

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:

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Association, Chair

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Hospice and Palliative Care

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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**

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

2 1:00 p.m.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 those votes from program to program.

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

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

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

17 Secondly, you'll see that as well with
18 the global malnutrition measure. That's MUC-
19 0032. That's used across two different programs.
20 Again, if there is no need for the committee to
21 feel like they want to revote unanimously, we can
22 carry over that decision to the different

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

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

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

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

14 MEMBER HATLIE: Okay.

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

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

22 DR. PICKERING: Yep, sure, and we can

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

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

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

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

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

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

22 If we have 60 percent or more that

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

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

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

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

1 MEMBER MCGIFFERT: I think that's the
2 one I have, but --

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

9 MEMBER MCGIFFERT: Yeah.

10 DR. PICKERING: Yeah.

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

13 DR. PICKERING: So, maybe --

14 MEMBER MCGIFFERT: Friday, what date
15 was Friday?

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

18 MEMBER MCGIFFERT: The 11th or the
19 9th? No, would it be the 8th?

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

1 MEMBER MCGIFFERT: That would be
2 great. Thank you so much.

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

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

11 DR. PICKERING: Yes, yes, I can.

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

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

1 MEMBER LUNDBLAD: Great, thank you.

2 DR. PICKERING: Thank you.

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

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

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

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

1 DR. PICKERING: Yes, it should work.

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

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

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

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

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

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

3 DR. PICKERING: Okay.

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

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

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

13 (Laughter.)

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

16 MEMBER NOLAN: Okay, okay.

17 DR. PICKERING: Right.

18 MEMBER NOLAN: Awesome.

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

22 MEMBER GHINASSI: I'm seeing the same

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

2 DR. PICKERING: Okay, okay.

3 MEMBER GHINASSI: Thank you.

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

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

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

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

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

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

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

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

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

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

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

6 MS. PERERA: Nothing that I see.

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

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

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

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

22 MEMBER MCGIFFERT: Okay.

1 CHAIR MORRISON: We're looking for
2 different --

3 MEMBER MCGIFFERT: Got it, thank you.

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

6 MEMBER MCGIFFERT: Okay.

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

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

12 CHAIR MORRISON: Could I ask you to do
13 that?

14 DR. PICKERING: Sure, sure, so --

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

1 separately.

2 DR. PICKERING: So, Lisa --

3 CHAIR MORRISON: Yeah --

4 DR. PICKERING: Sorry, Sean.

5 CHAIR MORRISON: Go ahead.

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

8 MEMBER MCGIFFERT: Yes, yes.

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

11 MEMBER MCGIFFERT: Great, thank you so
12 much.

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

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

22 This vaccination is a national

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

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

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

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

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

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

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

22 Moving down, related to efficient use

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

7 And the developer really indicates
8 that this measure will be submitted using COVID-
9 19 modules on the NHSN website. However, this
10 vaccine will be collected across seven different
11 job categories as we saw presented earlier, but
12 also listed within the actual measure submission.

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

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

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

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

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

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

1 continue.

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

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

22 So, this is the facility level

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

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

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

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

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

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

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

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

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

1 CMS, and NQF for facilitating the discussion.

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

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

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

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

1 considerations.

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

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

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

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

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

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

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

1 summary of my response. Thank you so much.

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

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

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

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

22 So, Jennifer, I have you next. And I

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

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

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

15 My question is about timing, and maybe
16 I was just a little confused on what I heard. I
17 think that in our joint session earlier, I
18 understood that this would go for fiscal year
19 2022, and so I'm trying to understand, as I think
20 out 18 months or so, and think about what comes
21 up in proposed rulemaking then.

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

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

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

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

15 MEMBER LUNDBLAD: Thanks.

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

18 MEMBER LUNDBLAD: Thank you.

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

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

1 In order for anything to go into a 2022 program,
2 it has to be introduced into rule writing in
3 2021.

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

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

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

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

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

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

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

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

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

22 CHAIR MORRISON: Thanks, Michelle, and

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

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

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

15 DR. SCHREIBER: They have.

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

22 I know we're talking about OQR, but

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 CHAIR MORRISON: Cristie?

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

1 measure is being proposed for.

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

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

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

1 something I'd be curious about.

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

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

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

16 CHAIR MORRISON: Sarah?

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

1 comments.

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

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

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

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

1 processes employers put in place to make the
2 vaccination happen.

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

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

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

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

22 MEMBER HATLIE: I did, Sean. Thank

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

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

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

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

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

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

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

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

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

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

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

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

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

8 DR. SCHREIBER: Yes, correct.

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

11 DR. SCHREIBER: Correct.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 the final say.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 and as easy to do.

2 CHAIR MORRISON: Thank you, Michelle.

3 And Frank, there's a great issue brief to your
4 question from the Kaiser Health Foundation around
5 influenza vaccine. Frank asked is there an
6 update around regional and state variability?

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

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

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

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

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

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

19 DR. SCHREIBER: Cristie, I suspect
20 this measure's going to come back in the
21 following year no matter what, I mean, unless we
22 --

1 MEMBER TRAVIS: Okay.

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

6 MEMBER TRAVIS: Okay, okay.

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

9 MEMBER TRAVIS: Thank you.

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

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

19 DR. PICKERING: That's correct.

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

1 the potential for mitigation.

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

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

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

16 DR. PICKERING: Yes.

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

19 (Audio interference.)

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

1 potential for mitigation, yes or no.

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

6 PARTICIPANT: Yeah, mine as well.

7 (Simultaneous speaking.)

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

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

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

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

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

4 DR. SCHREIBER: So vote again.

5 MR. DAWSON: Responses are coming in.

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

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

20 PARTICIPANT: I'm still having
21 difficulty.

22 DR. SCHREIBER: Yeah, it still keeps

1 flashing away once the --

2 PARTICIPANT: Yes.

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

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

7 DR. SCHREIBER: It is showing to me
8 now.

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

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

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

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

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

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

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

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

22 DR. PICKERING: And as you're waiting

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

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

12 DR. PICKERING: So no objections?

13 CHAIR MORRISON: Didn't see any, yeah.

14 DR. PICKERING: Okay.

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

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

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

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

8 DR. PICKERING: That is next.

9 CHAIR MORRISON: New comments,
10 questions, concerns?

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

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

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

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

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

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

11 CHAIR MORRISON: Oh, not quite.

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

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

4 CHAIR MORRISON: You sound pretty good,
5 Matt.

6 DR. PICKERING: Okay, thank you.

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

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

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

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

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

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

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

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

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

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

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

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

9 DR. SCHREIBER: Thanks.

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

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

1 certainly does help.

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

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

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

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

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

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

19 DR. ROACH: Home, everyone.

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

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

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

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

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

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

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

22 CHAIR MORRISON: Thank you. Are we

1 okay if we move to a vote? Matt?

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

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

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

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

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

17 CHAIR MORRISON: Maryellen, I see a
18 hand up.

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

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

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

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

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

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

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

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

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

22 DR. SCHREIBER: Sean, Michelle. Can I

1 just make a last comment from CMS point of view.

2 CHAIR MORRISON: Michelle, of course
3 you can.

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

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

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

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

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

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

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

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

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

21 MS. PERERA: I currently do not.

22 DR. PICKERING: I don't see anything in

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

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

1 the risk adjustment model.

2 Updates to the parameterization of
3 existing adjustment factors and reevaluation of
4 interactions and an indicator for patients' time
5 spent in a skilled nursing facility. These
6 updates have been reviewed and also endorsed by
7 NQF in the standing committee that it came
8 through. I was passed by CSAC, our Consensus
9 Standards Advisory Committee, for their review
10 this past spring and evaluation cycle, so Spring
11 2020.

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

22 With that, as well as going through

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

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

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

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

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

22 CHAIR DEMEHIN: Thanks, Matt. That was

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

9 MEMBER WILLIAMS: I apologize, I think
10 I hit the wrong button. I had a question for Dr.
11 Schreiber. Your slide this morning that you
12 didn't discuss that you flashed up for a while
13 regarding sociodemographic status adjustments, I
14 noticed the citation at the bottom was for the
15 2016 ASPE report, not last year's ASPE report,
16 which seemed to do an about-face from the 2016
17 report. I was just wondering if you could
18 clarify, because this to me is a measure that
19 would be appropriate for peer-grouping or
20 something of that nature. What exactly is CMS's
21 policy on this going forward?

22 DR. SCHREIBER: There is certainly

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

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

1 MEMBER WILLIAMS: I do read those
2 reports, Doctor.

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

6 MEMBER WILLIAMS: Thanks.

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

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

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

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

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

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

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

16 DR. SCHREIBER: Okay, thanks, Jesse.

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

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

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

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

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

1 make that happen.

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

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

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

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

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

1 priorities document.

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

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

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

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

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

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

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

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

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

22 CHAIR DEMEHIN: Janis?

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

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

22 CHAIR DEMEHIN: Great comment. Any

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

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

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

18 (Whereupon, the above-entitled matter
19 went off the record at 2:47 p.m. and resumed at
20 2:57 p.m.)

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

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

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

10 CHAIR MORRISON: -- yes.

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

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

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

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

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

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

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

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

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

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

1 admitted to inpatient service to receive care
2 appropriate to their level of malnutrition risk
3 and/or malnutrition diagnosis, if identified.

4 The appropriate care for inpatients includes
5 malnutrition risk screening, nutrition assessment
6 for that at risk -- or for those at risk, and
7 proper malnutrition severity indicated along with
8 a corresponding nutrition care plan that
9 recommends treatment approach. It's a facility-
10 level measure, and this is a composite. It has
11 been submitted NQF for Fall 2020. It addresses
12 an important topic that's not currently used
13 within these interoperability programs.

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

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

1 association with outcomes such as 30-day hospital
2 readmissions compared to those without sort of a
3 care plan in place, a malnutrition care plan.

4 However, submitted to the Fall 2020 NQF
5 endorsement process by the measure developer
6 notes that the screening for malnutrition risk
7 for conducting nutrition assessments was
8 indicated as a grade E or supported by level 4 or
9 level 5 evidence, so those are case reports.

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

16 Moving on to the quality challenge,
17 the developer does note that among hospitals that
18 meet a case minimum of 20 patients and at least 3
19 reportable measures in 2019, 44.7 percent of
20 hospitals were the highest-performing tier, tier
21 3; 14.9 percent were in tier 2; and 40.4 percent
22 were in tier 1, so you can see there's variation

1 there across the rates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 MEMBER LUNDBLAD: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

12 CHAIR MORRISON: Mike Woodruff? Saw
13 your hand.

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

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

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

1 endorsement.

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

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

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

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

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

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

4 CHAIR MORRISON: Thanks. Jennifer.

5 MEMBER LUNDBLAD: Thanks. A different
6 question. So for this one that we're looking at,
7 0032, is for the interoperability program, and I
8 think what you just described is terrific, and
9 it's going to be really helpful for critical
10 access hospitals who are included in
11 interoperability program, because they don't,
12 quite honestly, have very many rural relevant
13 ECQMs.

14 MR. VALLADARES: Right.

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

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

3 MR. VALLADARES: Yes.

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

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

13 CHAIR MORRISON: Thanks. Lisa.

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

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

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

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

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

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

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

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

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

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

17 MEMBER MCGIFFERT: Thank you.

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

1 steps. Matt, did I get that right?

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

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

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

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

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

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

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

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

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

4 MEMBER LUNDBLAD: Okay.

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

8 MEMBER LUNDBLAD: Got it, thanks.

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

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

1 DR. PICKERING: That's correct.

2 Thanks, Akin. So the Hospital Inpatient Quality
3 Reporting program, or Hospital IQR, is a pay for
4 reporting and public reporting program, with the
5 incentive structure that hospitals that do not
6 participate or participate but fail to meet the
7 program requirements receive a 1/4 reduction of
8 the applicable percentage increase in their
9 annual payment update. And really, the program
10 goals are to progress towards paying providers
11 based on the quality rather than the quantity of
12 care they provide to consumers and beneficiaries
13 as well as providing those consumers with
14 information about hospital quality to improve
15 their care decision-making.

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

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

22 (No response.)

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

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

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

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

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

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

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

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

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

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

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

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

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

12 (Simultaneous speaking.)

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

1 bringing ECQM performance public.

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

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

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

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

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

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

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

22 MR. VALLADARES: I am happy to speak

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

1 dietitians who come in and provide the
2 recommendations after conducting thorough
3 assessment of the patient to ensure that they're
4 indeed nutritionally compromised, and then the
5 physician who signs off on the diagnosis and
6 ensures that the care plan that was designed and
7 developed by the dietitian team moves forward.

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

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

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

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

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

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

8 MEMBER LUNDBLAD: Makes sense, thank
9 you.

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

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

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

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

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

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

1 said because this actually is correct.

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

15 MEMBER ORLOWSKI: Exactly.

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

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

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

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

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

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

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

1 measure belongs.

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

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

16 DR. SCHREIBER: Wonderful.

17 MS. McCAULEY: I am just --

18 DR. SCHREIBER: Thanks, Sharon.

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

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

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

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

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

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

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

18 DR. PICKERING: Steward?

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

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

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

10 (Pause.)

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

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

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

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

9 (No response.)

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

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

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

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

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

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

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

17 (Pause.)

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

21 (No response.)

22 MR. DAWSON: Okay. We have 22 results

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

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

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

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

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

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

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

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

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

15 CHAIR DEMEHIN: I thought so. Maybe
16 not.

17 DR. PICKERING: Okay.

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

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

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

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

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

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

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

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

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

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

1 start with Aisha.

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

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

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

1 reported to CMS?

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

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

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

1 on the phone?

2 DR. SCHREIBER: Yes, Lisa.

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

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

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

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

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

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

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

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

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

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

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

21 I did notice in one of the public
22 comments as well that in addition to the burden

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

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

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

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

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

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

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

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

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

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

19 MEMBER GANDHI: That's plenty, thank
20 you.

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

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

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

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

22 MEMBER MORSE: Hi. Thank you. I want

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

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

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

15 DR. SUTER: Yes, I am. I apologize.
16 It takes me a minute to get off mute. So the
17 response rates in CJR are in the range of 45 to
18 50 percent in general, and that is somewhat due
19 to the fact that CJR incentivized a threshold of
20 50 percent in the first year of reporting. So
21 it's a little bit hard to evaluate what the real
22 response rates are.

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

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

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

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

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

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

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

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

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

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

11 MEMBER HATLIE: Yes.

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

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

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

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

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

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

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

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

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

19 (Simultaneous speaking.)

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

22 DR. ROACH: Well, I mean --

1 (Simultaneous speaking.)

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

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

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

10 DR. SCHREIBER: Yes.

11 DR. ROACH: I don't think so.

12 DR. SCHREIBER: I don't think so.

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

1 MEMBER MCGIFFERT: That's good. That
2 captures it.

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

10 CHAIR DEMEHIN: Thank you. So --

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

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

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

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

13 MEMBER MCGIFFERT: So there's not
14 really an opportunity to cherry-pick the response
15 to the surveys?

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

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

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

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

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

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

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

21 MEMBER GUINAN: Okay. Thank you.

22 CHAIR DEMEHIN: Okay. This was a very

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 (Whereupon, the above-entitled matter
18 went off the record at 4:28 p.m. and resumed at
19 4:40 p.m.)

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

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

5 (No audible response.)

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

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

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

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

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

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

1 that works for you.

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

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

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

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

22 With all of this we did recommend a

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

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

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

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

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

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

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

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

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

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

2 DR. DRYE: Yes, I mean I have --

3 Karthik are -- he's going to -- can you speak to
4 that one?

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

10 CHAIR MORRISON: Thank you. Marty?

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

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

1 2005 -- and this is a, you know, an AHA mission
2 lifeline and ACC collaboration. And CMS was a
3 big part of this as well. And then times are now
4 reduced immensely and are now down to 59 minutes
5 as of the last migration of NCR in 2014.

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

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

11 MEMBER HATLIE: Okay. I appreciate it.

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

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

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

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

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

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

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

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

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

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

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

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

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

20 MEMBER WOODRUFF: Great, thank you.

21 CHAIR MORRISON: Akin?

22 CHAIR DEMEHIN: Thank you, Sean. So

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

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

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

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

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

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

22 CHAIR MORRISON: Thank you, Elizabeth,

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

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

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

14 DR. PICKERING: Go ahead, yes. And so
15 again, similar that we've -- in voting -- voting
16 to accept this, we will move it forward with that
17 preliminary recommendation. And if we don't have
18 60 percent or more, then we will have the working
19 group have their own separate board -- vote -- on
20 a decision category.

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

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

9 Okay. Voting is closed. The results
10 are 19 yes, and 3 no. The workgroup
11 conditionally supports for rulemaking, MUC20-
12 0004, Appropriate Treatment for ST-Segment
13 Elevation Myocardial Infarction Patients in the
14 Emergency Department for the Hospital OQR
15 Program.

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

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

1 calculate the percentage of beneficiaries with
2 mammography, or digital breast tomosynthesis, or
3 DBT, screening studies that are followed by
4 diagnostic mammography, DBT, ultrasound, or
5 magnetic resonance imaging -- or MRI -- of the
6 breast in an outpatient or office setting within
7 45 days. This is at the facility level.

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

1 and support in the literature.

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

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

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

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

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

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

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

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

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

7 MEMBER MORSE: The performance gap,
8 yes.

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

1 - fill that gap.

2 (Simultaneous speaking.)

3 MEMBER MORSE: And then --

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

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

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

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

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

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

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

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

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

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

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

11 CHAIR MORRISON: No, it's --

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

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

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

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

22 MS. McKIERNAN: Absolutely. So that's

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

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

1 work on to get their scores in the range?

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

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

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

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

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

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

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

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

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

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

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

6 CHAIR MORRISON: Thank you. Denise?

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

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

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

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

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

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

1 before I --

2 (Simultaneous speaking.)

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

5 CHAIR MORRISON: Okay, all right.

6 Thank you. Akin, you're next.

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

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

10 (Simultaneous speaking.)

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

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

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

12 (Simultaneous speaking.)

13 CHAIR MORRISON: Thank you --

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

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

1 practice.

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

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

22 And then finally I will note that we

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

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

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

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

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

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

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

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

22 CHAIR DEMEHIN: Sean, a kind of

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

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

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

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

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

1 CHAIR MORRISON: Thank you, Jennifer.
2 And Christie?

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

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

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

5 CHAIR MORRISON: Thank you, Christie.
6 Really helpful. At least to me. Any last
7 comments on gaps, folks? Okay. So my annotated
8 agenda says at 5:40 Sean will announce the
9 closing of the MUC voting portion or the meeting
10 and turn it over to Akin. I've got 5:27, so if -
11 - if people object, I can hold us out for another
12 13 minutes. But if there are no objections, I
13 will turn it over to Akin 13 minutes early.

14 (Laughter.)

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

17 (Laughter.)

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

1 -- any comments from the public?

2 (No audible response.)

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

14 (Simultaneous speaking.)

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

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

7 CHAIR DEMEHIN: Okay.

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

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

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

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

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

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

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

11 And of course thank you to the
12 developers and to CMS for listening and
13 participating as thoughtfully as you did
14 throughout the course of the -- the meeting.
15 Just let me kick it over to Sean.

16 CHAIR MORRISON: Yes, thank you, Akin.
17 I just echo everything that Akin said and also
18 wanted to thank Akin. This has been -- just an
19 absolute joy to work with him through this
20 process. And particularly the challenges of
21 doing this through Zoom.

22 I did want to particularly thank our

1 colleagues from CMS, from CDC and the folks not
2 on from FDA. This has been an unbelievably
3 challenging year for so many people in the
4 Federal Government who have been focused on the
5 healthcare of our nation. And I can't imagine
6 what it's been like to go to work every day with
7 everything that you guys have been facing. But I
8 wanted to thank you on behalf of the Committee
9 the -- for the work that you have done for our
10 patients and families this year. And quite
11 honestly for sticking with it, given everything
12 that you've been experiencing. So -- and for
13 being here today and being so good spirited and
14 good natured. So thank you very much.

15 DR. SCHREIBER: Actually, Sean and
16 Akin, if I could just, on behalf of CMS, say
17 thank you to all of you as well. This has
18 certainly been quite the challenging year. Quite
19 honestly I hope we never see another one like it.
20 But everybody -- everybody has risen to the
21 occasion. I think certainly front-line
22 healthcare providers, healthcare organizations,

1 certainly we at CMS, the FDA and many other
2 places have just tried very hard. I will tell
3 you it's been 24 hours a day frequently.

4 CMS at least has tried to provide
5 waivers and -- and thoughtful consideration as to
6 how to make it easier for healthcare
7 organizations to work. From things like
8 Hospitals Without Walls to the expansion of
9 telehealth to other appropriate waivers --
10 licensing across state lines. And I think these
11 things will persist and that's going to change
12 the face of healthcare really forever for the
13 future.

14 To everybody today, thank you so much
15 for taking the time and for your incredibly,
16 incredibly thoughtful comments. I always learn
17 from these groups and really appreciate it.
18 Appreciate all of the folks who have been on the
19 line and certainly to NQF -- what a great -- a
20 great day this has been, the Rural Health, and I
21 am sure tomorrow as well. I think NQF has really
22 done a spectacular job in a very short time frame

1 of turning around a lot of information. So thank
2 you to you.

3 DR. PICKERING: Thank you all very
4 much for all of your time. I echo everything
5 that has been shared. Thank you to our CMS and
6 CDC colleagues as well as everyone on the
7 Workgroup. A special thank you to Akin and Sean
8 for great facilitation. We will be following up
9 with the next steps, as Chris has mentioned, but
10 we will go ahead and adjourn early. Everyone, I
11 hope you have a great rest of your evening and a
12 great rest of your week. And thank you all very
13 much for your participation today.

14 (Whereupon, the above-entitled matter
15 went off the record at 5:35 p.m.)
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