both through paper or electronic formats.

The measure is specified and tested at the facility level of analysis at the hospital inpatient facility setting and it's aligned with that setting that it's proposed to be utilized in. It is a new measure not currently in use, and the subsequent preliminary analysis recommendation for this measure is to support for rulemaking. Akin, I'll turn it back to you.

CHAIR DEMEHIN: Thanks, Matt. So this is the opportunity for us to ask clarifying questions and raise concerns. So let me open it up to the group. And I see one hand up. Let's

start with Aisha.

MEMBER PITTMAN: Thanks, Akin. So first, I just want to say thanks to CMS for testing this measure as a voluntary measure through the CJR program. I think it's a great way to have voluntary reporting to help develop the measure. That said, I just wanted -- and I think it's probably from an NQF staff perspective and CMS as well -- to talk a little bit about the burden of data collection. I know for our member health systems, that was a huge issue in the voluntary reporting through CJR. But I know the measure has changed and evolved over time.

So can you just speak to how the data elements are different than when it was collected -- what was collected for the voluntary reporting under CJR and then if there are sort of differences in performance, whether you're collecting things electronically or on paper.

And then my final question is just through what reporting mechanism, if it's not electronic, is this information going to be

reported to CMS?

DR. SCHREIBER: It's Michelle. I'll just kick things off and I'm going to turn it over to our contractor, Yale CORE. But we recognize the issues of data collection with patient-reported outcome measures in general and think this is an area that needs some significant improvement, whether or not it's an electronic platform, which we think ultimately it's going to have to be, or what, because as we all want to hear the voice of the patient, now we recognize that it has been burdensome to capture it. Some places have to hire nurses to call people after the fact. Some people, you know, have to get information differently, and so this is something that is at top of mind and is being worked on.

For this particular one, though, I think some improvements or modifications were made. And let me turn these specific questions over to Yale.

DR. SUTER: Dr. Schreiber, thank you. This is Lisa Suter from Yale. Can people hear me

on the phone?

DR. SCHREIBER: Yes, Lisa.

DR. SUTER: Great. So you're correct, the specifications that are in the CJR voluntary data collection are slightly more onerous than the final specifications. They include collecting for hip patients both a hip-specific patient-reported outcome survey and a general health-related quality of life PROMIS Global score. And for knees, it's a short form just like the hips, knee-specific survey and the PROMIS Global.

We do use the PROMIS Global mental health score in the risk adjustment model but not the physical function score. And we do use some patient-reported, including health literacy, and clinician-reported, like BMI, that are collected with CJR.

So overall, the -- we have worked very hard with stakeholders and clinicians to reduce the number of questions to a very small number. The patient-reported outcome surveys are six and seven questions each. The -- and the measure

itself will reduce the number of questions compared to the CJR data requirements right now.

In terms of how the data will be submitted, CJR has provided a lot of learning on that front. You noted some of the burden. We're also learning about different requirements for thresholds and response rates and response bias, which the measure takes into account. And there is an effort right now to create a strategic implementation plan with the voice of patients, hospitals, and electronic health record vendors that is ongoing to inform CMS' strategy going forward to minimize burden.

CHAIR DEMEHIN: Great. We have a bit of a queue of folks lined up to ask questions, so let me start with Lindsey.

MS. WISHAM: Yes, good afternoon. I think I concur with Aisha's comments, and I think Lisa already addressed some of these, but while I think there is opportunity in providing the options and flexibility for reporting in how they capture this data, I do think, if we're going to

see successful implementation in a range of digital quality measures, this one goes beyond just eCQMs but has some digital capture opportunities. I think we have to be very specific in how it's implemented if we're going to see success.

If we're going to trust the data as it's reported and gain confidence in those very important PRO-PMs, I think as much guidance as can be provided by the measure developer, as it's implemented in these programs, I think, again, will just exponentially improve the trust in the data.

CHAIR DEMEHIN: Thanks, Lindsey. Let's see, I believe Tejal is next.

MEMBER GANDHI: Thank you. A couple of comments and a question. So first, I do think it's great that CMS is moving into the patient-reported outcomes space, and so I applaud the efforts on this.

I did notice in one of the public commments as well that in addition to the burden

issue, you know, understanding the impact of doing these surveys on response rate of other surveys was a question that had come up, so I'd be curious if there's any information about that. I thought it was an important point to bring up.

And then, you know, I did want to mention, too, that these surveys tend to focus on changes in, you know, pain or functional status or other things and, you know, it's also important to think about including the patient's perception of the success of the surgery. So not for this but I just want to put that out there, Michelle, to you and CMS to -- as something to be thinking about as you go forward in the patient-reported outcomes space.

And then the question I had was about non-response bias which came up a bit earlier. I would just be curious to understand a little more about -- I know in the detailed description it talked about, there is an effort in there to adjust for the non-response bias. But I just would like to learn a little bit more about how

that is, hopefully, minimizing bias that might be occurring.

DR. SCHREIBER: Tejal, thanks for your comments. I appreciate it. Lisa, I'll turn it back to you about bias.

DR. SUTER: Apologies, just unmuting. In terms of the question about the digitization of the measure and the burden, we really appreciate the feedback, and we'll -- you know, as I said, we're continuing to look at that. In terms of the response bias -- and I will provide a short introduction, and if additional details are needed, Katie -- Dr. Katie Balestracci, who is the -- you know, who led development of the measure, is on as well.

The team looked at all of the data that we have, and looked at the associations and what we have also are the administrative claims data behind, you know, in addition to the patient-reported outcome data that allow us to determine what we're calling response but is really much more of a, you know, a data capture, because we

don't actually know who the hospitals offered surveys to, so it's not a true response rate.

But it does allow us to capture the entire proportion of patients that met criteria for the measure denominator and using that, we were able to categorize patients into those that did not respond in any way or -- and those that responded but did not respond with complete data or those that responded with fully complete data.

And so the risk response bias adjusts for significant factors that include things like social risk, including the AHRQ SES index, and race and dual eligibility are incorporated because those are all statistically significant associated with response bias. I'm going to pause there. If you want more detail, Katie is probably better-equipped to provide the statistical explanations.

MEMBER GANDHI: That's plenty, thank you.

DR. SUTER: Great. And the one other thing I will note about your comment on response

on other surveys, we've also seen that comment about this measure. I think the biggest concern that has been mentioned is the influence on CAHPS, and there is probably the opportunity, since both CAHPS and HCAHPS and this data collection were included in CJR, we can look into the feasibility of examining response rates across those two -- across that measure, but note that the HCAHP response surveys are timed very differently than this measure.

This measure is a preoperative and close to a 12-month post-operative period to try and capture the full recovery period, whereas are HCAHPS sent out really immediately after hospitalization, and so we don't anticipate there being a huge influence or survey fatigue on those particular surveys. But again, there are other surveys that may be affected and we may not know how. Thank you.

CHAIR DEMEHIN: All right. A couple more questions in the queue. Let's go to Denise.

MEMBER MORSE: Hi. Thank you. I want

to echo what a lot of people said before about especially using a standardized tool and format for collecting the information to improve the validity and reliability across the different centers. That can make a big difference.

One thing I was wondering, and it was already mentioned a little bit, was about the burden assessment for patients in filling out these surveys as well as the timeframe is very long, up to a year following surgery. And I'm wondering how many are lost to follow-up or what the response rates were with that second survey?

CHAIR DEMEHIN: Lisa, are you able to answer that?

DR. SUTER: Yes, I am. I apologize. It takes me a minute to get off mute. So the response rates in CJR are in the range of 45 to 50 percent in general, and that is somewhat due to the fact that CJR incentivized a threshold of 50 percent in the first year of reporting. So it's a little bit hard to evaluate what the real response rates are.

We clearly know that increasing response rates rapidly over time is challenging for institutions. We've heard that feedback from CJR, but it is a -- we also have lots of experience with -- not me personally, but we have been in touch with clinicians and institutions that have had very successful collection of patient-reported outcome data.

The most successful institutions have created, you know, integrated workflows where the data is discussed with the patient at the point of care and used for clinical decision-making and, therefore, patients understand the value of the information.

I think there's a wide range of response rates, certainly in the CJR data, and I think nationally just any clinician's experience ranges widely. You know, certainly this is important information that I'm sure CMS will take into consideration in their implementation.

CHAIR DEMEHIN: All right. There's at least one more question in the queue and then a

couple in the chat functions. So let's turn to Marty's question first and then we'll handle the chat function ones. So Marty?

MEMBER HATLIE: Hi. This is a comment. I'm really happy to see this measure. I'd highlight that the American College of Surgeons gave it a very enthusiastic thumbs up in the public comment because of the patient engagement piece of it, the feedback that they will get from patients that has potential to improve care and engagement.

I do have a question basically based on Denise's comment, you know, a year follow-up, if there is patient death or incapacitation during that time, is there an opportunity for a family caregiver to respond to the survey? I don't think there is, but I don't know the answer to that.

DR. SUTER: That I'm actually going to pass to Dr. Balestracci. We certainly have been considering patients who die and reflecting that obviously, if they die that they may not be

eligible. The way we manage it in CJR maybe is likely to be different to how we might manage it, as you just described, allowing a caretaker or family member to complete the survey. We do have the capacity for including surrogate people filling out the data, but we've had very little of that in CJR. So I'll hand it over to Katie, see if she can add any insights into that.

DR. BALESTRACCI: Yes. Hi. This is Katie Balestracci. Can you hear me?

MEMBER HATLIE: Yes.

DR. BALESTRACCI: Terrific. As Lisa noted, there is -- CJR did, in its data collection model for these PRO data, allowed for a proxy response. I think our interpretation of the limited use of that probably didn't include doing so in the absence of the patient being alive, but certainly we can't necessarily confirm that.

What I can say is that in the development of this measure, because we need both preoperative and post-operative scores in order

to calculate a numerator event, that indeed patients who were deceased prior to the postoperative period did not get included in the measure. This is a very small percentage of people, as you might imagine, for this measure. Elective surgery is one that is generally taken on by people who are perhaps somewhat healthier, but it is something to look at in the future. Does that answer your question?

MEMBER HATLIE: Yes, it's very helpful. Thank you.

CHAIR DEMEHIN: Okay. We have a small handful of comments and questions in the chat function, so I'll try to read off a couple and my NQF colleagues, if I miss any of these, please do speak up. The first is from Jennifer Lundblad who says it's important to seek and measure patient-reported outcomes, so is supportive, but is wondering about the extent to which we're doing a good job of selecting patients who benefit from hip and knee surgeries. And she was wondering is there a companion measure for

clinicians in addition to hospitals. I suppose that's a question maybe for Michelle?

DR. SCHREIBER: I'm trying to think if there's a companion outpatient PRO for this. Off the top of my head, I don't think so, but I don't want to give you the wrong answer, too, so I might have to get back to you.

I will make one related comment though, and that's during the Rural Health MAP, they actually had a very good comment about extending this to the ambulatory facilities because more and more of these surgeries will probably be done in ambulatory facilities, either ASCs or hospital outpatient departments. And so that is something we're taking under advisement.

DR. ROACH: Michelle, was the question whether or not they had any outpatient PRO sort of --

(Simultaneous speaking.)

DR. SCHREIBER: Do you know, is there one for --

DR. ROACH: Well, I mean --

(Simultaneous speaking.)

DR. ROACH: -- the ICH CAHPS is for outpatient dialysis, so that would be one that we have.

DR. SCHREIBER: Thank you, Jesse. I was talking about the hip or knee one, if there was one that --

DR. ROACH: The hip or knee one? Oh, okay.

DR. SCHREIBER: Yes.

DR. ROACH: I don't think so.

DR. SCHREIBER: I don't think so.

CHAIR DEMEHIN: Okay, great. And then it looks like there are a couple of questions about mechanics from Lisa McGiffert including how many follow-up surveys will be sent to patients over the year following surgery, and since there are only 25 surveys required for the measure, will the hospital simply cut it off when they get up to that 25 number? And Lisa, if I've mischaracterized anything you asked, please do speak up.

MEMBER McGIFFERT: That's good. That captures it.

DR. SCHREIBER: And Akin, Michelle, I'm just reading also from the chat. Thank you to the commenter who reminded us of our own program, that there is an improvement activity in MIPS, not a measure but an improvement activity in MIPS related to capturing PROs for hip and knee patients. So thank you.

CHAIR DEMEHIN: Thank you. So --

DR. SUTER: And -- sorry -- and to try and respond to Lisa's questions, this is Lisa Suter. So in terms of the response postoperatively, so there is only a single postoperative survey that's required, a single, you know, assessment preoperatively and a single time point postoperatively. Those time periods were defined with clinicians and patients.

And in terms of the 25 minimum, because we are -- we think that providing information about response rates is important for this measure and the response rate, you know, the

response rate is accounted for in the measure. We think that most institutions will be motivated not for the bare minimum but to obtain responses from as many patients as possible.

I think, you know, for -- as with all PRO-PMs, we are going to keep a close eye on how differential responses from different groups that may be -- they have less access to care or may be more vulnerable in different ways, how that plays out, and that is part of the recommended measure monitoring that CMS routinely performs for their measures.

MEMBER McGIFFERT: So there's not really an opportunity to cherry-pick the response to the surveys?

DR. SUTER: You know, it's a measure where the hospital is submitting the data back to CMS. So I cannot say that there won't be any cherry-picking, but we do not believe that the design of the measure incentivizes you to collect less data from only the most responsive patients given that we hope to be transparent about

response rates so that those hospitals would be -- you know, would have some recognition that they were not trying to survey as broadly as other hospitals.

MEMBER McGIFFERT: Thank you. And I just want to say I'm really glad to see this measure. It's been a long time coming.

CHAIR DEMEHIN: All right. Just looking at the time, it is 4:21, and we do need to move towards a vote on the preliminary recommendation and a gaps discussion. So I do want to make sure we keep this moving along. But there is one more question in the chat function from Maryellen Guinan about health literacy. And Maryellen, I'm wondering if you can elaborate a little bit on your question. Are you talking about the health literacy level of the PRO as tested, or could you say a little bit more there?

MEMBER GUINAN: Thanks, Akin. Yes. I think I had just maybe not heard as clearly from Lisa Suter of -- you mentioned that testing was done or there were some adjustments made in terms

of health literacy and how you're capturing that. I know that's a critical component in terms of the administration of PROs that we've seen both language and cultural differences in terms of response rates.

DR. SUTER: So the literacy is captured -- used with the SILS2, which is a one-question standardized and validated assessment of health literacy. It fundamentally is asking for comfort with filling out surveys and health forms. And it was -- in the development of the hospital measure, it was -- literacy was significantly associated with your response to the surgery in terms of the PRO-PM outcome, the improvement rates. So that is captured in the actual risk model as well as -- I believe it's also captured in the response bias adjustment that uses inverted probability rates. But it's definitely included in the actual model, this model for the measure itself.

MEMBER GUINAN: Okay. Thank you.

CHAIR DEMEHIN: Okay. This was a very

robust conversation. It's a complex measure so really appreciate the opportunity to ask the clarifying questions here. I think what we'll do at this stage is to hold a vote on whether to support the NQF staff's preliminary analysis recommendation here. So let me turn it over to Matt to talk about how to do that.

DR. PICKERING: Okay. Thank you. Thank you, Akin, and thank you everyone for the lively discussion. Again, you're voting to accept the preliminary analysis recommendation on support for rulemaking for MUC0003, Hospital-Level Risk Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty. I'll turn it to Chris to open up the voting.

MR. DAWSON: Thank you, Matt. Voting is now open for MUC20-0003, Hospital-Level Risk Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty for the Hospital IQR program. Do you vote to support the staff recommendation as

the workgroup recommendation, which is support for rulemaking, yes or no? And I will ask again if we have Linda Van Allen on the line with us?

Okay. Voting is closed. The results are 18 yes and 4 no. The workgroup supports for rulemaking MUC20-0003, Hospital-Level Risk Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty for the Hospital IQR program.

CHAIR DEMEHIN: Okay. So I believe that clears our threshold. So let us now turn to a conversation about measure gaps in the IQR program. Any thoughts about measures that are missing from the program that would be important to capture or about any other aspect of the measures in the IQR. And Matt, if you want to scroll and show us a sampling of what's in the program, that may be helpful.

So while all of you think about gaps in the program, I do have sort of an overarching comment, and it's one that was raised in the conversation about the PRO measure. You know, I

do think the concept that some kinds of procedures are beginning to move out of the inpatient space is an important one for us to keep in mind as this measure set evolves and as care continues to evolve.

You know, I did note that there were some who actually called for possibly measuring hip and knee PROs in the ambulatory setting. That certainly deserves some, from my perspective, further exploration though obviously, the measure itself would matter a great deal to whether it would be appropriate to do that.

But I think my overarching recommendation to CMS would be to be mindful of that ongoing shift, because there are going to be some things that may not make as much sense to ask in the inpatient space five to ten years down the line than it does now. Other --

DR. SCHREIBER: Thanks, Akin. I think you're right. I think we will start seeing a shift of some of these things out of the

hospital, especially as the sort of hospital only designation is something that is lifted.

CHAIR DEMEHIN: Yes. Other feedback for CMS on the IQR measure set? Anything else on the PRO measure that you want CMS to consider?

All right, hearing none, I think we actually are just about on schedule notwithstanding any lengthy and robust conversation we've just had. So Matt, correct me if I'm wrong, but I think we are at the point of taking a 10-minute break. So we will reconvene at 4:40 if that sounds good.

DR. PICKERING: Good. Thank you, yes. We'll reconvene at 4:40 p.m. Eastern, and we'll close up the rest of the measures, so we'll come back then. So thank you all.

(Whereupon, the above-entitled matter went off the record at 4:28 p.m. and resumed at 4:40 p.m.)

CHAIR MORRISON: It is 4:40 in the East. So I think we will reconvene and we are into the -- the final stretches, as it were. And

we are now going to turn to the Hospital Inpatient Quality Reporting Program, which is purple. And let me just begin by asking for public comment.

(No audible response.)

CHAIR MORRISON: And seeing or hearing none, Matt, can I ask you for a brief description of what we're going to be talking about?

DR. PICKERING: Sure. I'll start -- I'll go on the program slide. Becky, if you can enhance -- just one more slide there. There we go. Yes, so just talking about the Hospital Outpatient Quality Reporting Program. So this is a paid for reporting -- public reporting program with the incentive structure. Hospitals do not report -- they don't report data or required measures. They receive a 2-percent reduction in the annual payment update. So the goals here are really to provide consumers with quality of care information to make more informed decisions about healthcare options and establish the system for collecting and providing quality data to

hospitals providing these types of services, or outpatient services such as ED visits -- emergency department visits -- outpatient surgery and radiology services.

And the measure that we'll be discussing today -- Becky if you could advance to the measure slide -- first measure. Yes. Is MUC-0004, which is the appropriate treatment for ST-segment elevation, myocardial infarction, STEMI, patients in emergency department. So this percentage -- this is a measure that is percentage of ED visits, or ED patients, with a diagnosis of -- of a STEMI who received appropriate treatment. The measure will be calculated using electronic health record data, or EHR data, and is intended for use at a facility level. So it's a facility level of analysis.

Sean, would you like me to proceed with the PA assessment?

CHAIR MORRISON: Yes, I think so. And then we'll come back to clarifying questions, if

that works for you.

DR. PICKERING: Sure, sounds good. So as far as the preliminary analysis, this measure assesses concepts that are similar to existing measures, such as fibronolytic therapy received within 30 minutes of emergency department arrival and median time to transfer for acute coronary intervention -- that are both within the Hospital Outpatient Quality Reporting Program. This measure is a process measure addressing timely treatment of ST-segment elevation myocardial infarction. And the developer cites a 2013 guidelines in which primary PCI -- or -- for coronary intervention is the preferred treatment approach with the initiation of PCI within 120 minutes from the first medical contact to -- or fibronolytic therapy administration occurring within 30 minutes of hospital arrival -- the situations where PCI is unlikely or impossible.

A 2015 study was cited also by the developer that found approximately 50 percent of patients who were eligible for fibronolytic

therapy received it. Of this population, only about 30 percent had administration occur in accordance with the clinical practice guideline recommendations. Therefore, showing that there is a quality challenge here and a gap that needs to be filled.

As far as efficient use of resources, or measure resources, the measure does cover a measure focus area of two existing other measures. So there is some -- some alignment there -- and combines both of these treatment options of fibronolytic therapy as well as coronary intervention, as well as a third option of transferring patients to a PCI-capable facility. It is feasible. The measure is fully specified and the developer notes that it has undergone alpha testing, face validity testing, and feasibility testing, as well as usability testing using an EHR-based assessment -- electronic health record -- using electronic health record data.

With all of this we did recommend a

preliminary analysis recommendation of conditions support for rulemaking. And that conditional support for rulemaking is for recommending that this measure be NQF endorsed. So Sean, I'll turn it back to you to see if there's any clarifying questions.

CHAIR MORRISON: Thank you for that. So, questions? Concerns from the group -- either to the developer or to CMS? Yes?

MEMBER LEGREID DOPP: Thank you. And thank you, Matt, for that overview. Some of the comments in the public comment portion of the analysis that you gave to us alluded to concerns about that this was tested in just two of the large EHR vendors and there is a request to consider testing it in additional ones. Is that something that would be worked out through the consensus development process with NQF? Or is that already too far down the stream to see it -- to see testing in other EHRs?

DR. PICKERING: So we do -- at NQF we do require a minimum of two. So it -- depending

on what the developer would like to do with future testing, which I believe they can talk to -- I believe the developer is on the line. They are -- they are planning on testing it in multiple different vendors as opposed to just two, but we do require a minimum of two.

DR. DRYE: Hello, it's Elizabeth Drye from Yale. We're the developers. Yes, I -- at this point there's not a plan to do more testing -- those systems we tested had multiple sites. They were large systems. And we did it during COVID, this past -- you know, we were ramping it up right as COVID hit. It's -- it's costly and time consuming. So we don't think that we'll learn a lot more from testing.

When you test site by site, which is what you need to do with these measures to really understand what it looks like to implement them, you know you learn those specific challenges of those sites and the current challenges include just interoperability -- within -- within system interoperability, since there's data from the

emergency department, the cath lab, and the main EHR system. Sites are in all different stages of that because of CMS rules on interoperability that require hospitals to move towards full -- basically file APIs that allow them to have file formatted data that they -- users who need it can access without special effort. That's going to get a lot better in the next few years across the board for hospital mobility -- just pull down the data we need for these measures, all of which is in standardized data fields. So I don't think we're going to get more information that would change how the measure is structured. You know, we did learn things from those two sites that -- that prompted us to modify the measure a bit. But I think it's straightforward to go forward from here without further testing, and it's just really costly.

CHAIR MORRISON: Thank you, Elizabeth. Others? Let's see. Denise wants to know whether all the exclusions were documented electronically through extractible fields and not chart audit?

I think, Elizabeth, that one is yours too again.

DR. DRYE: Yes, I mean I have -- Karthik are -- he's going to -- can you speak to that one?

MR. MURUGIAH: Yes -- yes, so all the -- the numerator actions, the denominator actions as well as the exclusions are all entirely based off of EHR. And, yes, so there's no piece of this which is chart extracted.

CHAIR MORRISON: Thank you. Marty?

MEMBER HATLIE: Hello. A comment in the PA caught my eye. The developer concerned is an -- as a possible unintended consequence is inappropriate expedition of care. I'm -- I need an example of that and I need to know, like, how likely -- or, how big a risk that is.

MR. MURUGIAH: Yes, so you know, obviously the door -- the balloon effort is sort of one of the leading efforts in -- in cardiology and STEMI care. And, you know, obviously, we've made great progress in door-to-balloon starting from over two hours when the program started in

2005 -- and this is a, you know, an AHA mission lifeline and ACC collaboration. And CMS was a big part of this as well. And then times are now reduced immensely and are now down to 59 minutes as of the last migration of NCR in 2014.

But obviously, you know, some concerns have been raised already about door-to-balloon times and which sort of leaks over to these other time-based metrics as well, so just transfer times, et cetera, as to whether that can cause any safety issues in inpatient care. And what they might be is essentially, you know, taking patients to the lab who may not need to be taken to the lab. And that is not something that can be measured because these patients may come out without the diagnosis of STEMI because it was sort of a false positive and there's no way to detect that. The other piece of it is also, you know, there may be an incentive for physicians to use more femoral access, which is more associated with bleeding and that is something that also has been raised as a concern before.

However, having said that, you know over the period of time that door-to-balloon times have been decreasing nationally, there's no signal of increased mortality and there's only a signal of benefit. So I think the evidence suggests that despite these valid concerns, I think, you know, physicians are, on an average, using good judgment and, you know, taking the right patients to the lab. So I think that was sort of the concern that was raised.

MEMBER HATLIE: Okay. I appreciate it.

DR. DRYE: I'm sorry. I didn't get Karthik to introduce himself, but he's an interventional cardiologist, so really active in the space and accountable for the timeline that we're setting.

CHAIR MORRISON: Thank you, thank you. Elizabeth McKnight, you had a question. If the STEMI metric is adopted as an HOPPS eCQM, would OP2 and OP3 be fast-tracked for retirement? Or would the measure sets run in parallel? I think that's a CMS question.

DR. SCHREIBER: Or -- now they may run in parallel but we do look at measures that are similar and retire those. So it would certainly come under conversation.

CHAIR MORRISON: Thank you, Michelle. And then Jennifer wanted to know that, on the abstraction question, the materials provided indicate only moderate agreement between chart abstractive data and EHR data. Are these data elements more nuanced and can be readily be pulled via EHR?

DR. DRYE: Yes, I am going to take that one again. It's Elizabeth. It's not so much that they're more nuanced. What we found at the sites where we did the testing is that the mapping of some of these elements within the sites EHR systems isn't really completely standardized yet. So again, we're pulling elements from the cath lab and emergency department and those -- the interoperability within -- within systems isn't really complete. Even use of the same data model, always.

So it wasn't that the data -- I think -- and Karthik, you can -- he was -- Karthik was actually deeper into the, you know, the conversations with these sites. But it wasn't so much that there was a problem with any of the data elements, it was just the mapping of those data elements so that the query that you used, which ultimately will be a lot easier once sites have mapped their data to meet CMS's and ONC's interoperability requirements, which is by January 2023, that -- they -- it was just a grabbing those data through electronic queries was difficult. Karthik, do you want to add anything to that?

MR. MURUGIAH: So, I mean, the assessment that was done, and like you know -- they rightly raise the concern about the disagreements. But this assessment has been done in the current state of the EHR. And all health systems are sort of moving towards, you know, various IT advancements, including, you know, my health system. And one of the health systems

that we tested in beta testing here as well. So we are hoping that, you know, with widespread adoption of common data models and file implementation, that this will vastly improve.

I think one of the key findings that we found -- and this was based on qualitative assessments as well -- was that measure logic, which was specified, was easily readable and easily implementable in everybody's EHR. But obviously they have to do, you know, some extra coding because, you know, all the data sources were not in the common data model. So they had to sort of create a different databases.

For instance, the times of when the balloon was inflated resides in a separate database. So those were some of the challenges which currently exist, which we hope, you know, will -- will reduce as time progresses. And plus, you know, if such a measure were to be implemented, that would also, you know, make all the EHR providers to include these elements -- easily accessible way.

CHAIR MORRISON: Thank you, folks. I've got Mike and then Akin. Mike?

MEMBER WOODRUFF: Yes, this is more of a follow-on question from Jennifer's, but how much new documentation -- or -- or different documentation on the provider level had to be developed? In other words, not just interface, but documenting differently in order to meet the specifications of a measure?

MR. MURUGIAH: None, absolutely, actually. And it was all on the back end of abstracting this data. It all currently resides even in the EHR in the current state -- it's just not easily accessible and the data pieces don't talk to each other. So that's the barrier that needs to be overcome, and that's an IT issue. And I think -- you know, and those can be implemented at system level. And there should be no change to the workflow of providers at all.

MEMBER WOODRUFF: Great, thank you.

CHAIR MORRISON: Akin?

CHAIR DEMEHIN: Thank you, Sean. So

this builds a bit on the question that Elizabeth raised. And that's the overlap between this or -- the apparent overlap between this measure and OP2 and OP3. I guess this may be a question more for CMS. Is the thought in doing this that those would indeed go away? Or in some way be de-duplicated? And was the intention of having this measure put into the program to sort of introduce an eCQM into the OQR? If I am not mistaken, this would actually be the very first eCQM that was actually included in the OQR. So could you talk a little bit about that?

DR. SCHREIBER: I'm chuckling to myself that -- by the way, I will apologize to all of you. You may hear my dog barking at the deer in my yard.

So Akin, yes, you can see that we are starting to introduce electronic measures into all of our programs. And I think you can also expect to continue to see that over time. So you are right about that. And the intent over time is also to de-duplicate measures. So although I

can't tell you what's going into rulemaking in the future, I think you can anticipate that this would be the direction that we would take.

CHAIR MORRISON: Thank you. Last comments or clarifying questions for either the developers or for CMS?

DR. DRYE: I would just add that, because this is a measure with a more complex than usual numerator -- this expands on OP2 and OP3. The -- you know, as -- I think it was Matt mentioning the standard cares PCI. And those two measures don't include PCI -- PCI-based facilities. So this greatly expands the group of patients that -- that we would be measuring for appropriate treatment for STEMI once implemented. Adding analytics transfer to a PCI facility from a non-PCI facility. PCI delivered at a PCI facility. All of those done in a timely way across the full spectrum of STEMI patients, and just putting it in one EHR-based measure, versus in two narrower, chart-extracted measures.

CHAIR MORRISON: Thank you, Elizabeth,

very much. So Matt, my -- I if I get this right, we are now going to vote whether we accept the PA on this measure. And can you just remind us all what we're voting on?

DR. PICKERING: Sure. Yes, so you're -- you're voting on this measure for conditional support and the conditional support for rulemaking, with the condition of pending EQF endorsements. So recommending that this be NQF endorsed. And I will turn it to Chris to open up the voting platform.

MR. DAWSON: Thank you, Matt. Just a second here.

DR. PICKERING: Go ahead, yes. And so again, similar that we've -- in voting -- voting to accept this, we will move it forward with that preliminary recommendation. And if we don't have 60 percent or more, then we will have the working group have their own separate board -- vote -- on a decision category.

MR. DAWSON: Thank you, Matt. So voting is now open for MUC20-0004, Appropriate

Treatment for ST-segment Elevation Myocardial Infarction Patients in the Emergency Department for the Hospital OQR Program. The votes support the staff recommendation out of the workgroup recommendation of conditional support for rulemaking -- yes, or no. And I will ask if Linda Van Allen (phonetic) to please let us know so that we may cast her vote.

Okay. Voting is closed. The results are 19 yes, and 3 no. The workgroup conditionally supports for rulemaking, MUC20-0004, Appropriate Treatment for ST-Segment Elevation Myocardial Infarction Patients in the Emergency Department for the Hospital OQR Program.

CHAIR MORRISON: Terrific. Thank you, everybody. Which brings us to our, I believe, last measure of the day, which is -- Matt, what is our last measure of the day?

DR. PICKERING: Thank you, Sean. Yes, the last measure of the day is MUC-0005, which is breast screening recall rates. So this measure

calculate the percentage of beneficiaries with mammography, or digital breast tomosynthesis, or DBT, screening studies that are followed by diagnostic mammography, DBT, ultrasound, or magnetic resonance imaging -- or MRI -- of the breast in an outpatient or office setting within 45 days. This is at the facility level.

And going through the preliminary analysis, there are no other hospital outpatient quality reporting program -- no other measures like this in the hospital outpatient quality reporting program that really address this, specifically, breast screening recall. The American College of Radiology recommends a recall rate of between 5 percent and 12 percent to appropriately follow up on abnormal screenings without the risk of overdosing or causing undue anxiety in the patients. However, NQF in looking at the evidence that has been provided -- the evidence for the measure -- the measure is really not based on any specific clinical guideline, but is really supported by expert clinical consensus

and support in the literature.

So we felt this was fairly low when thinking about evidence, and so we rated this as no for this category as far as that -- is there substantial evidence to support the measure? Going to the quality challenge, the developer does state that the mean measure performance is about 10 percent with a standard deviation of 6.2 percent, with a performance range of 5 to 12. And so there is some variation seen within the market, so arguing that there is a quality challenge.

The Hospital Outpatient Quality Reporting Program, again, does not currently include any measure of breast screening recall rates, or measures related to breast cancer screenings, and the data elements for this measure are available in claims and claims data for Medicare Fee for Service beneficiaries. So electronic data that can be easily reported.

And the measure is fully specified and has completed beta testing, reliability testing,

and face validity testing at the facility level. And so developer has provided some data showing reliability scores there that are listed within -- within the PA, but we feel that it's appropriately specified for the intended use of this program.

With that, we provided a preliminary analysis recommendation of conditional support for rulemaking. And again, the condition here being recommended -- recommended pending NQF endorsement of the measure. Sean, back to you.

CHAIR MORRISON: Thank you, Matt. So I will now open it up for questions or clarifying questions, concerns from the group. To either CMS or the developers. And Denise, you move quickly with your hand. Go ahead.

MEMBER MORSE: I did, I am ready. I have a couple of questions. One is kind of an NQF one. Is there a percentage of -- so there was a note that it was about three percent that were outside of the target range that is statistically significant. Is that considered

high enough to warrant a large enough performance gap? Is there any guidance from NQF regarding kind of that?

DR. PICKERING: So you're talking about the measure performance, which is ten percent?

MEMBER MORSE: The performance gap, yes.

DR. PICKERING: Right, with a performance range of 5 to 12? Right, so that -- really just coming back to looking at the American College of Radiology which recommends a recall rate of 5 to 12. I mean, this -- this also can be something that the workgroup should discuss -- whether or not that range is sufficient to consider evaluating a performance gap. But for the purposes of that range, there is a -- a 10-percent, as far as the average performance of 10 percent, with a standard deviation of 6.3. So it -- it may be considered to have some variation there. And could be worthwhile to -- to have a measure to fill that -

- fill that gap.

(Simultaneous speaking.)

MEMBER MORSE: And then --

DR. PICKERING: But I -- I'm sorry, Denise, didn't mean to cut you off. I -- I could also welcome the developer to comment on their measure and their measure calculation if they'd like to. But maybe, Denise, if you wanted to go to your second question.

MEMBER MORSE: Yes, so there was some comments related to that there were outliers both on the below rate -- so below that 5 percent -- as well as the above. And the differences tended to be rural or non-teaching hospitals in that lower, and then the higher being more of the teaching hospitals. And I wondered if there was any analysis done on why that was, and if it had to do with the availability of technology, for example. Some of the literature showing that the DBT has lower recall rates -- and is that maybe not as available in some of the other centers -- rural centers? Or not trained? And is it a

technology issue, or does it have to do on the other side with the types of patients being seen at some of those academic centers, such as those that had previously had surgery or biopsies that may make more complicated reads.

DR. PICKERING: So Denise, I -- I would ask the developer on this and maybe comment on the performance gap question as well. Do we have the developer?

MS. McKIERNAN: Yes, hello this is Colleen McKiernan from the Lewin Group. I'll go ahead and jump in here. So to turn to your first question, Denise, first. So I will note that more than 40 percent of the facilities that were in our analysis had their scores fall outside the targeted recall range. That 3 percent actually refers to those that are specifically different from the mean. So just to clarify, there were a bunch of facilities that were outside the 5 to 12 range, although not a lot as they went further out. So they tend to cluster around, like, close to 5 and close to 12, but not -- which made them

statistically similar to the mean, but they were outside of the recommended range.

And then the other question about the population of facilities that we see to the lower versus higher bounds -- so we have not performed a sensitivity assessment to try to determine why the facilities that are lower are rural, non-teaching, and higher are teaching and urban. But I think a lot of the points you made about -- at a teaching facility there's just more, kind of, I don't want to say rigor. But there's just more, kind of, procedures that are often performed in a teaching environment. And then also access to services, I do think, is a definite factor related to the lower recall rate.

So I will note, however, that we do include regular mammography and DBTs, so I know there are some slight -- there are some slight differences in the appropriate range for those two procedures. But if a rural facility doesn't have access to DBT they can use a regular mammography -- and that mammography -- and that

is fine. So I think that your feedback will be valuable as we prepare for NQF review and future next steps to determine if we're able to provide more input into the lower and higher populations.

CHAIR MORRISON: Thank you. Jennifer, you had your hand up, but I can't tell if you're there or not.

MEMBER LUNDBLAD: Yes, I'm here thank you. Yes, I don't know what happened to my video. Sorry about that.

CHAIR MORRISON: No, it's --

MEMBER LUNDBLAD: So my question stems a little bit off of where -- where Denise is headed. You know, if I think about the -- ultimately, when you have a measure, you want to be able to improve on it, right? If there's a gap between current performance and best performance. And so this is assessing outlier, but outliers on either end. And so I am trying to understand, from a patient perspective, having a breast screening recall is a -- is a concerning, thing, right? That causes stress and

anxiety among patients. And so I am not sure a rate is helpful from a patient perspective.

And then, from providers and hospitals, if there's a outlier and they're too high or too low, is there an improvement strategy to be had? So again, Denise was asking a little bit about -- is it about mammography technique? Or is it their imaging isn't good? Or do they not have access to the right kinds of services and supports? So I am just trying to figure out -- if you could just talk a little bit about, what do you do with a rate where you are -- and you're an outlier, but it could be an outlier in either end. And so are there the right incentives? Or are there sort of perverse incentives to try to get back in range?

CHAIR MORRISON: And I would just -- if I could bundle that with a question from Elizabeth McKnight in the chat which was around how -- how consumers interpret the metric and whether consumers can interpret this metric?

MS. McKIERNAN: Absolutely. So that's

actually a great question. We also received it when we went to the Rural Health Group last week. And so I think from the consumer perspective, the range can be a little bit difficult to understand. Like, what does it mean if a facility is 9 percent, versus 7 percent? And so from the consumer perspective, I think it's more important to think about whether the facility is in the range or outside of the range. And if they're below the range, they may be missing cases of cancer. If they're above it, they may be calling back too many people -- both of which can have difficulties associated with them, whether it's having the cancer progress to a later stage, or unnecessary stress and cost associated with a recall that wasn't necessary.

So, but having -- by looking at it, are you in the 5 to 12 percent? Or are you outside of it? I think that that's a good way to message it to consumers so that they can understand, you know, is my facility performing about right? Or are there things that they could

work on to get their scores in the range?

And then from the facility perspective, you know we don't -- as -- I'll just speak from the developer's perspective -- we don't provide specific quality improvement recommendations. We instead encourage facilities to work internally with their quality improvement officers and then we often refer them to the Q2IOs to do some more intensive remediation, if needed, because we know that there are a number of options that are available to try to consider as potential ways to get them into the range. So that's really outside the scope of what we have accomplished, but we have successfully referred facilities in the past to Q2IOs and gotten them back into a more kind of normal range for their scores.

CHAIR MORRISON: Thank you. And I am going to briefly tackle Lisa's before I go to Kelly, which was also in the chat box, asking about -- does an NQF endorsement require evidence? And wouldn't this fail if it went to

the NQF Committee for endorsement? Yes, NQF endorsement requires evidence. There's certain different levels of evidence for that and I think -- not speaking for NQF, but Matt perhaps you would agree -- the reason this was conditional was so that it would go through NQF endorsement and the evidence would be evaluated by the appropriate scientific group?

DR. PICKERING: Yes, that's correct Sean. Exactly it. Just looking at the evidence, again -- noting that there is some consensus -- consensus reports here to support the measure. Really the best suited group to evaluate evidence based on their own expertise -- both clinical and also methodological -- would be our standing committees in going -- having it go through NQF endorsement to evaluate it.

CHAIR MORRISON: So I've got Kelly, Denise, Christy and Akin. So Kelly, you're up first.

MEMBER GIBSON: Thank you. I also had the same concern just about the evidence. So

when it's consensus -- and I wondered if there was any look, just at the baseline risks of the different populations and if there was thought of what the recall rate is? What percentage of those are then diagnosed with cancer? Because I would imagine some places may have a higher recall rate, but if they're also diagnosing more cancer, that may be an appropriate higher recall rate? So is there any consideration for a balancing measure to make sure that we're not missing other cancers -- or maybe looking at, you know, of those recalled, did they not end up having procedures? Was there any look for that kind of balance for this measure?

MS. McKIERNAN: That's a great question. I've heard it a lot before. So first of all, to target -- to address the underlying population. So that is something that we're -- we've been exploring over the past several months, specifically trying to determine -- because it is claims-based, you know, we are limited to the number of data elements we can

identify through claims. But we are hoping to locate, for future updates to the measure, a way to adjust for patients for whom there is potential increased risks. So individuals with a BRCA mutation, as an example, would be a great population that we'd love to control for -- especially when you look at the prevalence of those populations within each facility. It's just from when they designed the data that are available in claims. So probably more to come in the future on how we can control for that if we're able to adjust.

And then at that -- for a balancing measure. So right now the focus for this measure, and then the larger measure set within which this measure operates within OQR, is on imaging sufficiency. CMS has in the past explored the development of a breast cancer detection rate measure, which was -- many years ago it was extremely difficult because of challenges with attribution and driven by the low -- the low relative incidents of breast cancer.

We still think that the measure is valuable to the clinical community based on the multi-stakeholder group with which we liaised during our beta testing effort to gather input on the validity, feasibility, usability of the measure.

CHAIR MORRISON: Thank you. Denise?

MEMBER MORSE: Yes, so I think piggy-backing a little bit on what Kelly was saying is, well, I think it was about 31 percent of survey respondents didn't think that this was -- didn't agree that this was a strong measure -- or improved quality -- based on the survey results. And I was wondering if that had to do, again, with the fact that it was a stand-alone versus part of more of a global program as mentioned by the public commenters, saying that this is only one piece of a larger need for, you know, more holistic look at screening?

MS. McKIERNAN: The answer is yes. And so, you know, in the ideal world, we would have a suite of measures that would look at the recall rate, and then either some sort of test

that might be an intermediary between breast cancer detection and recall rate -- or even getting to a DCR measure. But today, we're not there. So we're bringing this follow-up measure as a -- or, excuse me, the recall measure as a first step to improve the care for women in the Medicare population, as well as for oncology care. And we're hopeful that in the future CMS will be able to bring additional metrics that will help.

CHAIR MORRISON: And just let me follow up that so I get Karen's question as well. I think this is to CMS -- I think, Michelle, this is probably yours, is CMS exploring a composite measure around breast cancer screening?

DR. SCHREIBER: We don't have one at the moment. That would be correct. But I think this would be the first step in leading towards one.

CHAIR MORRISON: I had Christie Travis with her hand up, and then I -- it looks like she disappeared. So I just want to check, Christie,

before I --

(Simultaneous speaking.)

MEMBER TRAVIS: Yes, Kelly asked my question, so --

CHAIR MORRISON: Okay, all right. Thank you. Akin, you're next.

CHAIR DEMEHIN: So my colleagues have already asked some very similar questions to the one that I -- the ones I had in mind with this. I guess what I would -- what I would reflect on with this is, number one, I personally -- just taking my Chair hat off for a minute -- the notion of a measure that has a range of ideal performance does strike me as a bit tricky from an interpretation and usability perspective. And I do take the comments around whether focusing on this specific measure as opposed to a more holistic set is really giving us the kind of picture that we need around how well these facilities are detecting breast cancer, which is an incredibly important topic to try to reflect.

So as I kind of look at the measure in

front of us, I think what I'm struggling with is there -- are there questions that we have raised that can be answered in the course of NQF endorsement? Or is there something more significant underpinning this that we need to -- to get a closer look at down the line? I -- that's what I a struggling with. I am not sure I have a great recommendation along those -- along the lines of what to do about it.

(Simultaneous speaking.)

DR. SCHREIBER: Let me take a stab at that. I think, you know, I see where you're going with it. I think we -- you know, the -- there aren't all that many good measures around radiology, and certainly around mammography in particular, which is obviously impact to many patients. And so this is trying to get at, is your mammography -- is your facility doing mammography -- really doing it appropriately? The range doesn't bother me so much. I mean, we have plenty of things that have ranges for them as opposed to exact numbers. But I think this

really is, sort of, do you have a -- a good practice of doing mammography in your organization? You know, so are your recall rates within what we would consider a reasonable range? Are they way too high? Are they way too low?

I think that long-term, Akin, you're right that there are probably other measures to be added to this to create a composite measure, but that this is a first step in looking at efficacy of mammography I guess is the way that I am going to put it.

(Simultaneous speaking.)

CHAIR MORRISON: Thank you --

DR. SCHREIBER: Colleen, did you want to add to that?

MS. McKIERNAN: So I was just going to give some history on a previous measure from those in OQR. So CMS previously had OP-9, which was mammography follow-up rates in the program. And it -- it looks at -- it was very similar. But the reason CMS removed it is because the evidence base did not align with current clinical

practice.

And so CMS has brought the measure back because we added digital breast tomosynthesis as a screening and diagnostic procedure to the measure, in the denominator and numerator respectively. And then also, for the range specifically -- so the previous measure had a ceiling of 14 percent. But then did not have a lower bound. And so we just indicated that values close to zero may suggest that there might be missed cases of cancer.

So we think the measure that we're presenting today is actually an improvement upon the measure that was in the program before, because it does add TEP, so aligning with current clinical practice. And then also provides a more -- provides some clarity around that range. I understand your perspective on how reach it. But by providing actual bounds that are -- that are from a publication, we feel that it is just a more precise metric than what was used before.

And then finally I will note that we

did increase the number of facilities that are in the range. So previously we saw 20 percent of facilities fall outside of the window that we suggested. So near zero -- scores of zero or above 14 percent. And now it's 40 percent that are below 5 percent and above 12 percent. So actually with the addition of DBT the performance gap does increase.

CHAIR MORRISON: Thank you, Colleen. Last questions, comments? Going once, twice? Okay, then let me turn things back over to Matt and we are going to vote to either -- to accept or reject the NQF staff's recommendation, which is, Matt?

DR. PICKERING: Right, thank you Sean. The recommendation again is conditional support for rulemaking. That condition is pending NQF endorsement of the measure. I will turn it over to Chris to open up the vote.

MR. DAWSON: Thank you, Matt. Voting is now open for MUC20-0005, Breast Screening Recall Rates for the Hospital OQR Program. Do

you vote to support the staff recommendation as the worker recommendation, which is conditional support for rulemaking? Yes, or no? And if Linda Van Allen is on the line, please let us know and we will cast your vote. Okay, voting is closed. The results are 15 yes and 6 no. Can my team just confirm what the percentage is on that?

DR. PICKERING: Yes, with -- with 21 voting and 15 yes, it's 71 percent.

MR. DAWSON: Excellent. So the workgroup conditionally supports for rulemaking MUC20-0005, that's Screening Recall Rates for the Hospital OQR Program.

CHAIR MORRISON: So that -- thank you, everybody. That brings me to the gap discussion where I think -- let me just say that I heard at least one gap, which was the -- the thought of a composite measure for breast cancer screening and cancer care. So I will put that one on the table. And just open it up for others that people want to discuss.

CHAIR DEMEHIN: Sean, a kind of

broader comment about the OQR -- and this is a -- a problem that I think has always vexed this particular program. There is such variation in the sets of services that hospital outpatient departments offer, that coming up with that fully representative measure set that encompasses everything that you want it to encompass is a -- a tall task indeed. Not easy at all for our -- our colleagues at CMS.

I would -- I think I would just echo some of the issues we raised earlier around the IQR and being sensitive to the -- the changes that are taking place in healthcare and migration of certain kinds of services to the ambulatory setting. I do think there probably could be more measurement around patient safety issues -- one of our favorite words of the day -- reflected in the OQR measure set. It will also be very interesting to see the extent to which we can implement patient-reported outcomes for some of the procedures that are done on an ambulatory basis.

Again, hard to select what procedures you want to do it on. And what areas you want to do it on. But I think worth some further exploration.

CHAIR MORRISON: Thank you, Akin. I've got Jennifer and then Christie.

MEMBER LUNDBLAD: Yes, so in that spirit of what -- what can you do with the outpatient measures that represent such wide variation in what services and -- and the scope of things that are offered, it makes me wonder if there is a benefit to thinking about a measure around the effective use of shared decision making since so many of the things that occur in outpatient care are preference-sensitive. And they are trying to take that combination of what's -- the clinical options in which case there are multiple clinical options and patient preference and value in bringing those together. So it would be interesting to figure out how that -- how a shared decision making measure in OQR might fit in really well.

CHAIR MORRISON: Thank you, Jennifer. And Christie?

MEMBER TRAVIS: Yes, you know, this is a frustration that I have voiced before, but especially for the outpatient quality reporting program -- to Akin's point -- I think we need, instead of just looking at whether it's a process measure or an outcome measure, I think we need to think about what types of things are done in a hospital outpatient program -- like diagnostics, like surgical procedures. You know, like emergency room.

You know, like what are the major groupings of the types of -- and that would help us identify the gaps. You know, it's not a gap that we need an outcome measure just to have an outcome measure. What do we need that outcome measure in? And it's really hard, when I look at anything like this, I have to go and translate this into really thinking about what is it that happens in an outpatient program? And I just would suggest that we think about reorganizing

how we look at the measures in a -- in a program to identify gaps because this is just, I think -- you know, it doesn't help us really see where the gaps are.

CHAIR MORRISON: Thank you, Christie. Really helpful. At least to me. Any last comments on gaps, folks? Okay. So my annotated agenda says at 5:40 Sean will announce the closing of the MUC voting portion or the meeting and turn it over to Akin. I've got 5:27, so if -- if people object, I can hold us out for another 13 minutes. But if there are no objections, I will turn it over to Akin 13 minutes early.

(Laughter.)

CHAIR DEMEHIN: I think we have unanimous consent, Sean.

(Laughter.)

CHAIR DEMEHIN: All right, I think we are opening it up one last time for the opportunity -- for public comment on just about any aspect of the conversation that we had today. The measures, the gap areas that we talked about

-- any comments from the public?

(No audible response.)

CHAIR DEMEHIN: All right, hearing none, it is looking encouraging for us wrapping it up just a little bit early. So this has been a long and productive day. I have really appreciated the conversations around the individual measures and all of your thoughtful feedback. Let me turn it over to my colleagues at NQF to talk about immediate next steps for our recommendations and delivering the recommendations to CMS. Matt, do you want to do that? Or --

(Simultaneous speaking.)

DR. PICKERING: Sure. Thank you, Akin. I appreciate that, thank you. I just want to just double-check once more, because we are a little ahead of schedule -- but I just want to double check once more for any -- any members of the public to comment. I know sometimes it may be a little bit difficult to kind of pop off mute and get things ready -- situated together. So if

there's any members of the public that would like to provide any comments, please do so now and just give a little bit of a -- of an additional pause there. I know some folks provide comments in the chat box -- copy paste some things. I don't see any.

CHAIR DEMEHIN: Okay.

DR. PICKERING: Okay. So hearing none -- thank you, Akin, for -- for -- for that. Yes, so with that I will turn it over to my colleague, Chris Dawson. He will go through summary of the day and next steps. Chris?

MR. DAWSON: Thank you, Matt. So as you all can see on this diagram, following the MAP Workgroup meetings this week, the next step later this month on January 25 will be the MAP Coordinating Meeting to review the results from the various MAP Workgroups and finalize MAP recommendations. Following the MAP Coordinating Committee meeting, NQF will provide a final report that includes the MAP recommendations on all measures under consideration. And then

lastly, the pre- -- pre-rulemaking report will be published in March.

Additionally after this week's MAP Workgroup meetings, a public commenting period will be held beginning this Friday, January 15, through Wednesday, January 20. After this public commenting period the MAP Coordinating COMMITTEE will be held on January 25 to review the recommendations made by the MAP Workgroups and the public comments received before making the final recommendations.

And these final MAP recommendations will be made in a report to CMS on February 1. As a reminder, you may contact our team via email at MAPhospital@qualityforum.org and find all MAP-related materials on the project webpage and Workgroup Sharepoint site. If there is not any -- if there is no further questions, I will turn it back over Sean and Akin.

CHAIR DEMEHIN: Okay. Let me again thank all of you for taking a full day out of your schedule to have this important conversation

and give CMS incredibly thoughtful feedback on the measure set that they've presented. I've really appreciated the conversation and I strongly suspect my colleagues from CMS do as well. Let me also thank my partner in crime, Sean, for his incredible facilitation skills. And last but not least, I want to thank the NQF staff for turning all of this around so quickly and so coherently for all of us. It makes this process so much easier.

And of course thank you to the developers and to CMS for listening and participating as thoughtfully as you did throughout the course of the -- the meeting. Just let me kick it over to Sean.

CHAIR MORRISON: Yes, thank you, Akin. I just echo everything that Akin said and also wanted to thank Akin. This has been -- just an absolute joy to work with him through this process. And particularly the challenges of doing this through Zoom.

I did want to particularly thank our

colleagues from CMS, from CDC and the folks not on from FDA. This has been an unbelievably challenging year for so many people in the Federal Government who have been focused on the healthcare of our nation. And I can't imagine what it's been like to go to work every day with everything that you guys have been facing. But I wanted to thank you on behalf of the Committee the -- for the work that you have done for our patients and families this year. And quite honestly for sticking with it, given everything that you've been experiencing. So -- and for being here today and being so good spirited and good natured. So thank you very much.

DR. SCHREIBER: Actually, Sean and Akin, if I could just, on behalf of CMS, say thank you to all of you as well. This has certainly been quite the challenging year. Quite honestly I hope we never see another one like it. But everybody -- everybody has risen to the occasion. I think certainly front-line healthcare providers, healthcare organizations,

certainly we at CMS, the FDA and many other places have just tried very hard. I will tell you it's been 24 hours a day frequently.

CMS at least has tried to provide waivers and -- and thoughtful consideration as to how to make it easier for healthcare organizations to work. From things like Hospitals Without Walls to the expansion of telehealth to other appropriate waivers -- licensing across state lines. And I think these things will persist and that's going to change the face of healthcare really forever for the future.

To everybody today, thank you so much for taking the time and for your incredibly, incredibly thoughtful comments. I always learn from these groups and really appreciate it. Appreciate all of the folks who have been on the line and certainly to NQF -- what a great -- a great day this has been, the Rural Health, and I am sure tomorrow as well. I think NQF has really done a spectacular job in a very short time frame

of turning around a lot of information. So thank you to you.

DR. PICKERING: Thank you all very much for all of your time. I echo everything that has been shared. Thank you to our CMS and CDC colleagues as well as everyone on the Workgroup. A special thank you to Akin and Sean for great facilitation. We will be following up with the next steps, as Chris has mentioned, but we will go ahead and adjourn early. Everyone, I hope you have a great rest of your evening and a great rest of your week. And thank you all very much for your participation today.

(Whereupon, the above-entitled matter went off the record at 5:35 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Measure Applications Partnership Hospital Workgroup

Before: National Quality Forum

Date: 01-11-21

Place: Video Teleconference

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R. Gross

Court Reporter