

NATIONAL QUALITY FORUM

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SCIENTIFIC METHODS PANEL

SPRING 2020 MEETING

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TUESDAY

APRIL 1, 2020

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The Panel met via teleconference, at 9:00
a.m., Dave Cella and Dave Nerenz, Co-Chairs,
presiding.

PRESENT:

DAVE CELLA, PhD, Co-Chair
DAVE NERENZ, PhD, Co-Chair
J. MATT AUSTIN, PhD
BIJAN BORAH, MSc, PhD
JOHN BOTT, MBA, MSSW
DANIEL DEUTSCHER, PT, PhD
LACY FABIAN, PhD
MARYBETH FARQUHAR, PhD, MSN, RN
JEFFREY GEPPERT, EdM, JD
LAURENT GLANCE, MD
JOSEPH HYDER, MD
SHERRIE KAPLAN, PhD, MPH
JOSEPH KUNISCH, PhD, RN-BC, CPHQ
PAUL KURLANSKY, MD
ZHENQIU LIN, PhD
JACK NEEDLEMAN, PhD
EUGENE NUCCIO, PhD
SEAN O'BRIEN, PhD
JENNIFER PERLOFF, PhD
PATRICK ROMANO, MD, MPH
SAM SIMON, PhD

ALEX SOX-HARRIS, PhD, MS

MICHAEL STOTO, PhD

CHRISTIE TEIGLAND, PhD

RONALD WALTERS, MD, MBA, MHA, MS

TERRI WARHOLAK, PhD, RPh, CPHQ, FAPhA

ERIC WEINHANDL, PhD, MS

SUSAN WHITE, PhD, RHIA, CHDA

NQF STAFF:**SHANTANU AGRAWAL, MD, MPhil, President and CEO****ASHLIE WILBON, MS, MPH, FNP-C****SAM STOLPE, PharmD, MPH****MIKE DiVECCHIA, PMP****HANNAH INGBER, MPH****CAITLIN FLOUTON, MS****ALSO PRESENT:****KATIE BALESTRACCI, Yale CORE****LISA BERGERSEN, Boston Children's Hospital****LISA SUTER, Yale CORE**

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

2 (9:06 a.m.)

3 MS. WILBON: Good morning, everyone.

4 This is Ashlie Wilbon, the technical expert from
5 NQF. I want to thank everyone for joining us
6 today. This is NQF Scientific Methods Panel
7 Spring 2020 Evaluation Meeting.

8 We're certainly happy to have our
9 Methods Panel members on as well as those of you
10 who have joined and members of the public and our
11 developers given these trying and special
12 circumstances we're all living through at this
13 point.

14 So, we're happy to have you and we are
15 looking forward to an interesting discussion
16 today despite things that may be going on around
17 us. Again, welcome.

18 I did want to hand it over to our CEO
19 here at NQF, Shantanu Agrawal, to give us some
20 welcoming remarks, Shantanu.

21 MR. AGRAWAL: Thanks, Ashlie. Can you
22 hear me?

1 MS. WILBON: Yes, we can hear you.

2 MR. AGRAWAL: Excellent. I'll just do
3 a quick welcome -- very unique and trying times.
4 And so the fact that this committee would take
5 the time to be part of this meeting and, more
6 than that, be part of the work, we very much
7 appreciate.

8 I think we are trying to move forward
9 on our endorsement work as best as possible. We
10 will likely be giving some guidance to measure
11 developers and giving them some leeway in the
12 coming weeks in order to accommodate some of the
13 bandwidth constraints that developers and others
14 are feeling right now.

15 But again, we've gotten a host of
16 measures for this endorsement cycle which I think
17 is a great show of support. And just a great
18 statement on the part of our stakeholders.

19 We internally have reviewed the agenda
20 for today and there are a host of very
21 interesting, I think, measurement issues. And so
22 I think you'll have a really robust dialogue

1 throughout the day.

2 And I think you'll be able to provide
3 a lot of guidance and recommendations back to us
4 so that we ensure that our approach to measure
5 endorsement remains rigorous and we are tackling
6 some of these new issues as they come up.

7 So, again thank you very much. I want
8 to thank all of you for attending and want to
9 thank the NQF staff as well. They have really
10 done yeoman's work to create a great agenda even
11 in challenging times.

12 So thank you, Ashlie and team, and
13 thank you all for attending. I'll turn it back
14 over to Ashlie.

15 MS. WILBON: Thank you, Shantanu. And
16 I did want to see is -- Kathleen, are you there?
17 Kathleen Giblin is our acting senior vice
18 president of quality measurement.

19 I wanted to check in to see if you
20 would like to say any words or if you're there.
21 If not, we'll give an opportunity to our co-
22 chairs to provide some welcoming remarks and then

1 we'll get started here very shortly.

2 Okay. I don't think Kathleen is on.
3 So, Dave and Dave, would you like to give some
4 opening remarks?

5 CHAIR CELLA: This is, excuse me, this
6 is Dave Cella. Good morning, everyone. Thanks
7 for attending.

8 We have a lot scheduled to talk about
9 and I won't delay any further so that we can be
10 as efficient as possible and get right to some of
11 the meat of the meeting. Thanks.

12 CHAIR NERENZ: Yes, Dave Nerenz. I'll
13 echo that. Really tough time for folks and
14 particularly those who are active clinicians, who
15 are right on the front lines of what's going on
16 around us.

17 Thanks for your ability to spend some
18 time with us. So, without further ado, let's get
19 to it.

20 MS. WILBON: Thank you. Thank you
21 both. And just a couple of quick meeting and
22 webinar reminders. You can see from our agenda

1 today we do have -- we'll be meeting in about
2 two-hour blocks with a couple one-hour breaks.

3 We wanted to give folks sufficient
4 time to be able to grab a bite to eat, stretch
5 your legs and do other -- make sure you can check
6 in with your other obligations throughout the
7 course of the day.

8 We do understand that you guys have a
9 lot of other things going on around you. So, if
10 you need to step away outside of a break, please
11 feel free to do so.

12 We do just ask that if you are
13 stepping away, if you try to be present during
14 our measure discussions, particularly if your
15 subgroup is up for discussion, then we ask that
16 you try to attend during those times so that we
17 can make sure that we are able to maintain a
18 voting quorum for those measures.

19 And please feel free to use the chat
20 feature in the webinar. Our team is on and will
21 be able to provide any support you need.

22 We'll do our best to mitigate any

1 technical issues you might have in interacting
2 with us today. And we found the chat box very
3 useful to communicate during meetings. So please
4 feel free to use that.

5 As we go, since we're not sitting in
6 a room together and we don't have our table
7 tents, our proxy for that via the webinar is the
8 raise your hand feature. You each should be able
9 to raise your hand if you would like to speak at
10 any point during the discussion.

11 NQF staff and the co-chairs will be
12 watching those indicators to see who would like
13 to raise their hand and we'll do our best to call
14 on folks in a timely and orderly way. So, we'll
15 try to catch people in order of when they raise
16 their hand to make sure that everyone has an
17 opportunity to speak.

18 And if we're not catching you, please
19 feel free to send us a chat or kind of summarize
20 your comment in the chat and we'll make sure to
21 interject that comment so that we can call on you
22 accordingly.

1 We are transcribing the discussion
2 today similar to how we would do for an in person
3 meeting. We do have a court reporter who is
4 dialed in so that he can get an accurate
5 transcription and recording of today's
6 discussions.

7 So we do have a couple of asks in
8 order to make sure that goes smoothly.
9 Particularly if you're a presenter, if you could,
10 and that would be essentially anyone who is a
11 member of the Methods Panel, if you could
12 remember to keep your line muted on your phone so
13 that we don't get the background noise and
14 echoing during the discussion that allows him,
15 the transcriptionist to hear the speaking clearly
16 and make sure that he's able to get a clear
17 recording.

18 We will also ask that if you can
19 remember to be sure to introduce yourself as
20 you're speaking. Again, it helps him keep track
21 of who is making which remarks.

22 You may find us interrupting if we

1 don't know who is speaking to make sure that we
2 have a good idea of who is contributing to the
3 discussion. One more note that we were given as
4 a reminder so that we can make sure that the line
5 is as clear as possible, if you are able to dial
6 in and use a set of headphones or a headset of
7 some sort to speak rather than having on
8 speakerphone, I think that does also help with
9 background noise and the clarity of the sound.

10 So, if possible and you're able to do
11 that please do. And again, we'll be doing our
12 best to mitigate any technical issues as we go
13 along.

14 I think everyone is familiar with our
15 team at this point. I think we've all sent
16 enough emails at this point that everyone is
17 pretty familiar.

18 But I did want to just take an
19 opportunity to recognize my team. We've all
20 worked really hard.

21 They, in particular, have worked
22 really hard to pull this together and transition

1 and pivot from an in-person meeting to conducting
2 the meeting over the web and they've done a
3 really great job at being flexible and
4 accommodating for folks.

5 So, thanks to the team. I did also
6 want to just recognize Sam Stolpe, who I think
7 you all met last cycle. He is a senior director
8 here.

9 He will be my backup today in case
10 anything comes up and he'll be helping with some
11 of the measure discussion later on this
12 afternoon.

13 I did want to just offer an
14 opportunity for each of the team members to do a
15 brief introduction and to say hello to everyone
16 this morning.

17 Mike, are you there? You want to say
18 hello?

19 MR. DIVECCHIA: Hi. Good morning,
20 everybody. This is Mike DiVecchia and I am the
21 project manager for the SMP. And I'm looking
22 forward to the next couple of days.

1 MS. INGBER: Good morning, everyone.
2 This is Hannah Ingber. I'm also very excited to
3 hear the discussion. Thank you all for joining
4 us.

5 MS. FLOUTON: Good morning. This is
6 Caitlin Flouton. I am a new analyst here. I am
7 available in the chat and in email. If you need
8 any help, feel free to reach out and thanks for
9 joining us.

10 MS. WILBON: Thanks, team. So, at
11 this point in time we'll get a sense of who from
12 the Panel is on the line. We will be combining
13 the roll call with our disclosure of interests.

14 If you recall, any time we do measure
15 review, we will need to do a disclosure, an oral
16 public disclosure of interest. And so bear with
17 me.

18 Some of this process is scripted and
19 it will be very familiar to you. But it is
20 important that we do this and make sure that we
21 have any oral disclosures that are needed.

22 I will point out that I know a couple

1 of our West Coast Panel Members may be dialing in
2 a little bit later and we'll just make sure to
3 follow up with them as we get a little deeper
4 into the discussion.

5 So, we'll start with our co-chairs.
6 I think they are both on at this point. Dave
7 Nerenz.

8 CHAIR NERENZ: Good morning. Dave
9 Nerenz here. No conflicts to disclose.

10 MS. WILBON: Apologies, Dave. Sorry,
11 I should read my little script here. So, you
12 each received a disclosure of interest form from
13 us before you -- as you were named to the Panel.

14 And it asked you about some general
15 professional activities. And then we also
16 provided you with a measure-specific disclosure
17 of interest.

18 It's specific to the measures we
19 received and will be under review for this cycle.
20 So, in the interest of transparency today we're
21 going to ask you to orally disclose any
22 information you provided that you believe is

1 relevant to the discussions today and the matters
2 that will be under review.

3 We're specifically interested in
4 grants research, consulting, measure development
5 activities related to the work today. There are
6 seven measures for review today on the agenda.

7 So, we'll be specifically -- looking
8 to specifically hear any conflicts related to
9 those. And again, most of you have heard this
10 before. But just a couple reminders.

11 You sit on this group as an individual
12 and you do not represent the interests of your
13 employer or anyone who may have nominated you for
14 the Panel. We're interested in disclosures of
15 both paid and unpaid activities relevant to the
16 work today.

17 And just because you disclose does not
18 mean you have a conflict of interest and again,
19 the oral disclosures are in the spirit of
20 openness and transparency.

21 And just another brief reminder that
22 if at any point you believe that you may have a

1 conflict of interest or someone else on the Panel
2 may have a conflict we ask that you let staff
3 know so that we can address it in as real time as
4 possible or as soon as possible.

5 And at this time we'll jump back in.
6 Apologies for that. Dave Cella?

7 CHAIR CELLA: Good morning, again.
8 This is Dave Cella. I am an unpaid member of a
9 board of directors of the PROMIS Health
10 Organization which is a non-profit foundation
11 that supports PROMIS.

12 And PROMIS will come up in one of the
13 discussions today or tomorrow.

14 MS. WILBON: Thanks, Dave. Matt
15 Austin?

16 MEMBER AUSTIN: Yes, good morning. I
17 have no disclosures to offer related to this ---
18 this morning.

19 MS. WILBON: Thanks, Matt. Bijan
20 Borah?

21 MEMBER BORAH: Hi, good morning. I
22 have nothing to disclose relating to the measures

1 we will be discussing today.

2 MS. WILBON: Thank you, Bijan. John
3 Bott, are you there?

4 MEMBER BOTT: Yes, hello. Good
5 morning. John Bott, I have no disclosures of
6 interest related to the work of the Panel. Thank
7 you.

8 MS. WILBON: Thank you, John. Daniel
9 Deutscher?

10 MEMBER DEUTSCHER: Yes, hello. I have
11 no conflicts or disclosures related to any of the
12 measures submitted during this cycle, thanks.

13 MS. WILBON: Thank you, Daniel. And
14 I just want to recognize Daniel who is calling in
15 from Israel, I believe. So, thank you again for
16 your engagement. I appreciate that. Lacy
17 Fabian?

18 MEMBER FABIAN: Good morning. I have
19 nothing additional than what was disclosed on the
20 forms for the post-acute care measures. Thank
21 you.

22 MS. WILBON: Thank you. Marybeth

1 Farquhar?

2 MEMBER FARQUHAR: Good morning. This
3 is Marybeth Farquhar. I have nothing to disclose
4 with relation to the measures.

5 MS. WILBON: Jerry, I'm sorry, Jeffrey
6 Geppert?

7 MEMBER GEPPERT: Hi, good morning.
8 Nothing to disclose for today.

9 MS. WILBON: Thanks, Jeff. Larry
10 Glance? Okay, I think Larry is --

11 MEMBER GLANCE: Can you hear me now?

12 CHAIR CELLA: Yes.

13 MS. WILBON: Hi, Larry, yes.

14 MEMBER GLANCE: Hi, good morning.
15 Sorry about that. I was muted. I don't have any
16 additional things to disclose, thank you.

17 MS. WILBON: Okay, great. Thank you.
18 Joseph Hyder? Joe, are you there? Okay, Sherrie
19 Kaplan?

20 MEMBER KAPLAN: Hi, I'm a consultant
21 to the AHRQ-funded Shared Decision Making
22 Measures Development group. But that's not

1 relevant to the measures today.

2 And the PCORI, I have I -- I am a PI
3 on a PCORI-funded child-reported -- patient-
4 reported outcome, Type I diabetes, but also not
5 relevant for measures today.

6 MS. WILBON: Thank you, Sherrie. Joe
7 Kunisch?

8 MEMBER KUNISCH: Hi, good morning.
9 This is Joe Kunisch and I have no conflicts of
10 interest to report.

11 MS. WILBON: Thank you. Paul
12 Kurlansky? I think Paul might have been having
13 some trouble getting in. Paul, are you there?
14 Maybe on mute.

15 PARTICIPANT: I know he said that he
16 could not make both days. This may have been the
17 day he can't make.

18 MS. WILBON: Yes. I think we had some
19 communication from him this morning. He was
20 trying to get -- well, we'll come back to Paul.
21 Zhenqiu Liu?

22 MEMBER LIU: Yes, hi. I'm involved

1 with two measures we discuss today and tomorrow.
2 One is 3559. One is 2539.

3 MS. WILBON: Thank you, Zhenqiu,
4 appreciate that. Jack Needleman, are you there?

5 MEMBER NEEDLEMAN: Good morning.
6 Nothing to disclose.

7 MS. WILBON: Thanks. And Jack is also
8 joining us from the West Coast so thanks for
9 dialing in early, Jack. We appreciate that.
10 Gene Nuccio?

11 MEMBER NUCCIO: Hi, yes. Hi, no
12 disclosures on any of the measures today, thank
13 you.

14 MS. WILBON: Thanks, Gene. Sean
15 O'Brien? Jen Perloff?

16 MEMBER PERLOFF: Hi. No conflicts of
17 interest.

18 MS. WILBON: Thank you. Patrick
19 Romano? I know Patrick is one of our West Coast
20 folks so he may be dialing in a little bit later.
21 Sam Simon?

22 MEMBER SIMON: Good morning.

1 Mathematica is a measure developer and we have a
2 contract with CMS to develop a measure that is
3 very similar to 3559.

4 It's basically the clinician level
5 analog to 3559. So, that's the only thing I have
6 to disclose.

7 MS. WILBON: Thank you, Sam. Alex
8 Sox-Harris?

9 MEMBER SOX-HARRIS: Good morning. I'm
10 an unpaid workgroup member for the American
11 Academy of Orthopedic Surgery for some of their
12 measure development efforts. But nothing related
13 to the measures today.

14 MS. WILBON: Okay, thank you. Michael
15 Stoto?

16 MEMBER STOTO: Good morning, everyone.
17 I have nothing to disclose for today's meeting or
18 tomorrow's.

19 MS. WILBON: Thank you. Christie
20 Teigland?

21 MEMBER TEIGLAND: Hi, good morning.
22 And I also have nothing to disclose related to

1 the measures we'll be discussing over these two
2 days. Thank you.

3 MS. WILBON: Thank you. Ron Walters?

4 MEMBER WALTERS: Good morning. I have
5 nothing to disclose relevant to the discussion of
6 this committee.

7 MS. WILBON: Thank you. Terri
8 Warholak?

9 MEMBER WARHOLAK: Good morning. I
10 have nothing to disclose related to the measures
11 today. And as you will hear, there's a little
12 background noise but I'm actually in my
13 apartment.

14 So, I'm going to try to keep myself
15 muted as much as possible.

16 MS. WILBON: Okay. Thanks, Terri,
17 appreciate that. Eric Weinhandl?

18 MEMBER WEINHANDL: Good morning. This
19 is Eric. I am an employee of Fresenius Medical
20 Care North America.

21 It's a supplier of dialysis services
22 and products and I have no conflicts of interest

1 with respect to the measure development. One of
2 the measures being discussed tomorrow relates to
3 emergency department readmissions for dialysis
4 facility evaluation. So, my employer is
5 certainly subject to that measure.

6 MS. WILBON: Okay, thank you. Susan
7 White? I believe Susan let us know she probably
8 would not be able to attend. But just checking
9 in, in case. Susan, are you there?

10 Okay, she said she may be able to pop
11 in throughout the two days. So, thank you
12 everyone for that. As we get into the measure
13 review later on this afternoon we'll make sure
14 that those who speak are identified.

15 For those of you that are on the
16 Panel, you'll note on the annotated agenda we
17 have noted the conflicts that we've noted for
18 each of the measures. So please be sure to
19 review that, and if you are -- have been
20 identified as someone who should be recused,
21 please note that you should be refraining from
22 discussion and voting on the measure. So, thank

1 you again for that.

2 Just a quick review of our agenda
3 today. We're going to go through some evaluation
4 updates, a process overview, some evaluation
5 guidance discussion which is designed as the
6 emailed you guys later last week to really give
7 the committee or give the Panel an opportunity to
8 discuss some of the overarching issues that were
9 identified through the evaluation of the measures
10 this cycle.

11 And we'll be trying to use that
12 discussion to establish some common principles
13 that we'll be keeping in mind as we evaluate the
14 measures later on in the afternoon and early part
15 of tomorrow.

16 And so we'll pick up with the measure
17 evaluations later this afternoon. And tomorrow
18 we will be spending the morning on measure
19 evaluations.

20 And as we noted from our email update
21 yesterday or a couple days ago, we will be kind
22 of truncating the meeting on Day 2 to conclude

1 after measure evaluations, just keeping in mind
2 the many external activities and things going on
3 around us.

4 We'll try to keep Day 2 as brief as
5 possible. But obviously, we'll need to make sure
6 that we get through the measure evaluations for
7 the cycle.

8 So, the criteria recommendations and
9 evaluation guidance discussions will be moved to
10 a future webinar for the Panel in the spring.
11 So, thanks for that.

12 And we just went over the agenda. I
13 did just want to give a brief overview of the
14 meeting materials that we provided because we
15 will be referring to many of these today.

16 Obviously, the agenda provides some
17 good information about who we're expecting to
18 attend, who should be voting on the various
19 measures and what members should be recused from
20 discussion.

21 The discussion guide will be a
22 reference tool when we begin measure review. It

1 has all the important information about the
2 measures that will be under review.

3 It also includes links to the measure
4 information form and the testing attachments, as
5 well as the additional information that was
6 provided by developers in response to your
7 preliminary analyses.

8 There are also several background
9 materials that we provided, some for reference
10 and some that we were hoping you would be able to
11 review, to provide you with a little bit of
12 context of some of the upcoming discussions.

13 We'll be referencing various elements
14 from the 2011 NQF Testing Task Force Report as we
15 start thinking about some of the evaluation
16 guidance and policies and recommendations for
17 changing our criteria and evaluation policies
18 coming up.

19 We also provided the SMP Measure
20 Evaluation Guidance document that we have created
21 since the SMP has been in existence, which
22 basically outlines for developers and others some

1 of the preferences that the Methods Panel has
2 expressed in starting to review measures so that
3 developers have a sense of how we might like to
4 see data presented and so forth.

5 We also wanted to share the risk
6 adjustment paper that Larry led and has just
7 published and was supported by many of the SMP
8 members as background as well as a paper from He,
9 et al., on the PIUR which references a method for
10 reliability testing that would be for several of
11 the measures this cycle.

12 So, to just jump right in here and
13 give everyone some foundation on where we landed
14 with the measures this cycle. So, we had a total
15 of 50 measures that were submitted to NQF for the
16 2020 cycle.

17 And about a little less than half of
18 those were evaluated by the SMP. So, we had a
19 total of 21 measures. And again, about half of
20 those were new and the other half were
21 maintenance measures.

22 We have three subgroups this cycle,

1 about nine to ten folks. And each group had
2 seven measures.

3 We ended up with 14 that passed
4 reliability and validity, two that were consensus
5 not reached upon either reliability or validity,
6 and five that did not pass reliability or
7 validity.

8 And there are a total of seven that
9 are slated for discussion today, which combines
10 the two that were consensus not reached and the
11 five that did not initially pass a preliminary
12 analysis.

13 For most of those measures that did
14 not pass, as well as the ones that were consensus
15 not reached, the group did submit additional
16 information for consideration. So, we'll be
17 discussing that information in the context of
18 reconsideration and submitting additional votes
19 later on today.

20 And again, here is a breakdown of the
21 type of measures that we got. We had a set of
22 six top measures, one PRO-PM, one composite, and

1 the rest were outcome or intermediate clinical
2 outcome.

3 I just want to pause there to see if
4 there's any questions before we move on. But the
5 next section is around updates on the Panel's,
6 kind of, evaluation performance and some of the
7 disposition of the measures that have gone
8 through previous cycles.

9 But any questions about this cycle or
10 meeting materials or anything like that before we
11 move on? Okay, hearing none, I'll keep filing
12 away.

13 So, we did want to kind of bring back
14 to you some of the facts that we've been
15 selecting since the Methods Panel has been in
16 existence. And we've seen definitely some
17 fluctuation in the number of measures that have
18 been reviewed by the committee.

19 We certainly had a peak in spring of
20 2019 with almost 50 measures. And we've kind of
21 come down in terms of the number of measures that
22 have been reviewed from fall of 2019 to spring

1 2020.

2 And we've been more in the 20 range,
3 which certainly seems a lot more palatable, I
4 think, for us all. The number of measures that
5 have -- where consensus was not reached, I think
6 have certainly been decreasing over time.

7 And I think certainly the number is
8 consistent with the total number of measures that
9 have been reviewed by the committee.

10 And we'll actually share in the
11 following slide a little bar graph that actually
12 is able to show kind of how the committee is
13 becoming more consistent in evaluating the
14 measures and coming to consensus a lot more
15 frequently since the committee has been working
16 together.

17 So, this is what I was referring to.
18 So you can see over time that the number of
19 measures or the percentage of measures where
20 consensus was not reached is trending down.

21 So that is certainly positive from our
22 perspective, in that the committee or the Panel

1 seems to be coalescing around some common
2 principles and tends to be, more often than not,
3 on the same page about where the, you know, which
4 measures are -- should be considered passing and
5 considered for full endorsement and which should
6 not.

7 I did just want to go back to last
8 cycle to give a little bit more details of where
9 we landed. We did, we evaluated 22 measures. We
10 had 50 measures that were discussed at that
11 meeting.

12 And that was a combination of measures
13 being pulled by staff, being pulled by Panel
14 Members, and also there were six measures where
15 consensus was not initially reached in the
16 preliminary evaluations. Ultimately, the SMP
17 passed 16 of the measures and -- which was about
18 73 percent.

19 And there were four that did not pass,
20 two that were eligible for Standing Committee
21 revote and the -- both of those were pulled for
22 Standing Committee -- by the Standing Committee

1 for reconsideration.

2 And there were also additional, those
3 other two were pulled for further discussion as
4 well. And we did have one measure that was
5 withdrawn by the developer.

6 But if you recall, we did implement a
7 new process starting last cycle where Standing
8 Committees had an opportunity to pull measures
9 for discussion if they had not passed the SMP and
10 potentially be eligible for revote depending on
11 the reason for it not passing.

12 And I think I saw a hand from Matt.
13 Did you have a question or a comment?

14 MEMBER AUSTIN: I do have a question.
15 But you may get to it in the future so I sort of
16 inadvertently raised my hand.

17 But I'm curious to know if you have
18 any specifics on measures that haven't passed
19 that have come back to the Panel and if those
20 have passed the second time or if you have any
21 sort of statistics on those that we have
22 reevaluated.

1 CHAIR CELLA: Ashlie, are you there?

2 MS. WILBON: Hi, sorry. I was talking
3 on mute, apologies. It's a good question. I
4 don't have those numbers in front of me but it's
5 something that we can work on and bring back to a
6 future meeting.

7 I think it's something we should be
8 tracking. I do know this cycle that we did not
9 have any that came back that were previously
10 reviewed.

11 We have certainly, over previous
12 cycles, seen more coming back. And typically, I
13 think, this sort of experiential data, I can tell
14 you that it typically does take about a year for
15 them to come back.

16 So, they aren't typically coming back,
17 let's say, in the following cycle. But, yes,
18 it's a good question. I don't have it, but I can
19 get it.

20 MEMBER AUSTIN: Thank you.

21 MS. WILBON: So, switching gears a
22 little bit, but again just a bit of kind of Panel

1 maintenance if you will, we do have several
2 members whose terms will be ending in the fall.
3 And we did want to just do a check in with those
4 folks.

5 We will be distributing a survey to
6 you guys via email. And we just ask if you could
7 complete that. It's literally one question to
8 just let us know whether or not you would like to
9 continue on and extend your term.

10 We're acting now because, depending on
11 how many folks decide to let their terms expire
12 we may need to do additional nominations and we
13 need to do that before the next cycle. So, if
14 you could complete that for us and let us know if
15 at your earliest convenience that would be
16 awesome.

17 I did also want to let folks know,
18 Dave C., if it's okay for me to share that Dave
19 will be, his term will be expiring in September
20 and he unfortunately will not be returning with
21 us. So, we will hang on to him for as long as we
22 can through September.

1 But we'll be looking for another co-
2 chair in September and we'll be in touch about
3 that over the coming months. But we still have
4 him for several months.

5 But I just wanted to give a brief
6 update on that. Okay. So, we do have a few
7 updates here on the process I wanted to share.

8 As I think most of you guys are
9 familiar with this -- so I won't spend a lot of
10 time on these. They are things that you have all
11 seen before.

12 But I do think they are helpful
13 reminders as we get into review, just to make
14 sure we're all starting off on the same page. If
15 I am going too fast or you need me to repeat
16 something, please let me know and we will
17 certainly go back.

18 But again, in the interest of time and
19 not -- making sure we can get to the meat of what
20 we're doing here as quickly as possible, I'll
21 move quickly.

22 So, I did want to bring up the --

1 remind us about the process we implemented last
2 cycle, which was around the ability for Standing
3 Committee Members to be able to evaluate measures
4 that had not passed the Methods Panel's
5 evaluations.

6 So, similar to previous cycles, we
7 have not changed the process, in that measures
8 that passed the review or where the SMP does not
9 reach consensus, those measures will
10 automatically go to the Standing Committees.

11 And so, that has not changed. That's
12 been consistent since we started the Methods
13 Panel.

14 The newer process that we added last
15 cycle was about consideration of measures that
16 did not pass by the Methods Panel, by the
17 Standing Committee and the fact that some
18 measures may be eligible for revote if it's
19 considered eligible.

20 And so, the next slide here talks in
21 a little more detail about that. So, after the
22 Methods Panel's final vote NQF staff basically

1 reconvenes with the co-chairs.

2 They review the measures that didn't
3 pass, and discuss kind of the key issues on the
4 rationale for why they didn't pass, and see
5 whether or not they will be eligible for
6 consideration by the Standing Committees.

7 And typically, measures that do not
8 pass the SMP are not eligible for revote if it --
9 if the reason that it didn't pass hits one of
10 these four bullets. So, if there was an
11 inappropriate methodology or testing approach
12 applied to demonstrate reliability and validity,
13 there is incorrect calculations or formulas used
14 for testing, the description or testing approach
15 results, or data is insufficient for the Methods
16 Panel to apply the criteria.

17 That would be inclusive of, you know,
18 specifications being unclear or different
19 information that would be needed to correctly
20 calculate the measure. So, that kind of falls
21 under that bullet or the appropriate level of
22 testing was not provided or otherwise did not

1 meet our minimum evaluation requirements.

2 Typically, in our kind of screening of
3 measures before they go to SMP we try to catch
4 everything that does not have the right level of
5 testing. But that's not always clear in our
6 initial screening.

7 So, sometimes those do get through to
8 the Methods Panel for review. So there is
9 another stopgap at this point for us to be able
10 to catch those measures.

11 I'll just pause there to see if
12 there's any questions. I think we had some
13 questions previously from the Methods Panel and
14 other stakeholders about this.

15 So, I did want to just pause here and
16 just sure that the Methods Panel requested that
17 it was clear what the policies and procedure for
18 that. Okay.

19 CHAIR CELLA: Just a sec. Jeff
20 Geppert has a hand up.

21 MS. WILBON: Okay, Jeff, sorry. Hi.

22 MEMBER GEPPERT: Hi. Yes, so my

1 question isn't so much about the policy but where
2 the, will there be a feedback loop, you know,
3 from the Standing Committees back to the SMP
4 about, especially -- I think in your earlier
5 slide about 75 percent of the time there was
6 agreement, about 25 percent of the time there
7 wasn't.

8 So, it would be nice to know, you
9 know, if there are some lessons learned from when
10 they disagree.

11 MS. WILBON: Yes, that's a good
12 question. I think for the last cycle, for spring
13 2019, when we first initiated a policy where they
14 could pull measures for revote -- I do not have
15 in front of me kind of the disposition of those
16 measures, on whether or not they actually ended
17 up passing, and what the committee's rationale
18 was.

19 But it's certainly something we could
20 do, we could bring back, to provide that feedback
21 to you guys, certainly.

22 And I think even from an even broader

1 perspective, the measures that you do pass
2 forward, those 75 percent, was there any kind of
3 discrepancy in what the committee believed in
4 terms of their recommendations for endorsement or
5 for passing and not passing is certainly
6 something we could bring forward.

7 I think we have stats on that. But I
8 don't think I included it here. So, at this
9 point it's just something we'll look into.

10 Okay, moving forward again to the
11 ratings here. I think you guys are all familiar
12 with this.

13 But I did just want to just recap a
14 couple of things, particularly because I think
15 the rating scale has been something that has been
16 an element of discussion for the Panel in
17 previous meetings, and to just recap a couple
18 things, and differentiating high from moderate,
19 for example.

20 Moderate is the highest rating that a
21 measure can be eligible for if only data element
22 testing was presented or if only face validity

1 was conducted. So, typically score level testing
2 is required in order for a measure to receive a
3 high rating.

4 And the rating for the measures should
5 be -- should encompass your evaluation of, you
6 know, whether or not the test was appropriate for
7 the measure and the purpose of the testing,
8 whether or not the scope of testing was adequate,
9 so representative of the sample,
10 representativeness of the population, the right
11 sample size and then also of whether or not the
12 results were acceptable.

13 So, I'm kind of thinking about those
14 three elements and the findings or ratings all
15 just to be considered. Again, here this is just
16 a bit of a repeat.

17 Two-day consensus, we're looking for
18 a quorum of 66 percent of the Panel Members. So,
19 that will be a slide at the subgroup level. We
20 will be loading just within the subgroups.

21 Unfortunately, we were not able to
22 change the process at this point to do a full

1 Panel vote. It is something we're still
2 considering.

3 So, for this cycle we will continue
4 with our existing process for only subgroups to
5 vote. I do see a hand from Sherrie. Do you have
6 a question?

7 MEMBER KAPLAN: Yes. I have to be
8 really careful with my phone because the off
9 button is right above the mute button. And so, I
10 don't want to turn the phone off.

11 But I had a question on the
12 high/moderate. Can you go back to that for a
13 second because it doesn't really -- it's not
14 really relevant to whether the measure passes or
15 doesn't.

16 So, my interest is in trying to make
17 these distinctions meaningful what, if anything
18 are you going to do with the moderate ratings
19 because it doesn't really matter from your
20 perspective when the final vote is tallied,
21 right?

22 MS. WILBON: Right. It is something

1 that when in reviewing, in refreshing myself as
2 well on the initial, kind of, rationale for
3 having the high and moderate ratings was so that
4 the moderate rating gives developers a sense of
5 kind of the minimum that needs to be done in
6 order to be considered for endorsement.

7 And it's supposed to be an achievable
8 rating that can be sought after, that would
9 provide less kind of burden on the developer in
10 order to still be considered for endorsement.
11 So, I think that was the initial rationale.

12 But I think, Sherrie, you make a good
13 point. I think going forward, perhaps, you know,
14 there will be some -- we could come up with some
15 recommendations and theories from this group
16 about how we should be considering ratings going
17 forward and whether or not there is really a need
18 to have a high and moderate since it's really --
19 pass or not pass is really the ultimate decision.

20 MEMBER KAPLAN: Well, I was wondering
21 why -- if you're eventually going to a star
22 rating that makes a lot of sense. But if it's

1 pass/fail, at least at the Methods Panel, maybe
2 pass/fail is more efficient for us to be
3 considering as opposed to the three tiers. But
4 thank you.

5 MS. WILBON: Yes. It's a good point.
6 And we don't have any decisions yet. But I think
7 it's something that this group would be really
8 helpful in us thinking through some options and
9 how we might make recommendations to modify that
10 going forward.

11 So, we'll try to incorporate that into
12 our discussions about criteria recommendations.

13 MEMBER KAPLAN: Thanks.

14 MS. WILBON: So, achieving consensus.
15 Again, we're looking for quorums of 66 percent of
16 the subgroup members and we need greater than 60
17 percent to pass.

18 Consensus not reached is in the 40 to
19 50 percent range and less than 40 does not pass.
20 The next few slides are around, kind of, the
21 differences in the testing requirements for the
22 various types of measures.

1 I know you guys are all familiar with
2 this. So I'm going to kind of skim through this.

3 But again, if there's something there
4 that you would like me to spend more time on if
5 you have questions please let me know and we can
6 certainly do that. I'm getting a question here
7 in the chat box.

8 Just bear with me here for a second.
9 Let me make sure that -- there's a question. So,
10 there was a question about the guidance on
11 ratings, whether it applies to only initial
12 endorsement or that initial endorsement does not
13 require empirical validity.

14 So, yes, that's correct. But if, for
15 example, a developer only submitted face validity
16 for their initial submission, the highest rating
17 they could get for validity would be a moderate.

18 So, that's how that's interpreted.
19 And hopefully that helps out. If not, please
20 keep asking.

21 And there's another, Dave is
22 responding to that. Okay, so we're good there.

1 If there are other questions on the ratings, feel
2 free to speak up and I'll have a brief discussion
3 on that if it's necessary.

4 Okay. So, again the next few slides
5 here are about, kind of, reminders around the
6 testing requirements based on measure type. So,
7 outcomes, clinical, intermediate clinical
8 outcomes, cost and resource use measures.

9 For both reliability and validity we
10 only require either data element at the score,
11 measure score level testing. Again, this is our
12 current requirement.

13 This is actually kind of the core
14 piece of the discussion that we had planned to
15 have tomorrow afternoon as to whether or not we
16 can finalize some of the recommendations on
17 whether or not that requirement should be
18 changed. But again, we are operating under that
19 current requirement.

20 So, either or, either data element or
21 measure score. And again, face validity is
22 discussed for new measures.

1 The second element of our discussion
2 for the five tier recommendations is around this
3 second sub-bullet. That is data element validity
4 testing is provided.

5 We do not require additional
6 reliability testing. If they do this and if the
7 developer does submit a measure with this type of
8 testing we would apply the vote for data element
9 validity to the reliability vote.

10 And we did have at least one measure
11 this cycle that submitted based on this policy.
12 So, for composite measures we do -- we defined
13 that as both traditional composite and all-or-
14 none measures does not include multi-item scales
15 or survey questionnaires.

16 We require reliability testing on the
17 composite measure score. And they can also show
18 reliability of the components, but we don't
19 currently require that.

20 Score level testing is not required
21 until maintenance. And composite measures do
22 have an additional subcriterion. And you'll note

1 that so for those measures we do ask for revotes
2 of reliability, validity and the composite
3 construct.

4 And you'll see that reflected in
5 action in one of the measures we're going to
6 review, we did review, sorry. It's not on the
7 agenda today.

8 For instrument-based measures,
9 reliability and validity testing is required for
10 both levels, both data element and measure score.
11 And I know it's a little bit tricky to wrap our
12 heads around.

13 But at this point we do allow multiple
14 performance measures under one NQF number. And I
15 don't think we had any issues with this
16 particular bullet here, so I won't spend time on
17 it. It can be a little bit confusing.

18 So a few additional reminders.
19 Testing should align with the specifications. We
20 do our best to screen for this in the staffing
21 review before we send the measures out to you.
22 We don't catch them all, but we do our best. And

1 so just another reminder there.

2 For risk adjustment this will be a
3 discussion for today around the inclusion or not
4 inclusion of certain risk factors particularly
5 clinical or social factors should not be a reason
6 for not passing a measure on validity.

7 We do -- we would ask you to kind of
8 focus on concerns with the determination and
9 calibration or the methods they used for
10 adjusting the measures which would be a grounds
11 for voting down on the validity criterion.

12 But we should be very clear about that
13 in our rationale for the voting. If there are
14 comments about the clinical factors and the
15 social factors, that's certainly something that
16 you can discuss and provide recommendations and
17 other comments to the Standing Committee for
18 consideration. But again, it should not be
19 grounds for not passing the measure.

20 Again, incomplete or ambiguous
21 specifications are grounds for rejecting a
22 measure. And we do our best to offer developers

1 opportunities to provide clarifications through
2 the response process that we've added in. And so
3 hopefully those are resolved for the most part by
4 this point in the process.

5 There may be some measures where that
6 still may be a concern and that would be on the
7 table. And careful validity testing is discussed
8 at the time of maintenance for measures that are
9 returning for maintenance of endorsement.

10 This slide, basically it aligns with
11 one of the background documents that we shared
12 which is the SMP evaluation guidance.

13 These are some of the recommendations
14 that were shared in that document to provide
15 developers some additional guidance on the things
16 they should be paying attention to when they are
17 submitting their measure which included, you
18 know, more detail in describing the methodology.

19 Don't just, you know, kind of give
20 words. Provide the formula and any other, you
21 know, information for example that they could to
22 provide you as much context about how they tested

1 the measure.

2 Again, more than one overall statistic
3 in reporting signal-to-noise for reliability. So
4 sample sizes, distributions and things like that
5 are always helpful.

6 And then again more detail in the
7 description of the concept validity and how they
8 selected the measure, the relationships you
9 expect to see, the strength of the association
10 you would expect to see and so forth.

11 But again, that -- we're not
12 necessarily going to be rejecting measures based
13 on two and three. But that certainly, for number
14 one, if you cannot understand the methodology
15 that was applied to test the measure that that
16 would be something that would be on the table for
17 rejecting the measure if it was inadequate.

18 Okay, any questions? That was kind of
19 a mouthful, and I just want to provide an
20 opportunity to ask questions. The next section
21 we're going to kind of get into the meat of it
22 here.

1 I know a lot of kind of fluffy stuff
2 up front. But I am looking forward to hopefully
3 getting into some of the more interesting
4 discussion here coming up. Any questions before
5 we move on?

6 Okay. So our next section is around
7 some of the challenges that were identified by
8 various Methods Panel members through evaluation
9 of the measures this cycle.

10 You'll note that many of these have
11 come up not just this cycle but previous cycles
12 and have been the subject of discussion for many
13 of our meetings. Again, we, you know, given the
14 time that we have today, we don't necessarily
15 expect to come to consensus on any of these.

16 If we do, that would be great and
17 awesome, and we would love to have some level of
18 guidance that we could put forth for future
19 cycles.

20 The discussion here is generally
21 intended to make sure that as these issues come
22 up with measures we're going to review today that

1 we're consistent. We're not setting new guidance
2 now that would be applied to the measures we're
3 going to be evaluating this afternoon.

4 This is merely to make sure that if
5 there are any overarching discussions that we can
6 have now that would help facilitate the
7 evaluation of measures later on this afternoon
8 and tomorrow and make those discussions go faster
9 that we have them at a higher level now and that
10 will help us later on in the meeting.

11 I also just wanted to point out that
12 one of the strategies we're using today to help
13 move things along is to think about these topics
14 in the context of future White Papers.

15 We've been talking with the Co-chairs
16 about how we might be able to have a productive
17 discussion given the limited time we have to
18 really dive into these issues. They are very
19 complex, and we just want to make sure there is
20 adequate time to do that.

21 And we think the best way to do that
22 would really to be able to have a plan going

1 forward for how we carry on the discussion of
2 these topics in a thoughtful way in a written
3 product.

4 So, you know, repeating what we did
5 for the Methods Panel paper, as well as the risk
6 adjustment paper and taking these topics and
7 developing White Papers of them. So we will be
8 along the way asking for folks to volunteer if
9 you're interested in participating in the paper.

10 But also be thinking about what those
11 papers would entail. So what are the key
12 elements of the issue that we would want to
13 address in the paper?

14 What is some of the guidance that we
15 would want to offer and some of the kind of more
16 strategic challenges that we would want to
17 address in each of these papers.

18 So keeping that in mind, I did just
19 want to offer Dave N. and Dave C. an opportunity
20 to add on or provide any additional context to
21 that opener if you would like to at this point.

22 CHAIR CELLA: No. This is Dave C.

1 You've covered it so well, Ashlie, I'm fine.

2 CHAIR NERENZ: Dave N. You did, I
3 just want to reinforce the idea.

4 In these discussions that are coming
5 up now we don't seek or want to go back and
6 change any of the votes or the decisions for
7 measures that are not in front of us today and
8 tomorrow. That's not the goal at all.

9 The discussions we have now are not
10 going to change the rules by which developers
11 submitted materials on this cycle. There are a
12 couple ones on the agenda later today and
13 tomorrow to which this discussion we're about to
14 have might be relevant.

15 But a lot of this is really forward-
16 looking and say as this whole process evolves and
17 we continue to think more sharply about some of
18 these issues, how can we evolve these discussions
19 and eventually the requirements for developers
20 and the rules by which we operate, how can they
21 get better and better?

22 CHAIR CELLA: Larry Glance has his

1 hand up.

2 MEMBER GLANCE: Hi. I just want to
3 very, very quickly make a clarification. I just
4 wanted to point out that the white paper that my
5 group headed up was not a risk-adjustment paper.

6 It was a white paper on evaluating the
7 scientific acceptability of risk-adjusted outcome
8 measures. So it's not just about risk
9 adjustment.

10 It's about looking at data
11 reliability, data validity, measure reliability
12 and measure validity. It's the whole thing.
13 Thanks.

14 CHAIR CELLA: Good point.

15 MS. WILBON: Thanks for clarifying,
16 Larry, appreciate that. Sherrie, do you have a
17 question?

18 MEMBER KAPLAN: Yes. Just sort of in
19 general terms, I mean I'm not looking for any
20 more meetings.

21 But it's tempting when we do it this
22 way to discuss these issues first and then

1 discuss the measures the bleed gets problematic.
2 You know, it's sort of hard to straighten out.

3 And I'm wondering if it isn't better
4 either to separate the two, this kind of forward-
5 looking guidance for NQF for measures development
6 in the future versus considering current measures
7 in front of us and separate the two things pretty
8 distinctly because I'm finding the bleeds, you
9 know, harder and harder to track.

10 MS. WILBON: So, Sherrie, let me just
11 make sure -- I'm just going to repeat that to
12 make sure I understand. So you're suggesting
13 that we have a discussion now that's more about
14 how we would -- the question that would help us
15 evaluate the measures coming up and separate that
16 from future guidance?

17 MEMBER KAPLAN: Well if it's, you
18 know, I mean in a way what we're talking about is
19 forward-looking. It's, you know, what could be
20 done?

21 What are acceptable methods and
22 measures for establishing, for example, threshold

1 type scoring versus norm reference tested scores,
2 et cetera, et cetera?

3 That's the kind of thing that's
4 forward-looking. And then we go into the
5 discussion of the measures.

6 I was maybe suggesting either we flip
7 the order or at least, you know, it's too hard
8 for me to sort of -- maybe I'm just on West Coast
9 time and I'm cognitively impaired as I get older.

10 But this kind of thing is tempting to
11 kind of slide into the discussion then we have
12 about existing measures which are going to
13 evaluated based on former guidance not current
14 guidance.

15 CHAIR NERENZ: Dave N. here. Sherrie,
16 I think that's a good point, and we could
17 probably take the view that much of what we're
18 going to talk about now or the main emphasis is
19 the forward-looking.

20 Maybe the way to talk about the
21 connection is that a number of the measures this
22 cycle have exemplified or have crystallized some

1 of these issues. And you're right, we can't
2 treat them differently as a result of discussion
3 we're about to have.

4 But part of my thinking, a lot of
5 these may have exemplified some of the problems I
6 think we have to try to work through.

7 MEMBER KAPLAN: Thanks.

8 MS. WILBON: Thanks, Sherrie. I mean
9 you bring up a good point. And that is our job
10 as NQF staff to make sure that the criteria that
11 we apply for the measures being evaluated does
12 align with our current criteria.

13 So that's -- I will make sure that
14 we're on our toes for that discussion, but point
15 well taken.

16 MEMBER KAPLAN: Thanks.

17 MS. WILBON: So with that we'll dive
18 right in. Just a couple of quick reminders about
19 our current definitions for reliability, data
20 element reliability.

21 We consider repeatability or
22 reproducibility of the data elements for the same

1 population in the same time period.

2 And measure score on reliability is
3 focused on precision and the proportion of
4 variation in the performance score due to
5 systematic differences across measured entities
6 or, more commonly, the signal to noise.

7 So, Dave N., if it's okay, I will hand
8 it over to you. I'm happy to go over this slide.
9 But if you would like to take the discussion from
10 here.

11 CHAIR NERENZ: Yeah. Let me just tee
12 it up a little bit, then we'll have max time for
13 discussion. There was an email that went around.
14 I'll just try to summarize that briefly for those
15 of you who didn't get a chance to take a look at
16 it.

17 This is an old issue for us. We've
18 had this in some of our conference call
19 discussions before we even went into cycles of
20 measure evaluation. It's popped up now and then.
21 But my sense is a lot of the measures that we saw
22 this cycle really call the question on this issue

1 of thresholds.

2 You know, if we look back at the 2011
3 document that serves as the basis for much of
4 what we do so far when talking about reliability
5 and, you know, what criteria we should be looking
6 for, there's reference to vague phrases like so-
7 called accepted standards but without defining
8 what exactly those standards are.

9 There's a table in the back of that
10 document that does make reference to the .4 is
11 kind of a minimum threshold. It doesn't name it
12 that way. It doesn't come out and declare it
13 that way.

14 But the number appears. And I think
15 as we watch measures come through and we look at
16 how the developers describe what they're seeing
17 this often comes up.

18 The reference is usually to the Landis
19 and Koch article from late '70s that was set in
20 the context of the kappa statistic for inter-
21 rater agreement. But others have made different
22 statements about thresholds.

1 Adams, in the 2009 article for a piece
2 that's often cited about signal-to-noise, talks
3 about .7. Allan Kozlowski did a piece a couple
4 years ago pointing out that there could be even
5 significant misclassification of providers with a
6 reliability statistic of .9.

7 The Heet (phonetic) article that was
8 given to us this cycle to take a look at makes
9 passing reference to.7. So there are different
10 numbers out there that are offered as thresholds
11 or guidelines without any clear reason, I think
12 in my mind, for saying we should adopt one or the
13 other.

14 The call the question time comes when
15 you get measures that are bringing forward
16 reliability statistics in the .5, .6 range. And
17 at least in the subgroup I was part of, we had
18 many, many of those this time.

19 And the action question is clearly
20 what do you do about it? Do they pass or do they
21 fail?

22 And I noted also in the slide you saw

1 a little while ago that was defining the ratings
2 for low, moderate, and high, the phrase not
3 satisfactory was part of the definition of a low
4 rating. So what's not satisfactory?

5 Is something at .5 not satisfactory?
6 So, there's a clear call to question -- this year
7 when you come -- when you see reliability
8 statistics in this range.

9 Ultimately, do they pass or do they
10 fail? So I think somehow we need to come to
11 grips with this a little more sharply than we
12 have in the past.

13 And also Sherrie's question a while
14 ago about what's the difference between moderate
15 and high. The definitions don't link those two -
16 - these numeric values.

17 But in other settings, you know, that
18 kind of verbal label does. We may want to say
19 that if somebody shows us reliability statistics
20 in .9 range we might want to call that high and
21 have that label carry forward into the review
22 process.

1 We don't currently do that. So I
2 don't have a further clear direction. But I did
3 want to have this on our agenda to invite folks
4 who have been thinking about this to suggest
5 possible ways we might carry this forward.

6 Not that in the next half hour or so
7 we can agree on some specific number. But
8 questions, for example, like should the same
9 general threshold apply to all measures of
10 reliability or do different statistics lend
11 themselves to different thresholds?

12 Should we ask for different higher or
13 lower standards for measure score than for data
14 element? Are there certain criteria for data
15 element reliability that set an upper limit on
16 what we can expect to see at the measure score
17 level?

18 So I think these are in front of us,
19 and I'm hoping the people who have been thinking
20 about this a bit.

21 CHAIR CELLA: This is Dave C. I'm
22 going to call on Jack because he's got his hand

1 raised.

2 MEMBER NEEDLEMAN: Thank you. That
3 was a great summary. And I just want to add two
4 or three things to it.

5 One of the other issues that has
6 emerged in some of the reviews is our developers
7 are picking threshold levels. And, by the way,
8 the documentation we've been getting has been
9 extremely good.

10 Nothing I say about the measures is a
11 slight at any of the developers. They've been
12 doing a great job of trying to document things.
13 And as we've asked for more, they've been
14 incredibly responsive. So the developers have
15 been terrific. It's about the measures.

16 But one of the other issues that I
17 think has emerged here is the thresholds for the
18 number of cases or the size and practices where
19 we're getting reliability statistics across
20 different ranges of those numbers.

21 And the overall reliability may meet
22 an acceptable standard. But for the smallest of

1 the groups they don't look like they do.

2 And the question is how to deal with
3 reliability when we think the measure developers
4 picked a threshold that's simply too low in terms
5 of when they start, who they are including within
6 the measure. So that's another issue to throw on
7 the table.

8 With respect to the Landis-Adams
9 documentation here, I would simply note that
10 Adams when he said .7, analyzed things at .7 and
11 found that in a simple split of upper quartile
12 rest of the sample, .7 produced -- was a number
13 in which 20, 25 percent of them, if I'm
14 remembering the article correctly, could be
15 shifted from one side of that dividing line to
16 the other which suggests that -- and we've got to
17 think about how comfortable we are saying a
18 measure is reliable when 25 percent can shift.

19 Similarly, the Landis article these
20 classifications were arbitrary in that. They did
21 not ground their definition of these moderate,
22 substantial, almost perfect to any empirical

1 analysis.

2 They had simply picked those labels
3 based upon their -- some -- without analyzing the
4 impact on reliability or so forth. So I think
5 there is a real issue about whether the Landis
6 characterization of these levels should be
7 accepted by us.

8 And I personally think that the Landis
9 standard is too low.

10 CHAIR CELLA: Thanks. David, just as
11 a process, there's an interesting quirk on the
12 hand raise function where as the list comes up
13 they are ordered by alphabetical order by first
14 name.

15 So Alex and others are going to be
16 advantaged if we don't watch out for that, and
17 Zhenqiu is never going to get to say anything
18 ever at all. So I'm going to try to watch the
19 sequence as best we can.

20 I think actually in this case I've got
21 Alex and then Mike Stoto and then Larry. But
22 I'll try to watch the sequence in which they pop

1 up.

2 CHAIR NERENZ: That's correct. At
3 least we have correlation of one on that.

4 MEMBER SOX-HARRIS: Great, so this is
5 Alex --

6 CHAIR NERENZ: And then Sherrie is
7 next after that. This is Dave. Go ahead, Alex.

8 MEMBER SOX-HARRIS: Okay. I really
9 appreciate the opportunity to discuss this. I
10 think this is obviously an essentially important
11 issue for this group.

12 Unless we have some consensus or, you
13 know, reasonable agreement on this, it's very
14 difficult to make judgments on the measures. So
15 I think this is great that we're doing this.

16 So I went back to the Landis article
17 to really understand what it said and did and
18 what it didn't. And it was clear to me that it's
19 a really -- it's addressing a very particular
20 context.

21 It's element reliability for sure and
22 then it's a particular flavor of that which is

1 agreement between raters on a categorical
2 classifier. And it has its own range and
3 distribution of data.

4 The statistic kappa has its own range
5 and distribution including negative, you know,
6 numbers below zero. It's testing a specific
7 hypothesis of -- null hypothesis of no agreement.

8 And as Jack just said, the proposed
9 mapping of kappa to adjectives was completely
10 arbitrary and not evaluated in any serious way.

11 So even if it was the last word on
12 this particular context, you know, the agreement
13 between raters on a categorical classifier, it's
14 a conceptual and mathematical leap to other
15 reliability contexts.

16 And in fact, just in my little
17 literature review of previous thinking and work
18 on, or more recent thinking and work on this
19 particular context, it's not the last word.
20 There are people who have evaluated those ranges
21 and found it to be problematic if you apply those
22 ranges. And after my comment I'll put a link to

1 one such paper in the chat box.

2 But the overall point I'm trying to
3 make is that I think we need to think more
4 carefully about reliability context, not just the
5 element versus measure distinction, which I think
6 is essential.

7 But even within, like element
8 reliability there are different contexts. There
9 are different data generation methods. There are
10 different statistics that I think we need to be
11 more specific about.

12 And just as an example of another
13 element reliability context, think about
14 reliability of an instrument. Like I know some
15 of the measures that -- well one of the measures
16 we're looking at today has the KOOS and HOOS
17 instrument to measure hip and knee pain and
18 functioning.

19 So, and I believe the reliability
20 statistics was something like a test, retest
21 reliability of that instrument. So I mean there
22 are dozens if not hundreds of articles to give

1 guidance for what are acceptable ranges of test -
2 - test reliability of an instrument like that.

3 And none of them even overlap
4 practically with the Landis scale. You know, .7
5 is considered minimum commonly.

6 So I think in that context we would be
7 charged looking forward to look at instrument
8 level reliability and what is the current best
9 thinking of that separate from the agreement
10 between rater context and so forth.

11 And finally, and I apologize this is
12 a little long-winded. But, you know, and then
13 jumping into a completely different context which
14 is the measure level reliability where the
15 distribution of data and statistics are again
16 different.

17 And so we need to look, I believe, to
18 work that is specifically evaluated, what
19 different reliability levels mean in terms of
20 misclassification and so forth in that specific
21 context.

22 Not just, you know, take one mapping

1 of statistics, adjectives in a completely
2 different context and assume it applies across
3 all contexts. So I'll stop. Thank you.

4 CHAIR CELLA: Great. Thanks, Alex.
5 I think we have Michael next.

6 MEMBER STOTO: Hi, yes. Thanks. I
7 think those are both good comments. And I think
8 mine relates a bit to what Jack was speaking
9 about. And the idea is that reliability really
10 depends, in practice, on the number of
11 observations that go into the measure. You know,
12 if you're looking at what physicians did certain
13 procedures, you have to look at how many
14 encounters. If you're looking at a consumer
15 satisfaction survey, it depends on how many --
16 what was the sample size for that one.

17 So, you know, we tend to look at this
18 in terms of testing, whether there were
19 sufficient numbers in the reliability tests that
20 are presented to us. But that doesn't really
21 answer the question. If we say something has
22 good reliability in general, or in average, the

1 question I think we need to address is, when it's
2 actually used for a performance measurement, were
3 there enough elements, however defined, to have a
4 reliable score?

5 You know, I think what we need to say
6 is, you know, this only works if you have so many
7 encounters or a sample size of x and so on. And
8 really to set thresholds for when these measures
9 are used.

10 CHAIR CELLA: Okay, thanks. That's
11 good. I think we've got Larry, then.

12 MEMBER GLANCE: Hi. Great discussion.
13 I've got a couple comments to add to this.

14 I completely agree that that Landis
15 scale is completely ad hoc. Also suspect that
16 although the Adams criteria greater than .7 is
17 slightly more based on empiric analysis, I
18 suspect that if you were to look at different
19 measures and different parts of measures that you
20 would see different thresholds for the signal-to-
21 noise ratio to be when you see physicians
22 switching from one group to another in terms of

1 performance. In our white paper, I think that we
2 kind of suggested a level greater than .7 for
3 reliability which was reasonable. And I think
4 that may be a good starting point for this
5 discussion.

6 The second comment I have is that when
7 you're looking at data reliability I think that
8 it's important to consider which data element
9 you're looking at. I think it's critically
10 important that the outcome data element be highly
11 reliable, because that's the essence of the
12 measure. If the covariates that are used the
13 risk adjusted model are less reliable that's not
14 as much of a problem.

15 So, when we're talking about data
16 reliability we may want to think about having
17 different thresholds for the outcome versus
18 standard risk factors.

19 And the third and last comment that I
20 want to make is that -- and we talked about this
21 quite extensively in that white paper -- is that
22 a risk-adjusted measure that is poorly risk-

1 adjusted, meaning that you're not accounting for
2 differences in case mix between providers,
3 hospitals, and physicians, you may appear to have
4 pretty good reliability. But then when you start
5 to really do a good job of adjusting the
6 differences in base mix, all of a sudden you will
7 see that the reliability will go down
8 substantially. Meaning that you can't really
9 evaluate score level reliability independently
10 from score level validity. If you do a poor job
11 with risk adjustment it will end up biasing -- it
12 will upwardly bias your estimate of the measure
13 reliability. Thank you.

14 CHAIR CELLA: Thanks, Larry. I think
15 we're moving along here. I've got, at the
16 moment, Sherrie, Jennifer, and Eric.

17 MEMBER KAPLAN: Hi. I want to
18 disagree a little bit with Larry, unless I
19 misconstrued your point there, Larry. But you
20 can be reliably wrong. And so the idea that,
21 like my bathroom scale is reliably wrong, this is
22 the kind of thing that we need to kind of see in

1 context.

2 And so, the idea that reliability can
3 be uniquely and kind of we can do thresholds sort
4 of without paying attention to the type of
5 measure we're using and the purpose it's being
6 put to is I think a problem, at least for me.

7 There's all different kinds of
8 reliability. Inter-rater reliability, test-
9 retest reliability, internal consistency
10 reliability, split half reliability. It depends
11 on what you're trying to measure and why you're
12 trying to measure it, the purpose you're trying
13 to put it to.

14 And I think that's important for
15 things like between physician differences. And
16 we sent around a while back some work that we've
17 done showing the variation for different types of
18 measures, like attributing to the doctors the
19 number of office visits made, for example, for
20 efficiency purposes.

21 And the variation around that is very,
22 very big. You can't discriminate between

1 physicians using that kind of measure. The error
2 variances are too large. On the other hand, for
3 composite measures, you can narrow the variance
4 very tight and then risk adjust those and then
5 you can narrow the variance so that you could use
6 those kinds of measures.

7 So, I don't think that we can
8 establish sort of what's thresholds uniformly
9 across all different types of measures for all
10 different types of purposes.

11 But, having said that, I would also
12 say that the units of analysis are a problem here
13 for us. And we need to be thinking carefully
14 about them, especially for things like
15 composites, like functional status that we're
16 going to review, because you have another term in
17 the denominator for certain kinds of units of
18 analysis at the physician level, for example.
19 You have within patient across items in the
20 denominator. Then you have across patients
21 within doctor. And then you have between doctor
22 variance all in the denominator.

1 That reliability coefficient, which in
2 this case would be an interclass correlation
3 coefficient, is going to be low. It's not going
4 to meet the targets even probably here. I
5 suspect that it's going to be down around .05.

6 And so I think that those kinds of
7 calls that we need to make about what's an
8 acceptable threshold are not going to be uniform.
9 It's going to depend on the type of measure being
10 considered and then whether or not you have data
11 element reliability, for example. And I still
12 get a little confused about that. But if you've
13 got disagreement between two raters that's very
14 low, that rating is low, and if you square those
15 Landis coefficients you get the amount of
16 reliable variance. And you can see that. So .4
17 to .59 is about 16 percent. It's roughly 20 --
18 so 36 percent. So, that's considered moderate.

19 But, you know, it depends on the
20 purpose you're putting it to. But if it's at
21 that level and then you roll it up to the next
22 level of the score level and you've got

1 imprecision there, you've got a real problem when
2 you're kind of combining that and then
3 accelerating.

4 And I put it to David Nerenz's piling
5 on the reliability problem for the error
6 variance. We've got some issues around units of
7 analysis that I think are important to consider.

8 CHAIR CELLA: Okay, just David here.
9 So far, Sherrie, even though you mentioned
10 perhaps a little bit of disagreement with Larry,
11 I'm hearing largely so far some common themes
12 about thresholds or expectations being context-
13 dependent, statistics-dependent. You can't say
14 that a guideline or threshold for one
15 automatically then carries to the others. And
16 that's with respect to what we said in the white
17 paper that Larry led about, you know, .7 is at
18 least a rough general threshold of expectation.
19 So, I think we can work through that in a bit
20 more detail. But at least so far I'm not hearing
21 sharp and clear disagreement.

22 We need to start out -- so I guess so

1 far on the list we've got Jennifer, Eric, and
2 Sam.

3 MEMBER KAPLAN: Dave, can I just kick
4 back in for one quick second?

5 CHAIR CELLA: Sure.

6 MEMBER KAPLAN: Sorry. The Adams
7 thing, the .7 came from the group comparisons
8 from Nunnally (phonetic) originally. And so it
9 was thought, well, if you can't at least achieve
10 a sort of 50 percent reliable variance you're not
11 really doing very well. And it came from
12 Nunnally a long time ago. And I think that needs
13 to be reconsidered too.

14 CHAIR CELLA: Okay, thank you.

15 MEMBER PERLOFF: This is Jen. Just a
16 quick comment to repeat something that was said
17 earlier about the minimum sample size at the
18 physician and provider level.

19 One of the things we see in resource
20 use and cost measures is that developers will
21 choose a bottom threshold, often 20 or 50 events
22 or episodes at the physician level. And they

1 obviously make a trade-off. If they lower the
2 threshold, the more physicians, clinicians can be
3 included in the measure but the lower the
4 reliability sometimes.

5 So there is this tension. And it
6 would be helpful to see developers test different
7 lower bounds on the minimum thresholds for
8 participating in the measure. So I just want to
9 throw that idea into the mix.

10 CHAIR CELLA: Okay, thanks. That's
11 good. Eric.

12 MEMBER WEINHANDL: Yeah, thank you.
13 So, I was in Subgroup 3 this time. And one of
14 the interesting facets that I see in several of
15 the measures, and I think they were common to a
16 single developer, was an appeal to a quantity
17 profile IUR. And it was new to me, so I had to
18 read the literature about what that quantity was.
19 But, if I understand it correctly, it was
20 essentially about being able to identify reliably
21 outliers, extreme values in a distribution of
22 measure scores.

1 And so I sat there and thought to
2 myself, well, how do I evaluate this in the
3 context of the guidance of the SMP? Because here
4 we're talking about, you know, essentially
5 reliability statistics for individual measures
6 that look to be pretty modest or poor on some of
7 these scales that we're talking about. The
8 profile IUR appears to be quite good.

9 And so then it raises the question of,
10 well, if we're talking about reliability, do we
11 need to be thinking about reliability in the
12 context of the intended use of the measure or
13 what, say, a payer might be interested in grading
14 facilities, physicians, et cetera, on with this
15 measure?

16 That seems to me to be a little bit of
17 a tenuous strategy because you can, of course,
18 talk about how the measure is going to be used
19 today as proposed. But what if the measure --
20 which, you know, every facility or every
21 physician -- is using for an entirely different
22 purpose in a future application such that, you

1 know, worrying about outlying values becomes less
2 of a concern?

3 And so then, you know, the interest
4 should rotate back to, say, the inter-unit
5 reliability rather than a so-called profile
6 inter-unit reliability.

7 So, I think that, you know, the
8 general point that I'm trying to make is
9 essentially that, in the context of all this
10 discussion about what are appropriate threshold
11 values for reliability, it's the question of,
12 well, if we have a measure, how will it be used?
13 And does that influence what kind of reliability
14 statistics ought to be considered?

15 CHAIR CELLA: Eric, thank you. If
16 everybody could just sort of hold that thought in
17 mind. And I think that is really the essence of
18 our next block of discussion that appears on the
19 agenda. And I also was part of the same subgroup
20 and had the same sort of observation and
21 question. So, rather than follow immediately if
22 we can just hold that we can delve deeply into

1 that when we get on that guideline.

2 Sam, I think, is next.

3 MEMBER SIMON: Hi, thanks. Yeah, just
4 very quickly I wanted to go back to a point that
5 I think was originally raised by Alex around
6 context. And when we are thinking about data
7 element reliability I think one thing to keep in
8 mind is that the prevalence of the data element
9 is going to matter quite a bit in terms of the
10 maximum amount of agreement we might see.

11 We don't often see this contextual
12 information, but I do think it would be helpful
13 to us as evaluators. So I just wanted to sort of
14 put a pin in that and raise it to the group.
15 Thanks.

16 CHAIR CELLA: Okay, thanks. I've got
17 Zhenqiu and then it looks like we have Sherrie
18 again.

19 MEMBER LIU: Yeah, hi. This is
20 Zhenqiu. So, obviously, we are all concerned
21 about low reliability, and that's understandable.
22 But I also want to draw attention to that

1 sometimes like in a monthly cycle in the past I
2 have seen in several measures reported better
3 than one. Several measures and when they
4 calculate reliability for that measure it's about
5 25 percent or even 50 percent with measure
6 reliability as one. I mean, just I'm very
7 skeptical.

8 CHAIR CELLA: Let me just follow up on
9 that. I can think of a couple where we've seen
10 that. Is there any way that we could possibly
11 raise questions about a "too good to be true"
12 sort of situation? How do we think about those
13 when they come in front of us?

14 MEMBER LIU: I think it depends on
15 content also. You know, I would prefer more
16 detailed information, more nuanced information.
17 So it may just show you something that I
18 calculate this in that certain method. And
19 certain methods tend to give you higher number.
20 You know, I have seen the same data using
21 different methods to calculate you can get really
22 different. And, you know, some can get you .8 or

1 .9 and you use a different method you get .3, .4.
2 So, it's not easy -- I'm not sure there's an easy
3 solution.

4 CHAIR CELLA: Okay. So, Zhenqiu,
5 thank you. I've got Sherrie and Alex.

6 MEMBER KAPLAN: Hi, this is Sherrie.
7 The issue with the sort of really, really high
8 levels of reliability seen caused me to wonder,
9 and this happened a few times a few cycles ago
10 too, where it looked like the measure developer
11 was averaging at the patient level across
12 patients just averaging the patient level data
13 for each hospital, which isn't how you, you know,
14 would do hospital level, for example, interclass
15 correlation coefficient.

16 So, I think that's come up before.
17 And it does raise questions about it. But it
18 goes back to detail. If we could get more detail
19 about exactly how things were being done, what
20 measures were used, and how they were being
21 calculated, that would help us to understand
22 whether or not we can believe what we see.

1 CHAIR CELLA: Okay, Alex.

2 MEMBER SOX-HARRIS: Yeah, to continue
3 that thread, I mean the whole -- in research it's
4 more common for journals and others to ask for
5 source data and statistical code to enhance
6 transparency and evaluation of what people
7 actually did. It's a whole open science
8 framework that's similarly just asking for more
9 access to the details.

10 So, that's something that could be
11 considered. Is that some kind of minimum data
12 set? And actual statistical code, the computer
13 code that was used to generate the statistics, so
14 we can answer these questions more directly about
15 did they do it right.

16 CHAIR CELLA: Okay. Jeff.

17 MEMBER GEPPERT: Yes. Just a question
18 for the methods folks. So, does it matter if the
19 measure uses some kind of shrinkage to the mean?
20 Does that change the way that we think about the
21 reliability metric or any potential evaluation of
22 the reliability metric?

1 CHAIR CELLA: Sherrie, do you have an
2 answer?

3 MEMBER KAPLAN: Well, any time you
4 inflate the mean you're obviously going to reduce
5 the variance. But you probably spuriously
6 inflate the reliability as well because you're
7 inflating the mean and shrinking the variation
8 around the mean, which is going to usually help
9 you with precision.

10 CHAIR CELLA: Jack.

11 MEMBER NEEDLEMAN: Yeah. What the
12 shrinkage methods do is basically they say we
13 acknowledge that the folks with smaller sample
14 sizes are inherently less reliable. And they
15 move them towards the mean. They average the
16 mean of the overall sample with the value for
17 that individual unit. And the rating of that
18 averaging depends upon the sample size.

19 So, that's what's going on with
20 shrinkage, basically, which means that the
21 smaller practices are all pulled in closer to the
22 middle. And, you know, I sat on another panel

1 where one of the folks complained bitterly about
2 losing information about individual units. But
3 the fact is that we've got low reliability in
4 those small units. We see that when we get these
5 tables by size, the quartile by size, and we see
6 the reliability statistics much smaller.

7 So, they're trying to deal with the
8 problem of reliability smaller in these units.
9 The question is, from our perspectives endorsing,
10 whether the shrinkage method accommodates our
11 concerns about low reliability for smaller n's
12 within practices or whether we'd like to see the
13 thresholds simply increased, and whether the
14 shrinkage is an inherent part of the measure or
15 something that's done later on when people are
16 applying it in practice.

17 I can't remember seeing explicit
18 statements in any of the measures I've reviewed
19 that said "we're going to be using Bayesian
20 shrinkage here."

21 So, I think those are the issues that
22 are raised for us in looking at that. Is that an

1 acceptable way to deal with the inherently low
2 reliability of low volume units? Or do we want
3 to see the thresholds raised? And do we need to
4 see an explicit discussion of the impact of that
5 for the reliability?

6 CHAIR CELLA: Okay, thanks. Paul had
7 his hand up.

8 MEMBER KURLANSKY: Can you guys hear
9 me now?

10 CHAIR CELLA: Yes.

11 MEMBER KURLANSKY: Okay. So, this
12 issue of shrinkage is something that comes up in
13 the Society of Thoracic Surgeons database. And
14 it's something we struggle with in terms of the
15 reliabilities of the measures for small programs.

16 And one thing that might be helpful is
17 if there was some way, in such situations, for
18 the developer to show reliability over time. In
19 other words, you know, just in a simple
20 explanatory, you've got a small program that had
21 a zero percent mortality on a given year, so the
22 shrinkage would not assign that zero percent

1 mortality. But if you were actually to follow
2 that same site for three or four years and they
3 had zero percent mortality you would tend to
4 believe it.

5 So, I'm just wondering, in situations
6 where shrinkage is used, if there could be some
7 sort of additional requirement to show for the
8 small volume sites, for whatever is being
9 measured there, the reliability over time of the
10 measure.

11 CHAIR CELLA: Okay, good point.

12 Patrick has a hand up. Is Patrick on mute?

13 I guess not. David here again.

14 I'll quickly pass this question to our
15 NQF staff folks, and recognizing our time block
16 is about to close on this topic.

17 A lot of the discussion that we've
18 had, and I have a full page of notes here so far,
19 might be cast in the question of, what's the
20 minimum requirement? Essentially, what's the
21 pass/fail cut-off?

22 But if we go back to our ratings we

1 still have this moderate, high. In the future,
2 as you envision it, is there any possibility of
3 our group coming up with some kind of numeric
4 criteria for assigning values of moderate versus
5 high? And if we did that, would that make any
6 difference downstream in the other steps of the
7 process, or even all the way out the back side to
8 the way measures are identified as being
9 endorsed?

10 Is it conceivable that trying to work
11 on some kind of distinction like that would
12 matter in a tangible and positive way, or should
13 we focus strictly on the issue pass/fail?

14 MS. WILBON: Hi, Dave. This is
15 Ashlie. It's a good question. I don't know that
16 I have an answer. I would say to the -- I think
17 my first reaction would be: simpler is better.
18 Yeah, without thinking about it a little bit
19 more, I don't know if I have an answer right now.

20 But I think both are potentially
21 viable. So, I think, you know, again my gut
22 reaction is simpler is better, that maybe a

1 pass/fail might be more digestible, for not only
2 the Panel but for external audiences. And it
3 might be a good place to start and then if
4 there's more details we can filter that.

5 CHAIR CELLA: Okay. Seeing that
6 Patrick is having trouble with sound let's do
7 Daniel and see if we can get Patrick back on
8 before we close out.

9 MEMBER DEUTSCHER: Yes, thanks. This
10 is Daniel. I just wanted to note that in some
11 cases the extremely high reliability could also
12 be related to very high sample sizes analyzed.

13 And I think we're seeing some of these
14 examples through our last cycle. So, for
15 example, analysis as a health plan level.

16 So, I just wanted to note that's
17 probably also one possibility for those extremely
18 high reliability results.

19 CHAIR CELLA: Okay, thanks. Larry.

20 MEMBER GLANCE: I just put my hand
21 down, thanks.

22 CHAIR CELLA: Okay. So, I hate to cut

1 Patrick off here. Any chance Patrick is
2 reconnected?

3 MS. WILBON: We're troubleshooting
4 now. We're going to try to work in the
5 background on that. But I don't think he is on
6 yet.

7 CHAIR CELLA: Okay, because otherwise
8 just watching the time and making sure we stay
9 tight, I've got quite a good set of notes here
10 and I appreciate the discussion and the thought
11 that you've put into this.

12 What I can commit to doing is to
13 summarize the notes and try to organize it in
14 terms of a set of issues that we might look more
15 deeply into and at least potential, some steps
16 forward because clearly what seems to be
17 happening here is that we're moving away from
18 anything like a blanket acceptance of .4 as a
19 minimum standard.

20 I haven't heard any support for that
21 at all, which is a pretty significant thing
22 actually. And I'll summarize that.

1 And we can then sort of offline by
2 email take up some next steps of, you know, who
3 is specially knowledgeable about this, who is
4 interested, who might want to work further on it.
5 But I appreciate the thoughts and this has been
6 useful. Thank you.

7 We'll try to get Patrick on and we'll
8 get connected sooner or later and, Patrick, I
9 won't forget you.

10 MS. WILBON: Thanks, Dave. And,
11 Patrick, if you are able to type your questions
12 in the chat box we can at least try to read your
13 question out and maybe or comment and at least
14 have an idea of what you would like to say.

15 And we can come back to it. And
16 that's another way to communicate if you're not
17 able to get your audio. So, we'll keep moving.

18 And as Dave mentioned earlier, the
19 next set of discussions was around, for
20 reliability was around the IUR and PIUR which was
21 something which was a reliability statistic we
22 saw in several of the measures.

1 I believe that were in Subgroup 3.
2 And I think there were a lot of, we got several
3 comments not only in the preliminary analyses
4 notes but also from the Panel Members who emailed
5 us directly about wanting to have this discussion
6 about how we should be interpreting this and
7 particularly how the PIUR should be evaluated.

8 There were some measures that provided
9 the PIUR and some that didn't and how that should
10 be, how that should be interpreted.

11 The other question I think that was
12 posed in some of the analyses and from some of
13 the Methods Panel Members after their reviews
14 were whether or not this particular test or other
15 types of tests only demonstrate reliably for a
16 particular purpose.

17 So, for example, detecting extreme
18 outliers or demonstrating stability and whether
19 or not this is a method that would be acceptable
20 for demonstrating reliability of a measure that
21 may be used in any context for any purpose given
22 that our current criteria and process does not

1 provide endorsement for a particular use, but
2 just around the use for a particular, for any
3 accountability purpose.

4 And then I think the final issue which
5 we've already touched on quite a bit is around
6 the idea of volume and minimal sample sizes and
7 reliability testing and whether or not the
8 testing results should be explicitly associated
9 with the volume or sample size.

10 So, I'll pause there and I'll hand it
11 back over to the Daves to continue this
12 discussion. I did just want to point out that
13 one of the background materials that we shared,
14 the C.F. Howe (phonetic) article talked in detail
15 about the PIUR.

16 Hopefully you found that a helpful
17 reference for this question. And, Dave C. and
18 Dave N., I will hand it back over to you guys to
19 get this discussion going. Thank you.

20 CHAIR NERENZ: Dave C., this is Dave
21 N. I think we didn't choreograph this in
22 advance. How about if I continue this one and

1 then you get the next two? Does that work?

2 CHAIR CELLA: It does. I think this
3 is all yours. Go ahead.

4 CHAIR NERENZ: Well, now that's not
5 quite true. No, I think this is -- and Eric come
6 in earlier about this a couple times hinted at
7 this.

8 The, a number of measures this time
9 had this two-part analysis where they had IUR and
10 PIUR almost in every case. The IUR was not
11 impressive. The PIUR was pretty good.

12 And the conclusion would seem to be
13 then the measure is not very good for doing
14 things like putting people in quintiles or giving
15 star ratings or comparing Provider A to B,
16 somewhere in the middle of distribution.

17 The measure would be reliable enough
18 though to identify extreme outliers. That's not
19 the kind of rating or the kind of decision we're
20 asked to make.

21 The practical question is what do you
22 do with this? You know, we can take that

1 combination of statistics and say the measure
2 passes and it leaves our hand saying it's
3 reliable.

4 But clearly everything we've looked at
5 says it's reliable for one thing but it's not
6 very reliable for another thing. So, it's kind
7 of an open question here, what do we do with
8 this?

9 And I think, you know, NQF staff and
10 experts are certainly welcome to weigh in because
11 the -- I think we are only allowed as a practical
12 thing in what we've done this cycle and what we
13 have yet to do in the next day or so, we have to
14 use the criteria we're given.

15 We have to use the categories we're
16 given. But is that going to work going forward
17 in a situation like this?

18 And how can we handle something like
19 the ones we have in front of us, good enough for
20 one thing, not good enough for another purpose?
21 I have Alex, Eric, Michael, Paul.

22 MEMBER SOX-HARRIS: This is Alex. One

1 conceptual shift that might help us instead of
2 thinking of this as two uses of the same measure
3 is to say these are two different measures,
4 related measures but they're different measures
5 and need to be evaluated separately.

6 And if we think of measures as, you
7 know, specified with an output, one output is
8 just a distribution of, you know, performance.
9 And the other is okay, a determination of whether
10 each individual site is an outlier or not.

11 So, I think if we can put it in
12 separate measures we can evaluate them
13 separately. The analysis, validity would need to
14 map onto the actual structure of each measure and
15 that might solve the problem.

16 CHAIR NERENZ: Eric.

17 MEMBER WEINHANDL: Thank you. And
18 sorry for jumping the gun on this topic earlier.
19 I wasn't looking ahead on the agenda to realize
20 the level of detail.

21 And so, I like what was just proposed.
22 I wanted to ground it in a little bit of reality

1 insofar as I understood some of the measures that
2 I typically encounter in the analysis phase.

3 I think that the challenge is that we
4 truly don't have any control for how the measure
5 is used. And in fact, the measures -- The
6 individual measures are used for both profiling
7 the entire space of say thousands of facilities
8 being evaluated and in other applications they're
9 used specifically for outlier detection.

10 So, some of the measures it's not as
11 though we are in front of the SMP in this cycle.
12 So, your standardized mortality ratios,
13 hospitalization ratios for the healthcare
14 facility.

15 On the Compare website somebody could
16 use this when a consumer accesses the website and
17 they see evaluation of facilities that are within
18 their region or their area or their zip code
19 they'll simply see text labels that correspond to
20 as expected, greater than expected, lower than
21 expected.

22 So, essentially there is text labels

1 that correspond to outlier detection. So, that
2 said, all right. We'll profile IUR. That will
3 be a great new thing to track if that's what
4 you're using the measure for.

5 On the other hand, those very same
6 measures like standardized mortality and
7 hospitalization ratios are used in star ratings
8 and they're used in other kinds of payment system
9 that Medicare operates under Parts A and B.

10 And in those systems it's the point
11 estimate. It's literally only the point
12 estimate.

13 There is no consideration of the
14 competence or the precision of the point estimate
15 that's used when facilities are slotted in
16 through distribution and assigned a certain point
17 value that rolls up into a summary support
18 measure.

19 So, I guess I'm showing my cards here.
20 But I think that the practical reality is that we
21 have no control. And in fact, these measures
22 truly are used for, entirely just for purposes by

1 in this case the same payer, Medicare.

2 So, I think it's -- It would be
3 disingenuous for us to say well, as long as one
4 or two of the measures or one or two of the
5 reliability metrics are accessible, then we can
6 proceed with providing cover for the measure.

7 CHAIR NERENZ: Okay, thanks. Mike.

8 MEMBER STOTO: Yes. I think this is
9 going to be a really challenging discussion. I
10 personally think we actually have to challenge
11 the assumption that NQF makes that we either
12 endorse a measure or we don't.

13 I think that what we've just been
14 saying, you know, of how it depends on how it
15 will be used and how it depends on the sample
16 size essentially, means that it really isn't
17 scientifically justifiable to say this is either
18 valid or this is either endorsable or not.

19 And so, I think that the alternative
20 is to say this is endorsed for certain purposes
21 or this is endorsed with minimum sample sizes or
22 things like that. Basically, to work them into

1 the specifications.

2 I recognize that might be a big
3 change. But I think that we need to consider it.

4 CHAIR NERENZ: Yes, thanks. Ashlie
5 and others, any quick response to that? I know
6 this isn't the first time this has come up.

7 But for the next two minutes as we
8 talk about this should we spend time thinking
9 about how that might be done or is that forever
10 off limits?

11 MS. WILBON: It's a tricky question.
12 I will say that NQF has certainly been through
13 iterations of thinking through endorsement for
14 particular purposes.

15 And it's, you know, something that we
16 don't currently do. And so, we haven't actually
17 ever landed on that as a strong path forward
18 because there are just so many considerations and
19 nuances.

20 And we haven't ever, I think been able
21 to reach consensus at the level of stakeholders
22 and various leadership bodies to go in that

1 direction.

2 I think, I realize it does present a
3 dilemma of kind of the reality versus us trying
4 to, you know, have an endorsement type period
5 that is agnostic to use.

6 But I think at this point I think that
7 should be our path forward because we don't -- we
8 wouldn't be able to provide any guidance at this
9 point on kind of the concept of this
10 infrastructure in which, you know,
11 recommendations around, you know, reliability
12 testing or any other types of recommendations for
13 measures around a particular use of it.

14 So, it is a tough question. Again, I
15 don't have a specific answer.

16 But I think the safest place is to be
17 where our current policy lies which is, you know,
18 testing, you know, should be submitted and
19 presented in a way that there is confidence from
20 the reviewers that if the measure is used in any
21 accountability purpose that it is reliable for
22 that, you know, for that use in the context of

1 any particular accountability purpose.

2 So, yes. Apologies I don't have
3 anything more specific. And I think that's just
4 probably a question of where we are in this space
5 at this point for endorsement.

6 Yes, I think that's it. I'm not sure
7 that was very helpful.

8 CHAIR NERENZ: I know it's a tough
9 issue because we're talking about a fairly
10 significant change in NQF policy and past
11 practice.

12 It's just, I think it's in front of us
13 that a number of people wanted this discussed
14 because the developers themselves essentially in
15 their presentation told us reliable enough for
16 some things but not for other things.

17 They're sort of compelling us to think
18 it through. I see Patrick with a hand up.
19 Hopefully we've got the sound issues worked out
20 now.

21 MEMBER ROMANO: Yes, can you hear me
22 now?

1 CHAIR NERENZ: Yes, we're good. Thank
2 you.

3 MEMBER ROMANO: Okay, great. Yes,
4 sorry. I've just been waking up on the West
5 Coast and I thought I was on Zoom. So, I was not
6 dialing in properly.

7 So, anyway I wanted to make a point I
8 think others have here that as we think about
9 inter-unit reliability really we shouldn't be
10 thinking about a threshold.

11 We should be thinking about how the
12 reliability measures provide guidance in how the
13 measures should be used. It's not a question of
14 whether the measure is acceptable or not.

15 It's a question of how to use the
16 measure in a way that it becomes acceptable. And
17 so, we've already talked about some of these
18 suggestions.

19 So, I could easily as a measure
20 developer manipulate the inter-unit reliability
21 or I shouldn't say manipulate, maybe enhance is a
22 better term by, for example, using two years of

1 data instead of one year of data to do the
2 calculation or by setting a minimum volume
3 threshold and saying that this measure should
4 only be used for providers of greater than a
5 certain volume or as Jeff suggested earlier, you
6 raised a very interesting question.

7 Didn't really answer it. But the
8 point is that once you do shrinkage the classic
9 signal-to-noise estimation approach doesn't work
10 anymore because you've used that approach to
11 actually shrink or reliability adjust the
12 measure.

13 And so, that is a way of addressing
14 the problem. But we have to realize that we are
15 making a tradeoff then. We're making the measure
16 more reliable by shrinking it toward the mean for
17 small units.

18 But in so doing we're compromising
19 validity and there as we're introducing bias.
20 And so, we accept that tradeoff in certain
21 applications.

22 But we might not want to accept that

1 tradeoff in other applications. So, I think that
2 as we understand this problem of inter-unit
3 reliability better it really does challenge the
4 traditional assumption of, you know, whether the
5 NQF endorsement is a stop-go, red light/green
6 light kind of process or whether it's really an
7 issue of reliability particularly about providing
8 guidance to users about how to use the measure in
9 a way that it has acceptable reliability in
10 practice.

11 CHAIR NERENZ: That's good, thanks.

12 I currently have Paul, Larry, Sherrie in that
13 order.

14 MEMBER KURLANSKY: So, I think this is
15 extremely challenging issue which I struggle with
16 philosophically and practically. And it came up
17 in this context with the PIUR.

18 It also came up in context with the
19 socioeconomic risk adjustments, et cetera. And
20 it's extremely difficult.

21 I mean even if we were to provide
22 advice to how a measure could be used,

1 unfortunately I think, the more I think about
2 this I think there is probably no ability to
3 actually control what will actually be done once
4 the measure has received some level of approval,
5 which makes me tend to think that we should apply
6 sort of a minimum standard, if you will or maybe
7 that's not the right term.

8 But in other words, the measure should
9 be considered, the threshold should be high, in
10 other words.

11 There, for every application that we
12 can see this reasonably being used what would be
13 the reliability rather than the low threshold
14 which would be well, for this particular
15 situation, you know, to identify outliers it's
16 okay, but to develop and distinguish people who
17 are in the vast majority of the middle it is not
18 reliable.

19 Therefore, we would approve it for
20 this particular purpose. I don't think we can
21 practically do that.

22 And so, I'm tending to think now that

1 perhaps we should be very, have a very high
2 threshold and say or any, you know, application
3 for which this could reasonably be applied it
4 would have to be, they would have to demonstrate,
5 the results would have to demonstrate
6 reliability.

7 MS. WILBON: Hi, Dave. This is
8 Ashlie. If I could just jump in quickly. Jack
9 and I were actually having the chat on the
10 webinar about this exact issue.

11 And his question was, you know, am I
12 implying that given that we don't endorse the
13 specific uses of reliability just based on the
14 potential use that requires the highest
15 reliability.

16 And I think what Paul just stated is
17 exactly kind of what I would say but he stated it
18 much more eloquently. You know, given the
19 spectrum of accountability applications and we
20 don't know where the measure might be used and as
21 it's been stated we don't know how a measure
22 might be used by any program or we can't predict

1 that in the future that, you know, we should
2 thinking about evaluating the measure that is
3 good enough for any accountability application.

4 And that may be the highest level of
5 accountability down to the lowest level of
6 accountability and that we should kind of be
7 thinking in that context at this point in time.

8 And hopefully that's helpful. And I
9 think again, what Paul stated I think is very
10 much in alignment with what we would like to be
11 thinking here.

12 And so, based on where we are at this
13 point not having endorsements for particular
14 purposes. I think, you know, the other challenge
15 is that, you know, tagging measures before, you
16 know, particular purposes often gets lost.

17 So, when measures are endorsed, you
18 know, there's an asterisk next to it or, you
19 know, special consideration that this measure
20 should only be used for x purpose. That gets
21 dropped, it gets lost.

22 We had in the past a time-limited

1 endorsement where measures that didn't have
2 testing yet could have a time-limited
3 endorsement. And so, what we found is that what
4 people kind of latched on to was the endorsement
5 piece.

6 And all the other kind of asterisks
7 and details about the conditions of that
8 endorsement were lost. And so, that's one reason
9 why we kind of had moved away from that.

10 But I think having, you know,
11 endorsement means the same thing for all measures
12 is the place that we should, you know, kind of be
13 focusing and trying to think about how our
14 evaluations could support that perception for
15 people who are using an endorsement.

16 CHAIR NERENZ: Good. I've got Larry
17 and Sherrie and Jack if you want to jump in too
18 after that.

19 MEMBER GLANCE: I'm a little worried
20 about going right before Sherrie because she's
21 going to respectfully disagree with some things
22 I'm going to say.

1 CHAIR NERENZ: She can probably --
2 (Simultaneous speaking.)

3 MEMBER GLANCE: At the high level
4 validity or reliability or whatever we want to
5 say, so I've got a couple of points that I want
6 to make.

7 The first one and I think the most
8 important one is I think that we, you know, at
9 the end of the day we need to be kind of
10 pragmatic here.

11 We're having a really, really
12 difficult time choosing a threshold for just the
13 classic inter-unit reliability or what we often
14 times consider it's signal-to-noise ratio.

15 And that is going to be tough for us.
16 The profile inter-unit reliability, it's a very
17 interesting way of looking at reliability. This
18 is something that is just now appearing in the
19 literature.

20 And it uses the abstract. The authors
21 published this about a year ago said we propose
22 an alternative measure of reliability. This is

1 new.

2 I don't think we need to establish
3 this as one of our testing criteria for
4 reliability. I think we should let this play out
5 a little bit and see what other people think
6 about this before we adopt this as one of our
7 standard tools to evaluate measure level
8 reliability.

9 That's my first comment. The second
10 comment I really want to iterate I think this is
11 a lot -- Is that when you look at measure level
12 reliability you first need to convince yourself
13 that the risk adjustment for a risk adjusted
14 outcome measure is balanced because if it's not a
15 lot of the variability between providers, and
16 that's what's going to drive your reliability in
17 part, is maybe because you have inadequate risk
18 adjustment.

19 So, if you have a, you know, you look
20 at cardiac surgery if you're going to compare
21 quaternary care centers that take care of the
22 sickest of the sick to the community hospitals

1 that take care of really routine cases and if you
2 don't do any risk adjustment, that's the extreme
3 of broad risk adjustment, there's going to be
4 really good reliability because there's going to
5 be a big spread in outcomes between the providers
6 that have the high mortality rate and the
7 providers that had the lowest mortality rates.

8 So, I think you need to look at risk
9 adjustment when -- First before you look at
10 measure level reliability.

11 And then the third point I want to
12 make, I want to push back ever so gently on the
13 comments that Patrick made.

14 I think that what we call enhancements
15 so the use of volume cut offs, looking at a
16 longer time frame, the use of shrinkage, I think
17 those are perfectly acceptable ways truly
18 pragmatic ways to allow you to measure
19 performance, provider performance in a reliable
20 way.

21 So, if we know consistently that very
22 low volume providers and those that have case

1 volumes less than 25 that their performance just
2 jumps around in a very erratic fashion would be
3 what you would expect because of the small sample
4 sizes, it's okay.

5 And that doesn't mean something is
6 messed up. The second point is same thing with
7 time frame. There is nothing wrong with looking,
8 instead of looking at one year maybe looking at
9 two years or maybe even three.

10 It's a little problematic when you go
11 out further to the longer time frames because it
12 may be that the quality of a provider changes
13 over time. But that is still something that we
14 have to consider.

15 And then the third thing is use of
16 shrinkage estimators or reliability adjustment is
17 a very standard approach. And it's being used
18 increasingly by many groups.

19 It's what CMS does. And there are
20 some heated arguments about using it or not using
21 it. But I don't see any reason that we should
22 penalize measure developers because they use

1 shrinkage estimators.

2 That is a very valid and acceptable
3 approach. And what it does is it basically
4 minimizes the fairly, sometimes fairly wide
5 fluctuations that you see in provider performance
6 when the provider volumes are low, okay.

7 So, those are the main points that I
8 want to make. The first one again, profile
9 inter-unit reliability, I don't think we need to
10 go there.

11 The second point, consider risk
12 adjustment before you look at measure level
13 reliability. And third, the enhancements --
14 they're okay. There's nothing wrong with it.
15 Thanks.

16 CHAIR NERENZ: Okay, thank you. Good
17 place to go. Sherrie, do you want to
18 respectfully disagree or are you going to go a
19 different direction? Is Sherrie on mute?

20 MEMBER KAPLAN: There I am. Am I okay
21 now?

22 CHAIR NERENZ: You're good enough.

1 MEMBER KAPLAN: Okay. So, I wanted to
2 respectfully agree with everything Larry said.
3 And I don't want to agree on the shrinkage
4 estimating rabbit hole.

5 But I wanted to come back to a point
6 to Ashlie's point. I got confused about what
7 exactly the, you know, purpose of measurement,
8 what you're going to do with that now.

9 And I'm concerned again about if
10 you're going to use my weight on my bathroom
11 scale for my psychological well-being that's
12 fine. That's a good purpose.

13 But if you're using it to give me
14 anesthesia, you know, it's wrong and I'm going to
15 get into trouble. So, I really am concerned that
16 NQF, CMS changed the game when they started
17 adjusting compensation.

18 They adjust, you know, we went from
19 quality improvement when Helen and I were having
20 this discussion years ago about NQF's agnostic
21 position on the purpose of measurement, from
22 quality improvement to quality assessment and

1 then adjusting compensation.

2 So, maybe a way forward is to, for NQF
3 is to consider the reliability question for
4 different units of comparison.

5 While it may be okay at one level of
6 comparison unit like the hospital or something it
7 might not be as good for or reliable for
8 estimating physician performance, for example,
9 comparing -- certainly not comparing individual
10 physicians.

11 Is that a position NQF could think
12 about or have some basis for kind of adjusting
13 purpose at the unit of comparison level?

14 MS. WILBON: It could be. I think the
15 challenge is that we're not there yet. And it
16 would take some time to get there.

17 And again, I don't have a great answer
18 because, you know, it's something that we kind of
19 -- we tried a couple times in the past to think
20 about this issue and how it might impact the
21 weight of the endorsed measures.

22 It doesn't mean that we can't revisit

1 it and I think we should. But I just, I get a
2 little bit -- I don't want to have you guys
3 coming up with recommendations or guidance on a
4 future that could be and we're not sure what the
5 context of that is or what the kind of parameters
6 for that would be.

7 And so, I guess, I think my response
8 would be, yes, it's something we can and should
9 consider. But it would be a future, you know, a
10 potential future state.

11 MEMBER KAPLAN: Thanks.

12 CHAIR NERENZ: And actually, Dave N.
13 here. Clearly, we get into highly forbidden
14 territory if we cross the line in starting
15 endorsing or approving uses themselves.

16 It's not really our territory. Our
17 focus should be on the measures.

18 But clearly again, examples as with
19 these IUR/PIUR distinctions we're looking at data
20 that tell us that a measure is reliable enough
21 for a certain kind of use, is not reliable enough
22 for another.

1 It doesn't mean we're judging the use
2 itself. We're just saying, is the measure good
3 enough for this or that.

4 I'm also, I noticed here as we go
5 along the point Eric made a few minutes ago
6 about, you know, if you look at the portfolios
7 ways in which CMS uses certain measures.

8 And sometimes in which it's the point
9 estimate and the variance, but other times it's
10 the point estimate only. It's the same measure
11 that's used because it's NQF endorsed.

12 But if we really pull back the layers
13 of the onion we might say that the endorsement
14 should have supported one or two of these uses,
15 but not have supported the other one.

16 So, I'm left with the idea that it's
17 hard for us to fully step up with integrity to
18 our task as a scientific methods panel to judge
19 reliability without somehow going a little
20 further and saying reliable enough for x, y, and
21 z, but not reliable enough for p, q, and r.

22 I understand there are a lot of

1 details to work through all the way through the
2 CSAC and Board level at NQF about how that might
3 play out.

4 But I just, you know, I'm sort of
5 going back to the beginning of this that in some
6 of these cases the measures, the cycle of the
7 measure developers themselves have essentially
8 made that statement.

9 And then we have to somehow deal with
10 that. Daniel has got a hand up. Go ahead,
11 Ashlie, and then Daniel.

12 MS. WILBON: Yes, a quick question in
13 response to that. Is it, could it be though that
14 this particular task is not one that we would
15 want -- if it is narrow in scope in that way and
16 the idea is that NQF endorsed measures could be
17 used for any accountability application, is it
18 that this just isn't one that we would want to be
19 for measures that are presented?

20 I'm kind of thinking about it the
21 opposite way instead of us thinking about
22 applying endorsements or a particular purpose

1 based on the test submitted, but to provide some
2 guidance to say if you were looking for, you
3 know, measures that could be used for, you know,
4 the spectrum of accountability applications that
5 these are the types of tests that could
6 demonstrate that and that maybe this is one of
7 those tests.

8 Is that something to consider? I'm
9 just trying to kind of digest the discussion as
10 well.

11 CHAIR NERENZ: Yes, Dave here. I
12 guess just responding for myself, I wouldn't go
13 that way at all because it seems to me that the
14 more information that we get about reliability in
15 different forms and different flavors is just as
16 useful scientific information about the
17 evaluation measures suitable for this or that
18 purpose.

19 So, I would not ever shut anything off
20 and say we don't want to see it. I think the
21 question is, what do we do with it when we do see
22 it? I've got Daniel and Jack in the queue now.

1 MEMBER DEUTSCHER: Yes, this is
2 Daniel. What if I ask a question on whether
3 there may be a suitable first step could be that
4 instead of going all the way to an endorsement
5 for a particular purpose which definitely
6 requires more thought and I acknowledge it could
7 be difficult to monitor and control, my question
8 is could NQF request that at least the minimum
9 threshold of number of cases or minimum time
10 period needed to achieve an acceptable level of
11 reliability first identified by the developers
12 and then added to the specification?

13 MS. WILBON: Daniel, could you repeat
14 the last part of your comment, sorry?

15 MEMBER DEUTSCHER: Yes, sure. I was
16 wondering whether NQF could request that the
17 minimum threshold of number of cases or the
18 minimum time period or a combination of both
19 needed to achieve an acceptable level of
20 reliability be first identified by developers
21 because we've noted that not all of the
22 developers go ahead and identify those

1 thresholds?

2 And then add that to measure
3 specification. It sounds like you would need,
4 you know, a compromise on maybe a first, a
5 suitable first step going forward with some kind
6 of restriction in terms of the use of the measure
7 under certain conditions.

8 MS. WILBON: Yes, I think that's a
9 good question. It's actually something that we
10 have been trying to do when possible to encourage
11 developers to indicate, you know, sample size
12 requirements and include it in the
13 specifications.

14 I think that is something very
15 feasible that we could do and it is something
16 that we do try to do. It's not -- and we could
17 probably be more explicit about it in our
18 guidance.

19 But I think that's certainly a very
20 feasible approach.

21 MEMBER DEUTSCHER: Okay, thanks.

22 CHAIR NERENZ: I've got Jack and Mike.

1 MEMBER NEEDLEMAN: Thank you. We are
2 in a very rich discussion. And flying through a
3 bunch of things on the schedule. I really want
4 to come back to this issue of reliability for
5 use.

6 But just want to note, shrinkage we
7 ought to have on another call because there are
8 multiple methods there including not ignoring
9 things which, you know, right now most of our
10 shrinkage measures are towards the general mean
11 and the question is whether those methods are
12 appropriate, whether we're losing information
13 about relative performance and we simply average
14 to the general mean.

15 And we've got risk adjustments later
16 in the discussion. So, I just want to endorse
17 the thought that if the risk adjuster isn't doing
18 the work it's supposed to do, we do not have a
19 valid measure.

20 But coming back to this issue of
21 reliability for specific uses. I think one of
22 the elements that we've seen in this discussion

1 is that NQF does not endorse for specific uses.

2 We've been told that. The question is
3 how that will affect our reliability judgment.
4 What I've seen specifically from new measures is
5 to some extent recognizing they won't immediately
6 be used for payment of the area where people
7 generally feel is the highest reliability is
8 needed.

9 So, to accept a lower level of
10 reliability for an early endorsement of a
11 relatively new measure to see how it plays out to
12 get more data and so forth.

13 But given what we've said there is not
14 going to be endorsement for use, the question is
15 whether we should all be moving our standards for
16 reliability to the level that we would require
17 for the use that we think requires the highest
18 level of reliability?

19 I think one of the consequences of
20 that is a bunch of measures may not get endorsed
21 that would have gotten endorsed in the past.

22 But we ought to be thinking

1 individually and collectively about whether
2 standards for reliability ought to be in the most
3 restricted use or the use that requires the
4 highest reliability.

5 I'm taking from this conversation,
6 that's where I'm going to be moving in my
7 assessments. But we ought to be thinking about
8 that and I'd love to hear some guidance from the
9 other, from the governing boards and to some
10 extent from the developers about their
11 preferences about endorsements for use versus
12 always applying the most restrictive or the
13 highest levels of reliability.

14 And I think we ought to be inviting
15 people to give us that feedback to help us in how
16 we use the and how we assess the reliability.

17 CHAIR NERENZ: Thanks, Jack. I've got
18 Mike in the queue. But I've also got Apryl with
19 a hand up. Apryl, do you want to come in on
20 something that should be said or talk about some
21 of the policy issues?

22 MEMBER STOTO: Well, this is Mike and

1 I actually do want to do that.

2 CHAIR NERENZ: Okay, Mike, go ahead.

3 MEMBER STOTO: Yes. I just wanted to
4 second Daniel's suggestion and maybe extend it a
5 little bit. I think that asking the developers
6 to say what's the minimum sample size I think
7 would go a long way.

8 And, you know, in a way it's not that
9 different from what we already do because we
10 require that they test it based on data that's
11 related to how it will be used. And sometimes
12 the developers lay out, you know, how the
13 reliability depends on the number of encounters
14 and things like that.

15 So, I think that we could just try to
16 look at that more carefully and get that to be
17 done more extensively.

18 CHAIR NERENZ: All right, thanks.
19 Apryl. On mute maybe. Okay, so let's get to
20 Gene, sorry.

21 MS. WILBON: It's Ashlie. I was going
22 to ask the operator if you, we'll try to get

1 Apryl on a future line.

2 CHAIR NERENZ: Okay. Let's go to Gene
3 then.

4 MEMBER NUCCIO: Real quick, given that
5 we've got about five minutes before we're
6 supposed to have a break. This is a second
7 bullet and I don't know whether we're still on
8 the first bullet.

9 It falls on the same line. It's not
10 exactly about use.

11 But when we look at the data that's
12 provided, for example, detecting extreme outliers
13 and discover that the measure is very good at
14 detecting extremes but very poor at detecting
15 differences and nuanced differences between 2 and
16 9 in our ten point or categories, I think we
17 should always think about the general use of
18 these measures which is for public reporting at
19 the very minimum. And for performance for many
20 of the measures either individually or as a
21 composite.

22 And so, if they provide -- if the

1 developer provides different information about
2 how well the measure detects extremes it's very
3 important evidence that it can detect the large
4 majority of differences or differences among the
5 large majority of our providers we should be, I
6 would suggest rejecting that because the normal
7 use for these measures will be for public
8 reporting and/or pay for performance.

9 CHAIR NERENZ: Good point, thank you.
10 And if I could just paraphrase it may be that if
11 we don't end up ever in the near future
12 specifically endorsing for use we could
13 anticipate the range of uses out there and set
14 reliability thresholds and presumably validity
15 thresholds with endorsed measures for the kind of
16 uses that the developers talk about or we think
17 will happen.

18 So, it's a matter of where you set the
19 threshold more so than specific yes/no decisions
20 on acceptability for certain uses. Did I go too
21 far in my paraphrase or is that about right?

22 MEMBER NUCCIO: That's about right.

1 My point is that as evaluators of the measure we
2 should be thinking about how do they, what's the
3 evidence that the measure performs well in all
4 reasonable situations?

5 And reasonable situations, can you
6 detect outliers? If they give us good
7 information that they will then fantastic.

8 But if they can't make a distinction
9 between a 2 and a 9 on a ten point scale then,
10 you know, it doesn't pass basic reliability.

11 CHAIR NERENZ: Okay. Do we have Apryl
12 connected?

13 MS. CLARK: Hi, all. Can you hear me?

14 CHAIR NERENZ: Yes.

15 MS. CLARK: Hi. So, this is Apryl
16 Clark. I am the acting vice president of quality
17 measurement here at NQF. And so, I have been
18 working with Ashlie on the Methods Panel.

19 So, it's great to talk with you all
20 today. I just wanted to maybe just chime in
21 about sort of, you know, endorsement for use.

22 It's actually something that we, the

1 NQF has actually been thinking about. We have
2 had some other issues that have come up in
3 endorsement committees where we would consider
4 different type of measures.

5 So, as you guys talked about there are
6 sort accountability measures. There's quality
7 improvement measures. There's appropriate use
8 measures.

9 And so, many times those measures
10 don't necessarily always fit exactly into our
11 criteria. And our Standing Committees have kind
12 of talked about how you, you know, they think
13 they are important measures but how do they feel?

14 So, reliability is one of those things
15 that has come up. And so, we've actually been
16 thinking about is there different levels of
17 endorsement or different ways of endorsement?

18 So, I'm not sure I would call it
19 endorsement for use per se. But I think that's
20 the idea is that maybe endorsement would be for
21 accountability measures and they have a certain
22 like criteria that they have to meet.

1 But maybe there's a clarification that
2 would be for quality improvement measures because
3 they would have a different level to meet. And
4 then that's kind of how we would kind of think
5 about both the criteria and Part B.

6 And as Ashlie mentioned, I think, you
7 know, a little bit the challenge in making sure
8 that measures are used in the appropriate way.
9 But it actually is really something that we're
10 thinking about.

11 So, I think this has been a really
12 fantastic conversation.

13 CHAIR NERENZ: Thank you. All right,
14 I'm inclined then to turn back to Ashlie. We
15 have hit the bottom of the hour.

16 Want to respect people's time and
17 biological needs and other pressing things. So,
18 Ashlie is here.

19 MS. WILBON: Yes, absolutely. Thank
20 you, Dave. And thanks, everyone for really great
21 discussions.

22 I think we'll be looking forward to

1 getting hopefully some participation from
2 everyone on getting these ideas down on paper and
3 having more thoughtful discussions about them in
4 future papers as well as future webinars. So,
5 with that again with attention to your other
6 needs, including those biological ones we want to
7 -- We're going to take a break for an hour.

8 Let's plan to reconvene at 12:30. And
9 so, hopefully you guys will be able to tend to
10 all of your needs.

11 We're looking forward to coming back
12 and finishing our last few kind of content level
13 discussions before diving into our measure
14 evaluation discussions later in the afternoon,
15 around 3:30 after another break.

16 So, we'll see you back at 12:30. If
17 you are able to, obviously if you want to hang
18 up. You might want to stay on the webinar.
19 We'll keep the webinar open so that you don't
20 have to go back that process.

21 But keep in mind that you will need to
22 dial back in and to give yourself time to get

1 back on the line so that we can be ready to go at
2 12:30.

3 CHAIR NERENZ: Ashlie?

4 MS. WILBON: Yes.

5 CHAIR NERENZ: Can we leave the phone
6 lines connected if we don't need to hang up?

7 MS. WILBON: Yes, you can, you can.

8 CHAIR CELLA: Ashlie?

9 MS. WILBON: Yes.

10 CHAIR CELLA: This is Dave Cella, Dave
11 C. Is it possible for Sam Simon and Dave N. and
12 you to stay on for just three minutes if we could
13 talk about the next session?

14 MS. WILBON: Also, sure. I also
15 wanted to ask Alex Harris because I realize I
16 inadvertently swapped their names. And I think
17 Alex was the one who emailed me about this issue.

18 CHAIR CELLA: Okay.

19 MS. WILBON: But I for some reason put
20 Sam down. Sam, I'm happy to have you still
21 participate and I think it will be great to have
22 a couple other discussors.

1 But I also wanted to include Alex if
2 you're able to stay on. Apologies for that mix
3 up.

4 PARTICIPANT: No problem.

5 MEMBER AUSTIN: So, Sam, you can stay
6 on. Alex, can you stay on and Dave N. and
7 Ashlie? Everyone else can sign off.

8 (Whereupon, the above-entitled matter
9 went off the record at 11:33 a.m. and resumed at
10 12:29 p.m.)

11 MS. WILBON: Let's go ahead and get
12 started.

13 I wonder if folks from the Methods
14 Panel, if you're on or didn't hang up and you're
15 back on, or you're back on from dialing in, if
16 you could just give us a hello, just so we have a
17 sense of how many folks are on the line?

18 Or, Operator, could you give us a
19 sense?

20 CHAIR NERENZ: Or you can raise your
21 hand and lower it, too.

22 MS. WILBON: Oh, perfect, Dave.

1 That's a great idea.

2 CHAIR CELLA: If that was Ashlie, by
3 the way, your voice is very distant.

4 MS. WILBON: It was. Thank you. Let
5 me try to fix my headset here.

6 CHAIR CELLA: That was a little
7 better, actually. Maybe just speak up.

8 I've seen about five or six hands go
9 up. Mike Stoto is sending a message saying he's
10 back.

11 I think we can get started. People
12 will join in.

13 And this first topic for the second
14 half of the morning or early afternoon, to a
15 large extent, is a continuation of the previous
16 discussion, particularly that part of the
17 discussion in the previous session that related
18 to reliability demonstrated for a specific
19 purpose. But the specific question came up --

20 (Simultaneous speaking.)

21 MS. WILBON: Hi. Could we have folks
22 mute your lines?

1 Operator, I'm not sure if you can help
2 us with the muting of the lines. That would be
3 great.

4 CHAIR CELLA: Thank you. Thanks.

5 MS. WILBON: Could everyone who's
6 speaking please mute their lines?

7 CHAIR CELLA: Okay. I'll try again.

8 So, welcome back.

9 And now, we're going to talk about the
10 relationship between reliability and validity.
11 It may be a shortened session because we covered
12 this topic to some degree in the previous
13 session.

14 But this was a specific question that
15 came from Alex, actually, although Sam is named
16 on the agenda. And the discussion question was:
17 if the measure has been shown to only reliably be
18 used to characterize outliers, should the
19 validity testing mirror this use? This issue
20 came up, actually, in the previous discussion.

21 So, Alex, would you like to tee it up
22 specifically with regard to the

1 reliability/validity question?

2 MEMBER SOX-HARRIS: Sure. So, this
3 issue came up for me on several of the measures
4 that we were evaluating. And as our previous
5 discussion highlighted, many of the measures the
6 developer presented reliability for either two
7 uses or two forms of the measure, however you
8 want to think about it, one being the inter-unit
9 reliability for the whole distribution of
10 performance scores and the other the reliability
11 for the PIUR for the identification of extreme
12 outliers. And we had a very rich discussion
13 about how we should think about that.

14 And extending it into validity, and
15 moving on to the validity analyses and evidence
16 that was presented, sometimes the evidence would
17 pertain to the IUR formulation and other times it
18 would be constructed in such a way to map onto
19 the PIUR formulation. So, I think the general
20 question is, how should validity evidence
21 presented map onto the sometimes multiple forms
22 or uses presented in the reliability analysis?

1 CHAIR CELLA: And, Dave N., did you
2 have a comment you wanted to make, also, as part
3 of kicking it off?

4 CHAIR NERENZ: No, I think that's
5 enough to get it started. I just was observing
6 that I don't think in the earlier discussion, we
7 specifically linked the reliability and validity
8 discussions, but there may not be a whole lot to
9 add. The question seems to be, if you looked at
10 reliability using a certain approach or a certain
11 kind of purpose, like getting rid of outliers,
12 should the validity testing match? But I think
13 that's already been teed up.

14 CHAIR CELLA: Good. Okay. So, the
15 floor is open for input, discussion.

16 It may be that people feel that this
17 has been sufficiently discussed in the previous
18 session. I don't see any hands up.

19 CHAIR NERENZ: Yeah, I would tend to
20 agree. I mean, if the question is, should the
21 reliability and validity analyses match, I think
22 a reasonable answer is yes.

1 CHAIR CELLA: Hearing no objection to
2 that reasonable answer, and seeing no hands still
3 up, we may be able to steal a little bit of time
4 for some of the future discussions and move
5 things along.

6 So, last call for any comments on this
7 issue.

8 MEMBER ROMANO: This is Patrick.

9 CHAIR CELLA: Go ahead.

10 MEMBER ROMANO: One thing I might add
11 is that -- I think this was alluded to earlier --
12 but in some cases the reliability, the inter-unit
13 or inter-provider reliability could be falsely
14 high because the provider signal is capturing
15 both the variation in risk and variation in
16 outcomes. So, if the risk portion is not dealt
17 with appropriately, then you're essentially
18 exaggerating the provider signal because the
19 provider signal is capturing both features.

20 So, again, this has some implication,
21 right, because what it means is that these
22 metrics of reliability are to some extent

1 dependent on our ability to separate confounding.
2 And I don't know how that applies to this
3 particular question, but it may have an
4 application.

5 We're probably on the cutting edge of
6 research in this field to understand it better,
7 but we know, even, for example, the Adams
8 approach assumes no variation in risk. It
9 assumes that everyone has the same risk. And
10 that's really not a valid assumption for outcome
11 measures. So, the Adams approach is sort of
12 geared more towards process measures, where
13 everybody can do what they're supposed to do.
14 And we have to be thinking a little bit
15 differently for outcome measures.

16 CHAIR CELLA: That's a great point.

17 Eric, you've got your hand up. Go
18 ahead, Eric.

19 MEMBER WEINHANDL: Yes. It's an
20 interesting question. I must admit to speaking
21 of my own way of sort of processing these when I
22 think about hospitals or other kinds of

1 facilities that are being evaluated.

2 To the extent that a measure developer
3 draws attention to outlier detection, I certainly
4 am interested -- or maybe I should say that I'm
5 suspicious, of course -- that outliers may
6 actually be more likely to reflect unmeasured
7 risk adjustment or residuals of modeling, just
8 because of unique sociodemographics within a
9 particular area where the facility is located.
10 There may be particular sort of patient
11 characteristics or medical phenotypes that a
12 particular facility is concentrating on, and
13 sometimes with an administrative database those
14 can be very difficult to extract.

15 So, I must admit that, although I
16 didn't think about it in this cycle as I was
17 looking at these measures that had a profile IUR
18 reported with them, it would be nice to see that,
19 if a measure developer proposes that a measure is
20 focused primarily on outlier detection, that
21 there was some evaluation or some reassurance
22 that these outliers that are being detected also

1 are as ably addressed by the risk adjustment
2 scheme as sort of overall is.

3 CHAIR CELLA: A good point again.

4 Okay. So, I think we should move on.
5 Thank you for that input.

6 Can we move the slide to the next
7 session?

8 And we're going to talk now about risk
9 adjustment. I think that we'll focus on social
10 risk adjustment, but probably risk adjustment
11 generally. And, Ashlie, you were going to set
12 this up for us.

13 CHAIR CELLA: Sure. Thanks, Dave.

14 Can everyone hear me okay?

15 CHAIR NERENZ: Still a little faint,
16 but not bad.

17 MS. WILBON: Okay. Is this better, a
18 little bit better?

19 CHAIR CELLA: That's better, yes.

20 MS. WILBON: Okay. Great. I pulled
21 the mic a little bit closer.

22 So, with this discussion of social

1 risk adjustment I think we had actually a very,
2 fairly extensive discussion over email just after
3 the evaluations were done. I think that was
4 triggered by an article maybe that Gene shared,
5 or someone. And I think that was an initial
6 start for this discussion, and then, I think
7 certainly after the results for the preliminary
8 analysis were shared back, there was some more
9 discussion amongst the panel via email about the
10 Methods Panel's role in providing evaluation of
11 social risk adjustment.

12 I think certainly everyone understands
13 at this point that NQF prefers that decisions
14 around the actual factors included in the risk
15 model, including social and clinical factors, are
16 left to the standing committees, although we
17 certainly recognize that SMP members will have
18 substantial and important feedback on those
19 factors as well, given your own backgrounds and
20 expertise in risk adjustment and other areas.

21 And so, we certainly want to provide
22 the opportunity for the Methods Panel to give

1 feedback to standing committees on things they
2 should be thinking about when they're looking at
3 the measure in totality, as we look through all
4 of the criteria and in more detail at the
5 clinical aspects of the measures.

6 And I think the question, then, comes
7 up, so if the Methods Panel is not voting on
8 validity, particularly with an eye on social
9 factors, but certainly has perspectives to share
10 what is the best way to provide that guidance to
11 standing committees and how can we ensure that
12 the standing committees are considering all the
13 factors that were not only recommended in the NQF
14 report, but also ensuring that developers are
15 kind of using methodologies and making decisions
16 on risk adjustments that align with current
17 guidance and research?

18 So, I'll pause there, and then,
19 certainly hand it over to Dave N. for comments,
20 as he was very involved with NQF's report on
21 social risk adjustment, as one of the chairs.
22 So, I'll just hand it over to you, Dave, for

1 additional comments.

2 CHAIR NERENZ: Yes, thanks, Ashlie.

3 I'll just mention a few things specifically about
4 the issue of social risk factors.

5 As Dave and Ashlie both pointed out,
6 I think the practical questions in front of us
7 apply to risk adjustment in general. The social
8 risk factors are just a specific example. And
9 this was on my mind in the cycle because a couple
10 of the measures that came to the subgroup that I
11 was on coupled social factors in a certain way
12 that raised questions for me. And then, it
13 raised the subsequent question about how do we
14 convey that message. If we think something is
15 not correct, how do we convey that? Where does
16 that message go?

17 Again, this is not new to us. So,
18 I'll do this very briefly. I think, as most
19 people know, prior to 2015 and 2014, the strict
20 policy at NQF was that social factors like
21 poverty, homelessness, minority status could not
22 be included as adjusters in performance measures.

1 And then, a panel was convened in 2014. I was
2 co-chair of that. We had a group of experts kind
3 of like the one we have gathered together today,
4 but experts on this issue. We had conference
5 calls. We had meetings. We then issued a report
6 that basically changed the policy or recommended
7 that it be changed.

8 And a couple of the essential things
9 were that, after we really talked this through,
10 we said social factors should be treated exactly
11 the same as clinical factors in their inclusion
12 or exclusion from risk adjustment models.
13 There's no reason to treat them differently.

14 Then in both cases you think about
15 whether the variable was present before the start
16 of care. The fundamental constant was that, if a
17 particular variable stands as a marker or somehow
18 reflects differential quality of care, then you
19 don't want to adjust for it because you may be
20 adjusting away quality differences that you want
21 to see reflected in the adjusted measure.

22 On the other hand, if the variable

1 reflects other influences apart from quality of
2 care, particularly if the providers being
3 evaluated have no control over it, you do want to
4 adjust because, then, you get the clearest, least
5 biased signal about quality of care.

6 And so, that report was issued. The
7 CSAC and the Board did change the NQF policy. So
8 now, as you see actually in the text, in the
9 materials that the developers use, they're asked
10 to work through, is there a conceptual
11 relationship for the variable? Is there an
12 empirical relationship, so that there's some
13 association between a factor like poverty and the
14 measure? Usually, outcomes are the ones we're
15 talking about here. And then, ultimately, is or
16 is not included in the adjustment model?

17 Now what we've seen over the years,
18 since when this report was issued, the public
19 comment was vastly in support of all the national
20 provider organizations' plans, everybody in its
21 court. CMS weighed in against, as did six other
22 organizations.

1 And so, to this day, we still have
2 situations where a measure is presented to us.
3 All the background work is done, in some cases
4 very thoroughly. Is there a conceptual
5 relationship? Is there an empirical
6 relationship? The answers come up yes, yes, yes.
7 And then, in the end, they say, but we choose not
8 to include this factor like poverty because we
9 choose to.

10 We never see that for factors like
11 diabetes or depression. If they seem to be
12 associated with the outcome, and it's understood
13 that it's harder to achieve good outcomes with
14 patients with these kinds of problems, they're in
15 the adjustment models, they never get pulled out
16 after. So, there is a differential treatment.

17 Okay. That's all just background.
18 The reason this is on my mind in this cycle is
19 that in a couple of specific measures I was asked
20 to review, I thought that the analysis of some
21 candidate social factors was wonderful. I mean,
22 it was thorough. It was thoughtful. It brought

1 in all the relevant data. It did careful
2 analysis. It was great. And all of that, to my
3 mind, said that these factors should be in the
4 adjustment model. Then, the developer said, no,
5 we choose not to include them because we don't
6 want to. Okay.

7 So now, my quandary, as a reviewer,
8 is, what do I do about that? I'm not allowed to
9 fail the measure on either reliability or
10 validity grounds, except perhaps down Larry's
11 line of thinking, if I say this problem
12 essentially invalidates the reliability
13 statistics. But I'm left with the question, what
14 do I do? I can write a comment, but what happens
15 to it?

16 So, that's sort of the end of my
17 framing, and I am looking forward to some
18 discussion, including from our NQF experts about
19 what actually can we do and what should we do in
20 situations where we believe the risk adjustment
21 is not appropriate, not good enough? And that
22 would be true if it's a social factor or a

1 clinical factor.

2 CHAIR CELLA: Well, that's a really
3 great history and setting up of the issue. And
4 there's a lot to unpack there, Dave, but I think
5 the core question you're asking is, how can we
6 send a message that the standing committee will
7 hear that relates to concerns about not including
8 social risk adjustment when it appears that it
9 should be included? And the only sure way to
10 have that seen would be to vote low on
11 reliability, based on what Larry has pointed out,
12 as you said, that if the risk adjustment isn't
13 right, then the reliability is off. But I don't
14 know if you can tell that from a submission.

15 So, I open it up for discussion,
16 including NQF, if you want to help guide the
17 parameters of what's possible here, or what's not
18 possible.

19 Mike's got his hand up. Go ahead,
20 Mike.

21 MEMBER STOTO: Yes. I think this is
22 a really important issue. I'm not quite sure I

1 understood the issue about, not risk adjustment
2 being a reliability issue, but it certainly is a
3 validity issue. That's why we talk about a risk
4 adjustment in the validity section. And it seems
5 to me that we should treat risk adjustment as it
6 either makes this valid or not valid, regardless
7 of whether we're talking about clinical issues or
8 socioeconomic factors.

9 If we think, and the evidence
10 suggests, that there really are sociodemographic
11 factors that matter, and the developer doesn't
12 want to do that, I think we could say, therefore,
13 the method scores low on validity, just as we
14 would if it were on clinical characteristics.

15 CHAIR NERENZ: Yes, Dave here. Let me
16 just, I'll channel Larry here, but he can
17 certainly jump in.

18 I think the connection to reliability
19 was this idea that, if you're dealing with
20 signal-to-noise statistics and then, because you
21 didn't do acceptable risk adjustment, some of the
22 apparent signal is based on things other than

1 quality, then the lack of adjustment means that
2 the reliability statistics are inflated and,
3 therefore, questionable.

4 MEMBER STOTO: Okay. Thanks. This is
5 Mike again.

6 That clarifies it, and I agree with
7 that, but I still think that what I said holds.
8 If we think that it should be risk-adjusted for
9 whatever characteristics, and if it's not, that's
10 a reliability -- excuse me -- that's a validity
11 issue.

12 CHAIR CELLA: I'm just going to try to
13 see. Jack had his hand up, but, apparently, he's
14 on mute. I don't know if he can speak. Jack,
15 why don't you give it a try?

16 MEMBER NEEDLEMAN: Okay. Can you hear
17 me?

18 CHAIR CELLA: Yes, I can hear you.
19 Let me add one thing just so people
20 know. I believe that Larry is not on the call
21 right now. He had to take an hour off for a
22 COVID situation, but he'll be back later, if we

1 want to bring him into this.

2 But go ahead, Jack, and then, it will
3 be Patrick and Paul.

4 MEMBER NEEDLEMAN: Yeah, just so we
5 have consistency and we're scoring things, I
6 think we want to decide whether the problem with
7 risk adjustment is a reliability problem or a
8 validity problem. I tend to think of it as a
9 validity problem because the core of our measures
10 for a lot of these are observed to expected. And
11 the expected is driven by the risk adjustment.
12 If the risk adjustment model is wrong, not doing
13 what we think it's supposed to be doing of
14 getting an accurate assessment, a valid
15 assessment of expected, then the measure is not
16 valid.

17 CHAIR CELLA: Yes, I suspect, based
18 upon the setup of this question on the slide,
19 that NQF agrees with that because they did say
20 that this would not be a basis for voting
21 low/insufficient on validity. And I think if
22 they saw it as a reliability issue, they would

1 have probably said reliability. I'll let them
2 speak for themselves, but my guess is that that's
3 probably where NQF is on this question as well.

4 MEMBER NEEDLEMAN: Well, then, can we
5 get some clarification? If we're supposed to be
6 assessing validity, and we think poor risk
7 adjustment is making the measure invalid -- we
8 haven't got the right expected count -- are we
9 supposed to nonetheless accept the measure on
10 validity, waive that concern? What concerns do
11 you want the next committee to do, put that in?
12 How do they want us to handle this? I'm happy to
13 handle it in any way I'm told to.

14 MS. WILBON: Right. This is Ashlie.
15 I think there's a couple of things
16 that -- can you guys hear me okay?

17 CHAIR CELLA: Yep, yes.

18 MS. WILBON: Okay. I think there's a
19 couple of things that would be potentially on the
20 table for us. I certainly sense the frustration,
21 and I do want to also reiterate that we do pass
22 on that discussion. Each measure that occurs at

1 the Methods Panel level is summarized and
2 provided to the standing committee in relatively
3 great detail. We give them the preliminary
4 analysis, the combined PAs. We give them a
5 summary and their worksheets when they evaluate
6 it. And so, those issues are passed on. I
7 think, certainly, we could maybe find some ways
8 internally, as staff, to make the issues I think
9 a little more clear and stand out a little bit
10 more.

11 The other thing is that we had this
12 kind of moratorium -- I don't know if moratorium
13 is the word -- but kind of prohibition in place
14 in terms of voting down the measure before we had
15 the policy in place where standing committees
16 could pull measures for discussion, even if they
17 did not pass. And so, something that could
18 potentially be on the table is, you know, we
19 could still allow the Methods Panel to vote as
20 they have been voting, as they would like to
21 vote, and in alignment with what they're seeing
22 in the submission. And so, the signal about the

1 validity would be in the vote, but, then,
2 standing committees would have the option to pull
3 a measure for that reason for discussion. So,
4 that's something we could, you know, it would
5 potentially be in that bucket of measures that
6 could be pulled for further discussion.

7 And at that point in time, we would
8 certainly share the details about why the Methods
9 Panel felt that that measure did not pass
10 validity, if it was something specific to the
11 risk adjustment or the inclusion or not inclusion
12 of social factors. So, that's something we could
13 consider.

14 Again, it's one of those process
15 issues, but I think there may be some things we
16 can do on our end. But, certainly, if there's
17 other guidance that the Methods Panel has for
18 developers, in particular, or for standing
19 committees as they're evaluating it, I think that
20 will be helpful as well.

21 CHAIR CELLA: This is Dave C. I'm
22 just going to, I think, repeat what you said

1 there, Ashlie, but make sure that my repetition
2 doesn't distort what you're saying.

3 I think you're indicating that NQF
4 will consider a change in this position that not
5 including social factors in a risk model should
6 not be a basis for low/insufficient validity.
7 And the reason you can consider that change now
8 is that, between the time this policy was written
9 and today, you've allowed for standing committees
10 to pull measures back in for discussion. So,
11 they would be able to pull in a measure
12 application that has been deemed low/insufficient
13 on the basis of social risk adjustment, or any
14 risk adjustment, for that matter. The fact that
15 they can pull that in would enable this committee
16 to actually go ahead and make that vote, which I
17 think gets at Dave N.'s concern about not knowing
18 how to signal this concern other than putting a
19 comment that might not be seen. Is that right?

20 MS. CLARK: This is Apryl. Yes. So,
21 hi. This is Apryl. I just wanted to sort of
22 jump in here.

1 I'm sort of new to the quality
2 measurement side, but certainly I've been working
3 on, I've been here since the social risk trial
4 started. So, I appreciate the background.

5 I think I would want to make sure that
6 we have the social risk trial actually being
7 funded. We're actually looking at measures that
8 come in. You have the conceptual basis and how
9 we're sort of thinking about that. And before we
10 make any changes, I'd want to make sure that
11 we're kind of tying the work that you guys do to
12 the work that that's doing and we can come out
13 with sort of an organizational-wide kind of
14 policy on social risk.

15 So, I'm not saying that we wouldn't
16 necessarily consider having the Committee -- you
17 know, as Ashlie mentioned, but I'd want to make
18 sure that we're sort of thinking about it a
19 little bit more broadly across the endorsement
20 portfolio, tying it into the current work that
21 we're doing, before we would make any policy
22 changes. But I understand the frustration, as

1 Ashlie mentioned, about being able to do that.
2 But I just want try to bring that other work in,
3 make sure that we're thinking about it, you know,
4 sort of holistically.

5 CHAIR CELLA: No, that's helpful. So,
6 Apryl, I was careful to say that consider as
7 opposed to making a policy change here on a phone
8 call.

9 MS. CLARK: Yes.

10 CHAIR CELLA: So, would you say that
11 that is accurate, that sort of a reconsideration
12 of this could be done in the context of the
13 larger picture, as you say?

14 MS. CLARK: Yeah. I mean, I think
15 that there is lots of discussion going on all
16 around the table --

17 CHAIR CELLA: Right.

18 MS. CLARK: -- including with our
19 standing committee, about this issue.

20 CHAIR CELLA: Yes.

21 MS. CLARK: So, I'll make that part of
22 the discussion about that.

1 CHAIR CELLA: Okay. So, thank you.
2 That's very helpful.

3 So, with that in mind, are we now on
4 Patrick? Or Paul?

5 MEMBER ROMANO: Yes.

6 CHAIR CELLA: Patrick. Go ahead,
7 Patrick. And then Paul, and then Gene.

8 MEMBER ROMANO: Yes, I think that I'm
9 putting this discussion in the context of the
10 refresher that Ashlie gave us a few hours ago
11 when I was just waking up about the validity and
12 how we assess validity, and the fact that we can
13 take into consideration the performance
14 characteristics of a risk-adjustment model,
15 including its discrimination, its calibration, et
16 cetera, but we're not supposed to take into
17 consideration presence or absence of any specific
18 risk factor. And, of course, as we're now
19 talking about social determinants, that fits into
20 that framework clearly.

21 But, obviously, this is a bit of a
22 funny distinction, right? Because we know that,

1 let's say that we see from the evidence that has
2 been presented that the model is miscalibrated
3 with respect to low-income people, right? I
4 mean, the natural consequence of excluding social
5 determinants from a model where those
6 determinants belong is that the model will now be
7 miscalibrated for those individuals. So, the
8 absence of those factors from the risk model
9 becomes a calibration issue, and then, it becomes
10 fair game for us to discuss, as it were.

11 In other cases, a risk model may
12 appear to perform well. I mean, the C-statistic
13 may be, let's say, .75. But we know from
14 previous published literature that the
15 C-statistic ought to be .85. And if they had
16 adjusted for other things that they didn't adjust
17 for, then it probably would have been .85.

18 So, again, that leads us to say, well,
19 even though .75 might be considered adequate, we
20 know that it's not where it should be, and this
21 means that there's residual confounding or
22 omitted variable bias. And we have a pretty good

1 sense what those omitted variables are, even
2 though we're not the clinical specialists who are
3 on the standing committee, and therefore,
4 empowered to comment on the specific things that
5 should be in the model.

6 So, I'm just saying that this idea of
7 evaluating the overall performance of the model,
8 including particularly its calibration as well as
9 its discrimination, is not completely separable
10 from this issue of what's in the model.

11 CHAIR CELLA: Thank you, Patrick.

12 Paul?

13 MEMBER KURLANSKY: A few comments,
14 though, some of which are going to echo things
15 that have already been said.

16 But I don't think we need to say
17 definitively that this is an issue of either
18 validity or reliability. I think Larry's
19 analysis is probably pretty sound that a very
20 inadequate risk model can skew your assessment of
21 reliability. I mean, I have to agree that it is
22 fundamentally an issue of validity, but it can

1 certainly impact reliability. So, I don't think
2 we need to say that it is purely an issue of one
3 or the other. I think we can just acknowledge
4 that it impacts both.

5 Having said that, I guess I would
6 strongly hope for a potential change in policy
7 because, as other people have said, if we assess
8 a risk model and find that it's methodologically
9 flawed and inadequate, so if we find that it's
10 methodologically flawed and inadequate because of
11 this particular issue, then we can't comment on
12 it or we can't use that to vote that it is low
13 validity. But if we find a methodologic issue,
14 that it's inadequate based on some other
15 parameter, we can. It puts us in a very
16 compromised and untenable position, just as a
17 methods group.

18 So, I think that there is a certain
19 ambivalence right now in the policy to where it
20 has to be included and assessed, but it can't be
21 used as a criterion. I think that really puts us
22 in a very odd position.

1 The final comment is, having said
2 that, this gets back a little bit to the issue
3 that we talked about before as to what the
4 metrics are going to be used for. For example,
5 if you elected not to put in these factors
6 because you were going to use this metric in
7 order to identify those sites which needed more
8 assistance and more support and more finances,
9 then you might specifically want to leave this
10 metric out -- I mean, excuse me -- you may want
11 to leave these parameters out for that particular
12 reason, because you want to identify sort of
13 underserved sites that need help. Then, it might
14 be a very compelling reason to leave it out.

15 But if we can't know or determine
16 exactly how the metric is going to be used, then
17 I think we have to go back to the sort of maximal
18 criteria. And based on maximal criteria, I think
19 if the risk model is inadequate, it's inadequate.

20 CHAIR CELLA: Thank you, Paul.

21 Gene?

22 MEMBER NUCCIO: Yes. Hi. In the

1 interest of complete disclosure, I was a member
2 of the NQF panel that Dave Nerenz chaired a few
3 years ago on sociodemographic risk factors. And
4 so, I come to this with a certain bias.

5 Kind of working from the bottom up in
6 terms of the questions on the screen, not all
7 risk factors have an equal impact on an outcome
8 or a provider's ability to achieve an outcome
9 with a patient. And as the number of risk
10 factors increases -- and I had examples this time
11 around where there were in excess of a hundred
12 risk factors that were used in the equation for
13 the prediction equation -- obviously, no single
14 risk factor is going to make that much
15 difference.

16 So, I think the rationale provided by
17 some of the developers that, well, it only
18 accounted for 1 percent of the difference, and so
19 that's not much, so we're going to ignore it --
20 one of these sociodemographic risk factors -- is
21 bogus. Because when you put a hundred risk
22 factors into an equation, individually, there

1 isn't going to be a lot of change with any
2 individual risk factor, adding it in. Stepwise,
3 it might show something different.

4 The second question that's asked is
5 the decision to include or exclude in the
6 provider's control. I call this is the
7 developer. So, in many cases the developers did
8 a really excellent job of showing that, in fact,
9 there is a relationship between a patient risk
10 factor of which the patient -- or the provider
11 has no control over, such as maybe the
12 availability of health care institutions in this
13 area or nutrition, or whatever, but then simply
14 decides not to do it.

15 Well, if the developer can simply
16 ignore the suggestion -- I think it's stronger
17 than a suggestion -- the directive from the NQF
18 that sociodemographic risk factors be included in
19 a prediction model for risk adjustment, then, you
20 know, what teeth is there in terms of having them
21 acknowledge the fact that hospitals, for example,
22 that deal with patients who are primarily

1 homeless are going to have poor risk factors if
2 you're not adjusting for whether or not they have
3 a permanent residence? Now we're not asking them
4 to correct the problem of homelessness, but we
5 are simply saying that the outcomes that the
6 provider can achieve is directly affected by
7 these kinds of risk factors.

8 And finally, I agree with the previous
9 presenter or caller where they said it is not
10 validity or reliability; it's both, primarily, in
11 my mind, validity. And if we're asking if these
12 measures are being used to make distinctions
13 among providers, not just in terms of the quality
14 of their work, but also in terms of whether or
15 not they get rewarded monetarily -- and there's a
16 lot of value-based purchasing measures out there
17 -- then we need to enforce in some way that, when
18 you demonstrate that there is a relationship
19 between the sociodemographic risk factor and an
20 outcome, that those need to be included just as
21 the clinical risk factors would expect to be
22 included.

1 I'm sorry I took so long.

2 CHAIR CELLA: No problem, Gene. Great
3 points. Thank you.

4 Christie, you've got your hand up. Go
5 ahead, Christie.

6 You may be on mute, Christie. Can you
7 try to unmute yourself?

8 (No response.)

9 MS. WILBON: We'll work with Christie
10 to make sure she's connected.

11 CHAIR CELLA: Yeah. I think we'll do
12 something offline here, some on-the-side work to
13 see if she's muted remotely, and we'll come back
14 to you, Christie.

15 Jennifer has her hand up. Go ahead,
16 Jennifer.

17 MEMBER PERLOFF: Okay. Great. I have
18 multiple phones ringing here.

19 One concern I have with some of the
20 sociodemographic risk factors is that they often
21 require bringing in external or new data not
22 necessarily related to the core data source, like

1 claims or surveys. And we rarely see what
2 missing data gets introduced into the mix because
3 of these factors being added. So, are there
4 missing data elements? Does the assessment
5 sample size go down when you try these measures?
6 That's just something I feel like we never get
7 good visibility on, and maybe it's a non-issue
8 sort of in this space, but a little bit
9 tangential, I just wanted to raise it.

10 CHAIR CELLA: Okay. Thank you.

11 I guess Christie's going to be trying
12 to dial back in to a number that allows us to
13 hear her.

14 Any other comments?

15 CHAIR NERENZ: Yes, Dave N. here.

16 Just a quick response to Apryl.

17 At least in my framing of this issue
18 and the questions I raised, I wasn't seeking in
19 any way to change broad NQF policy or to get out
20 of line with broader discussions of policy about
21 social risk factors. It was really about how to
22 implement the policy currently in place, where

1 developers are asked under certain criteria to
2 include social risk factors if a set of criteria
3 are met. And our question is, as the Methods
4 Panel, what action can we take and what decisions
5 can we make if the treatment isn't satisfactory
6 according to the policies that currently exist?
7 So, again, not pushing for any change that's out
8 of line.

9 CHAIR CELLA: This is Dave C.

10 I don't know if Ashlie or Apryl want
11 to say anything to that.

12 But, if I'm not mistaken, at least one
13 of the seven submissions we'll talk about, this
14 will come up in that context. So, even though
15 it's good to know that NQF is going to take this
16 up under kind of a more general set of issues
17 that are under review and discussion, we will be
18 hoping for some guidance during this meeting,
19 specifically when these come up, when this comes
20 up again in the specific measure context.

21 I still haven't seen Christie join in.

22 So, we'll go to Eric and, then, Jack.

1 Are you there, Christie?

2 MEMBER TEIGLAND: Can you hear me now?

3 Yes?

4 CHAIR CELLA: Yes, I can hear you now.

5 So, go ahead, Christie. You're up next.

6 MEMBER TEIGLAND: All right. Yes, I

7 had to call in. I could hear, but I couldn't

8 speak, I guess.

9 Yes, I just wanted to reinforce

10 everything that has been just said. This has

11 been a thorn in my side since we started this

12 process and it seems to be getting worse, not

13 better.

14 And I just wanted to bring it home

15 with a real example. Well, there are many in the

16 measures I evaluated this round. But there were

17 some cost measures, and, yes, they did a great

18 job, as you said, laying out the conceptual

19 basis. They found that the social risk factors

20 were significant.

21 And when they presented the data, this

22 time they actually showed what the difference

1 was. These are cost measures. So, the cost for
2 a dual-eligible patient in a skilled nursing
3 facility is 18 percent higher across. For a non-
4 white in a skilled nursing facility it's 25
5 percent higher. But, then, they said, yes, we
6 already have 120 variables in the model and this
7 doesn't improve the model fit.

8 What does that say about those skilled
9 nursing facilities operating on very tight
10 margins who have 14 to 25 percent higher costs,
11 who are treating patients with these social risk
12 factors? Is it going to hurt the quality of care
13 or is it really going to impact access to care
14 for those people?

15 And the variables were significant
16 even in the model. It wasn't even like, oh, we
17 added them in at the end. And, of course, they
18 didn't add any -- you know, they weren't
19 significant. They were significant in the model.

20 So, there's something wrong with the
21 model, right, when you have that big of a
22 variance in cost for these groups, but you're not

1 finding that in the risk-adjustment model. So,
2 there's something wrong here.

3 There was absolutely zero rationale,
4 as far as I could tell, to not include them, but
5 you're right, they just said, but we're not. We
6 decided not to. So, I think we need to do
7 something about those kinds of situations.

8 CHAIR CELLA: Well, that really brings
9 it home. Is that one you're referring to one of
10 the seven we'll be discussing?

11 MEMBER TEIGLAND: I don't think we're
12 going to discuss this measure. It's the PAC
13 Smith measure. I think they passed. Yeah, I
14 think they passed. These measures passed because
15 they had decent validity/reliability, which kills
16 you to make those judgments when you know they
17 are not being appropriately specified.

18 CHAIR CELLA: That really does bring
19 it home, Christie. Thank you.

20 MEMBER TEIGLAND: Yes, yes.

21 CHAIR CELLA: Eric?

22 MEMBER WEINHANDL: Hi. This topic

1 absolutely tortures me. And part of it is
2 because I've got training in epi and I've got
3 training in biostats. And the two parts of my
4 brain don't really totally agree on this one.

5 (Laughter.)

6 MEMBER WEINHANDL: And then,
7 complicating the fact is, you know, that when I
8 think about these social risk factors,
9 definitely, my mind always goes toward the
10 denominator of patients who are Medicare-eligible
11 or Medicare-enrolled. The simple binary factor
12 of just the previous example: are you also
13 enrolled in Medicaid, yes or no? And so, that's
14 the easiest one for me to think about.

15 Obviously, there's lots of other social risk
16 factors that could be used, and some of them are
17 measured on a continuous gradient, and the
18 methodological challenges become more severe.

19 I guess a few thoughts. One, I want
20 not to forget is just reacting to the text on the
21 screen. And that is that question of the word
22 control. I guess it's the second-to-last bullet

1 point.

2 I find that the notion of control is
3 pretty context-dependent. And what I mean is,
4 imagine that you're concerned about something
5 like food supply or about home security. Home
6 security may be a poorer example than food
7 supply. But you can imagine how there are,
8 depending on which provider is being evaluated in
9 this measure -- maybe it's a health care provider
10 or maybe it's a Medicare Advantage plan sponsor
11 -- there are genuinely different statutory
12 restrictions about what can be controlled in the
13 home for a patient or for a person, depending on
14 who the actor is that is being evaluated.

15 And so, there's a part of me that says
16 -- and I don't know if it's the word control or
17 in in the provider's control. I don't recall. I
18 have read the report from the NQF before, but I
19 don't recall if that specific language is part of
20 the policy or invoked in the report.

21 I think that it's tough to ask, say,
22 the Scientific Methods Panel, to opine, or even a

1 measure developer maybe, to opine on whether
2 something ought to be in control or not, unless
3 you have a really detailed knowledge of what the
4 legal restrictions are for what is in control. I
5 mean, Medicare Advantage plan sponsors, by virtue
6 of the 21st Century Cures Act, have the ability
7 to do certain things now with respect to social
8 risk factors and food security that they didn't
9 have the province for before. So, you can
10 imagine it then becomes complicated.

11 I'm definitely receptive -- so, that's
12 kind of the policy part of me. The biostats part
13 of me says, if you know that, among your list of
14 risk factors that explain your outcome, dual-
15 eligibility is a prognostic factor, then it's
16 kind of a black-and-white decision for me. It
17 should be in the model. And I suppose that my
18 judgment there is partly because of this lack of
19 clarity about what's in control versus what's not
20 in control.

21 I mean, it's easy to talk about a
22 social risk factor and pretend that we think that

1 this is something that's exogenous to the system
2 and that, you know, you can make a principled
3 argument that you should be treating people who
4 are poor the same way that you treat people who
5 are not poor. But couldn't you make the same
6 argument rather easily about a lot of comorbid
7 conditions? If you have a drug therapy, would
8 you make a distinction between heart failure, yes
9 or no; diabetes, yes or no?

10 I find that when I think very
11 critically about this question of whether there's
12 something truly distinctive about social risk
13 factors, I often find myself eventually asking,
14 well, is there actually anything different or is
15 the same ethical decision in play for comorbid
16 risk factor as for a social risk factor? So,
17 then, the distinction begins to wash away.

18 And then, I guess that, on a related
19 note to all of that, it is that, when it comes to
20 the volume of risk factors in a risk-adjustment
21 scheme, I mean, no doubt, with administrative
22 databases, you're going to consistently find the

1 poverty of associated dichotomous, continuous
2 gradients -- it's going to be associated with
3 poorer outcomes.

4 But I often find that, to some degree,
5 when you see that independent adjusted
6 association of, say, dual-eligibility with a poor
7 outcome, there's often a connection between the
8 strength of that association and how many other
9 medical factors are in the model. And sometimes
10 I think that we concentrate on the social risk
11 factor when, actually, it's a proxy for poor
12 adjustment for a lot of other medical risk
13 factors.

14 And that's why I bring it up at the
15 exact same time as talking about the distinction
16 between social and medical risk factors.
17 Because, from a statistical perspective, I'm not
18 sure that we're looking at anything other than a
19 large collection of very interrelated correlated
20 factors. So, that's the biostat part of me
21 that's speaking.

22 Finally, the epi part, and then, I'll

1 wrap up. One of the things I'm struck by is
2 that, if we were to accept that we should include
3 social risk factors if we know that there are
4 good data that support an association between
5 them and outcomes, would it be reasonable or, is
6 it overstepping, for this evaluation process of
7 measures to encourage that, when measures are
8 reported, they aren't simply reported en masse
9 with an adjustment for social risk factors, but
10 that the measure is also reported in those who
11 are poor and not poor, those who are dual and not
12 dual? So then you have an opportunity to see not
13 only the risk-adjusted perspective.

14 You know, given the world as it is,
15 how is the provider doing? But also
16 understanding for that provider what is their
17 difference in all terms between poor and not
18 poor. So that you can begin to understand
19 whether that delta is actually unique for that
20 provider versus other providers.

21 CHAIR CELLA: It's kind of like
22 reporting actual observed means and modeled means

1 in a patient.

2 MEMBER WEINHANDL: Yes, yes.

3 CHAIR CELLA: Yes.

4 CHAIR NERENZ: Dave N. here.

5 That actually was one of the specific
6 recommendations of the 2014 panel report.

7 CHAIR CELLA: To report both?

8 CHAIR NERENZ: Yeah. If it makes
9 sense on all the criteria to do adjustment and
10 use adjusted measures, that's fine; that's good.
11 And that was a change in NQF policy.

12 But also then, a parallel
13 recommendation listed right in there is to
14 encourage reporting of what's referred to as
15 stratified rates. So, it's basically what was
16 just said, that, depending on what the variable
17 is and what the relevant categories are, report
18 out referring to that stratified fashion. And I
19 thought it was feasible because of some of these
20 issues and a few other considerations. But, as a
21 concept, yes, it's desirable.

22 Now that gets us into this territory

1 of use and reporting and who mandates the
2 reporting, and that sort of thing, but we did
3 agree clearly as a concept it's an important and
4 good idea.

5 CHAIR CELLA: Eric, did the
6 epidemiologist part of you finish?

7 MEMBER WEINHANDL: Oh yeah, that was
8 my last part. Thank you.

9 CHAIR CELLA: Okay. We heard from
10 three Erics. You said epi and biostats, but we
11 also heard from the policy Eric. So, thank you.
12 It was a great expose.

13 Now Jack had his hand up, but I don't
14 see it up now, would be next, if you do want to
15 speak. And then, Larry is on.

16 So, Larry, welcome back.

17 MEMBER NEEDLEMAN: Yes, my hand is up.

18 CHAIR CELLA: Okay.

19 MEMBER NEEDLEMAN: My hand is up and
20 somehow the screen seems to keep lowering it.

21 CHAIR CELLA: Somebody doesn't want
22 you to talk, Jack. It must be that.

1 (Laughter.)

2 MEMBER NEEDLEMAN: Right. Okay. Very
3 rich discussion, and I think a discussion of risk
4 adjustment in general dealing with issues of
5 what's downstream, what's under the control of
6 providers, is particularly to some of the cost
7 measures which look downstream three months, six
8 months, nine months, is valid. But I'm going to
9 stick with social risk adjustment for the moment.

10 And I think there are a couple of
11 things we have been seeing in these measures.
12 Often, the reason for we're not going to add them
13 is it doesn't add very much to the predictions.
14 The r-squared doesn't change very much. The
15 relative rankings of folks don't change very
16 much. And by very much, what I really mean is
17 what we're told is the r-squared changes
18 virtually not at all and the rankings change
19 virtually not at all. So, we're basically
20 saying, if we throw these in, it's de minimis.

21 And I think it's useful to reflect a
22 little bit on why that's the case and how it's

1 affecting the rankings it provides. One of the
2 reasons is some of the things that the social
3 risk factors do are downstream from and included
4 in the models through other downstream variables.
5 So, we've got mediated relationships. The
6 marginal contribution of the risk factors to the
7 outcomes are smaller than the total contribution
8 of the risk factors to the total through all the
9 different pathways. And that, I think, is one of
10 the reasons why Christie commented about being
11 higher, and so forth. That's, I think, one of
12 the reasons why.

13 But the second reason is we are only
14 looking at Medicare data. This issue keeps
15 coming up in the CMS measures and we're only
16 looking at Medicare data. And what we know about
17 the facilities, particularly the facilities that
18 treat high-volume either minority patients or
19 low-SES patients is they tend to have smaller
20 volumes of Medicare.

21 So, we're looking at a small
22 contribution, a small volume in these providers,

1 adding to our uncertainty, but, also, you're
2 going to see higher volumes of Medicare patients,
3 including some in not particularly low-SES-
4 serving providers, where some of the low-SES
5 folks there, you're going to see the balance
6 there.

7 The concern that drives a lot of the
8 are we being unfair to low-SES-serving providers
9 is about their capacity to provide the kinds of
10 services and meet the kinds of needs that their
11 patient loads have. But an awful lot of the
12 patients that we're concerned about are not
13 Medicare.

14 So, we've got this real imbalance
15 between a small number of Medicare patients in
16 those facilities, and they're not the only ones
17 whose care we're worried about. And the Medicare
18 quality is focused on just the Medicare patients.
19 So, we've got this small contribution to
20 r-squared, the small changes in ranking being
21 driven by the fact that we also have smaller
22 numbers of Medicare patients in those low-SES-

1 serving facilities. And I've been told this by a
2 couple of folks who run these. Given the small
3 number of Medicare, given that they're often paid
4 by Medicaid lump sums or per diem, they don't do
5 as a good of job coding, which means, at the same
6 time you get some of the SES coding there, you
7 may have lower risk adjustment scores on the
8 other factors that influence the risk adjustment
9 because all their comorbidities are not being
10 coded on.

11 So, we've got a broader issue of,
12 should we be just including this as a matter of
13 principle? Should we be not including it because
14 it doesn't change the r-squared very much? And
15 that, I think, has been some of the context in
16 which we've seen these measures discussed by the
17 developers where we would have to figure out what
18 we want to do about it.

19 CHAIR CELLA: Thanks, Jack.

20 Larry, you're up.

21 MEMBER GLANCE: Great. I'm sorry I
22 missed a good 30 minutes of this discussion, but

1 I'll make a couple of comments, and I'll try to
2 be succinct.

3 The first one is that, at some level
4 whether or not to include SES is not so much a
5 statistical question; it's a philosophical
6 question. So, if you believe that socially
7 disadvantaged patients are more likely to have
8 worse outcomes and to incur higher costs, and you
9 believe that institutions/hospitals that care for
10 these people are being potentially financially
11 disadvantaged with these performance measures
12 that do not account for SES, then you end up
13 hurting those more vulnerable institutions that
14 are taking care of the most vulnerable
15 populations. Then philosophically, I think it
16 makes sense that, when that sociodemographic
17 information is available, that it should be
18 included in the risk adjustment, period. So,
19 that's the first point.

20 The second point is that I agree that
21 the standard approach that CMS and some of the
22 other measure developers have used is they'll put

1 SES in the model and they'll look at overall
2 model performance, and they say, it doesn't
3 change. And then, what they'll do is, again,
4 they'll put SES in the model, if they choose, SES
5 will move out, and then, they'll compare hospital
6 rankings overall and they'll say, it doesn't
7 change. It doesn't matter. We're not doing it.

8 I think maybe a more pragmatic
9 approach, and one that we could maybe discuss,
10 would be to say, okay, you know, if you have 2500
11 hospitals, it probably isn't going to make much
12 of a difference overall for that population of
13 2500 different hospitals. But if you were to
14 limit your comparison to, say, safety-net
15 hospitals, those hospitals that, say, have more
16 than the top 10 percentile or quartile in terms
17 of their proportion of socially disadvantaged
18 patients, and then, see how much of an effect
19 including SES has on the rankings for that
20 particular group of hospitals. And then, if it
21 has a significant impact, then you ought to
22 include it.

1 The problem is I think it would be
2 hard to come up with a cutoff for how much the
3 rankings have to change. But I think if we could
4 sort of maybe talk about that a little bit, that
5 might be one way to get around that.

6 But, again, philosophically, there
7 really is no cost to the measure developer to
8 including sociodemographic risk factors if
9 they're already in the data. And I think,
10 although people have debated back and forth
11 whether you should include them or not include
12 them -- and I'm not going to get into that whole
13 discussion -- I think most people, at least what
14 I'm hearing, are falling into the camp that,
15 yeah, you ought to include them.

16 So, why not, as a group, why shouldn't
17 the NQF say, look, if you have that data element
18 -- and certainly CMS does -- you ought to put it
19 in the model, period?

20 Thank you.

21 CHAIR CELLA: What a rich discussion
22 that's been. I don't see any -- oh, now I see

1 another -- I see Paul's up. So go ahead, Paul.

2 CHAIR NERENZ: And then Sherrie.

3 MEMBER KURLANSKY: There is a
4 quantitative metric that you could use called the
5 Net Reclassification Index, which does have
6 certain parameters attached to it that you could
7 actually see what would be the impact in terms of
8 reclassification by including it in the model,
9 which may be more meaningful than how it changes
10 the C-statistic, which frequently is minimal,
11 because the C-statistic deals with the overall
12 population, but not necessarily with the impact
13 on individual sites.

14 CHAIR CELLA: Elaborating on Larry's
15 point. Thank you, Paul.

16 Sherrie? We can't hear you, Sherrie.
17 Did you call into the 833 number? It seems to
18 me you need to call the 833 number to be able to
19 be heard.

20 Why don't we wait and see if Sherrie's
21 going to maybe redial? She sent a note saying
22 she's back on the call, but maybe came in through

1 the other number.

2 Quite a rich discussion. I see
3 Christie and Paul have hands raised. I think
4 those are recycled raised hands. So let's check.

5 Christie, do you have a comment?

6 MEMBER TEIGLAND: I just had one quick
7 other comment. And that was that I also saw a
8 couple of measures this cycle where they made
9 just the opposite argument for including some
10 clinical factors that didn't show statistical
11 significance in the model, but they let them in
12 purely for face validity, which we know has been
13 done for a long time.

14 CHAIR CELLA: Yeah

15 MEMBER TEIGLAND: So I like to -- you
16 know, when you talk out of both sides of your
17 mouth kind of thing.

18 CHAIR CELLA: Well, I think it goes
19 back to, I think it was Eric's point that, you
20 know, at the end of the day, there's not much
21 difference between social risk adjustment and
22 clinical risk adjustment, and they are correlated

1 risk factors, at least from a statistical
2 perspective. So it's hard to make the case that
3 one's more important than the other.

4 Okay. I still don't see Sherrie back.
5 She says she called the 833 number and "unmuted
6 my line, but still can't be heard."

7 MS. WILBON: Sherrie, try hitting
8 star-1. See if that gets you on.

9 CHAIR CELLA: I still don't hear her.
10 I assume she heard you saying hit star-1.

11 Let's go to Daniel, and then we'll see
12 if Sherrie has found her way in.

13 Go ahead, Dan.

14 MEMBER DEUTSCHER: Just a couple of
15 notes. First, as a general perspective, I think
16 at least from my perspective, I'd like to see
17 developers first test for SES factors, and is
18 actually currently expected. Now we do have
19 sometimes -- I've seen, you know, with my real
20 experience on this panel, some cases where they
21 just say, "We don't have any SES data."

22 So I think we also need to address

1 this situation. So what do we do about that? Is
2 that okay? Because that's a really easy way to
3 get around that, just say, "We don't have the
4 data." So are we expecting or will NQF be
5 expecting in a certain amount of time for every
6 measure developer to get SES data and test for
7 it? That's one question.

8 Another thing I think is that, once an
9 SES factor has been identified as significant,
10 whether it contributes more or less to the
11 predictive power of the model, I can't think of
12 very good reasons not to include it in the model.
13 And I just want to give an example.

14 There are studies that show that an
15 SES factor or grade is significant, that it's no
16 longer significant once treatments are adjusted
17 for. So I think that's a case where developers
18 should really be careful about including an SES
19 factor that goes away once treatments are
20 adjusted for.

21 And there could be multiple reasons
22 for that. Maybe low-SES patients get worse

1 treatment for some reason that's not really
2 dependent on the overall resources. Maybe it's
3 just the selection of treatments that's
4 different. And there are studies that show that.

5 But, in that case, I would expect the
6 developers to provide evidence to support that,
7 not just throw out a philosophical argument
8 that's not supported by evidence.

9 Those were my two comments.

10 CHAIR CELLA: Thank you. Thank you,
11 Daniel. We're going to check back with Sherrie
12 again, who's going to try to speak. Go ahead,
13 Sherrie.

14 MEMBER KAPLAN: Can you hear me now?

15 CHAIR CELLA: Yes, there you are.

16 MEMBER KAPLAN: Sorry about that,
17 Dave. I think they entered me as a non-
18 presenter.

19 I just wanted to back up and agree
20 completely with Larry about the need to sort of
21 -- the face validity question, if you will, of
22 including socioeconomic status data where it's

1 available in the data source. And that is,
2 there's evidence from a number of studies, some
3 of them are older, that academic medical centers
4 and public hospitals are disproportionately
5 represented in the penalty arena for adjusted
6 compensation by CMS.

7 So I think -- you know, and some of
8 the argument is well, we don't have -- some of
9 the case mix of variables should adjust for all
10 the arguments that poor people are sicker, but,
11 in fact, there's a lot of evidence that -- for
12 example, the Area Deprivation Index in our local
13 situation moves hospitals around in terms of the
14 distribution. So I think that, with just a
15 blanket you need empirical evidence
16 collection, you know, does the empirical evidence
17 support it, in this day and age probably isn't
18 adequate.

19 I mean, there's a fair amount of
20 opinion out there that this should and does
21 matter just from a philosophical standpoint. And
22 I think that warrants at least watch, you know,

1 look at the adjustment, see if it is costly, and
2 there's probably no reason not to, if possible,
3 do it.

4 CHAIR CELLA: This is Dave C. again.
5 A quick note that we're being reminded, and I
6 don't think this applies to Sherrie, in
7 particular, but the use of a speakerphone is not
8 encouraged because it's harder to get a good
9 quality tape recording. So if you can avoid
10 using a speakerphone when you're speaking, please
11 do.

12 The other thing I wanted to say is
13 that I think this has been a fascinating and very
14 rich discussion from several people who have
15 thought deeply about this topic.

16 And the note to NQF I think is that I
17 think it's a fair summary to say that there is a
18 lot more support for including social risk
19 adjustment than for not including it, even if the
20 delta in the r-squared is not substantially
21 changed, although I don't think that's everyone's
22 opinion, but I think I heard more in favor of

1 including it, at least on philosophical grounds
2 and also even on statistical grounds in terms of
3 having a common, you know, similar standing with
4 clinical risk factor adjustment.

5 So I think it's a fair summary to say
6 that the majority of the Committee does endorse
7 NQF going back to look at this, as Apryl said, in
8 a larger context and maybe letting us know at our
9 next meeting where you are with that.

10 Understanding that Dave N. raised this
11 not to start a revolution, but it did stimulate
12 quite a discussion. And so with knowledge that
13 Dave's motive was really to get guidance on how
14 to respond now to these submissions, it does
15 raise the larger policy issue. And it's good to
16 know NQF is paying attention to it and will be
17 revisiting this with the standing committees and
18 internally.

19 Is that a fair summary?

20 MS. WILBON: Sure. Hi, Dave. It's
21 Ashlie. I think that was a great summary.

22 And I did also just want to note that,

1 you know, I think there are things that we can be
2 doing at NQF, to Dave's point about not starting
3 a revolution, to make sure that both developers
4 and committee members, and NQF staff, really
5 understand what the current policy is under the
6 trial.

7 And so I think we can do more on our
8 end to make sure that that's communicated and to
9 make sure that the policy is accurately kind of
10 carried out and applied in the measure
11 evaluations at the standing committee discussion
12 as well. So thank you for that summary and agree
13 -- we agree.

14 CHAIR CELLA: And I think -- you know,
15 it's probably not appropriate for me to volunteer
16 people, but, you know, you heard from at least a
17 dozen people who have obviously thought a lot
18 about this and can be helpful, I think, to you in
19 going forward with your thinking about it.

20 In the meantime, I would ask everyone
21 to keep this discussion and the earlier
22 discussions from the morning in mind as we do go

1 through the submissions that we have to vote on
2 as the meeting progresses.

3 So we're still -- sorry, go ahead.

4 MS. WILBON: I was going to say, Dave
5 N., really quickly, did you already start an
6 outline for this topic? I know you had mentioned
7 that you had started taking some notes and had
8 some ideas about a paper. Is there something
9 that you already have in mind? And should folks
10 reach out if they are interested in helping you
11 with that?

12 CHAIR NERENZ: Yes, that's right. I
13 was motivated just to put some things on paper as
14 I was doing some of the reviews of measures that
15 I thought needed some kind of discussion made
16 about inadequate risk adjustment. And so maybe
17 if it's just a process issue, if people want to
18 let me know if they're interested in being part
19 of the writing group, I can send around at least
20 what I've got, getting started.

21 I wanted to hold it pending this
22 discussion this morning to just see where people

1 are coming from and who seemed engaged in the
2 issue, and if there was a general direction where
3 we were going. So we can pick it up from there,
4 if there are folks who are interested.

5 MS. WILBON: Thanks. That's helpful.
6 Thank you.

7 CHAIR CELLA: Okay. Well, let's
8 proceed on to the next topic on the agenda, if
9 you can advance to the next slide. It's on cost,
10 cost measure evaluation challenges.

11 And I think Jack and Jennifer were
12 tagged for teeing this up and helping to set up a
13 discussion. Jack and Jennifer, do you want to
14 walk us through this?

15 MS. WILBON: Dave, I'm going to give
16 just a quick tee-up, and then I'll have Jack and
17 Jen, and actually Bijan, share some thoughts.

18 CHAIR CELLA: Sure.

19 MS. WILBON: They were part of a
20 recent discussion with the Cost and Efficiency
21 Standing Committee.

22 CHAIR CELLA: Perfect.

1 MS. WILBON: But I tagged Jack in
2 particular because he emailed these issues. So
3 definitely would appreciate his input on
4 expanding on some of these questions that are
5 here on the slide.

6 But I did just want to give a little
7 bit of context. Obviously, cost measures come to
8 the Scientific Methods Panel for evaluation. We
9 got six this cycle. We are anticipating seeing
10 at least a handful of measures every cycle going
11 forward. I think CMS is working on developing
12 several measures that will be submitted to NQF
13 over the next several cycles. So this will be
14 kind of a mainstay in our portfolio going
15 forward.

16 And so I think it is certainly
17 important to have some principles that underpin
18 our evaluations for these to make sure there's a
19 common understanding of how we're approaching the
20 evaluation for these. And I think that the Cost
21 and Efficiency Standing Committee is grappling
22 with some of the same issues. Many of them are

1 economists and methodologists as well as
2 clinicians.

3 And I think we, understanding that, we
4 actually put together a call just a couple of
5 weeks ago with them to discuss some of the
6 challenges, particularly in evaluating validity,
7 based on some of the concerns that were raised in
8 the spring around the validity testing for some
9 of those measures.

10 So we had, I think, a really great
11 discussion with the Cost and Efficiency
12 Committee. And in addition to the issues listed
13 here, I just want to kind of offer an opportunity
14 for Bijan and Jen and Jack to share some of their
15 takeaways from that discussion and maybe
16 summarize some of the issues here on the slide
17 for us.

18 MEMBER PERLOFF: Great. Jack?

19 MEMBER NEEDLEMAN: Okay. So I'm just
20 talking about the evaluating exclusions issue.
21 We've got two bullet points on this page, just
22 the evaluating exclusions issue.

1 We've seen something in the
2 submissions that I do not recall seeing before.
3 You know, we've got a number of these submissions
4 where there's an index event, and then we're
5 going to look at all the things that happened
6 three months, six months, I think we've got one
7 that's nine months, out. And sort of attribute
8 that to the provider at the incident event. And
9 I'm not arguing about that logic. That's a whole
10 other subject.

11 But what they said in the
12 specifications of a number of these is we have
13 excluded certain downstream events that the
14 committee, our Technical Expert Panel, and the
15 CMS docs judge outside of the control of the
16 incident provider. It might be -- one of them
17 was planned readmission, which makes a lot of
18 sense.

19 But the issue that I had, as a
20 reviewer of these things, is I had no idea how
21 the process of identifying the costs for
22 exclusion as outside of control and/or otherwise

1 predictable were being done. Was there a
2 systematic review of possible things? Did they
3 say yes to this one and no to that one, and we
4 did not see the noes? Did they -- is it an ad
5 hoc process where somebody says well, I think
6 this could happen and we ought to exclude it?
7 And only the ones where somebody said this could
8 happen, we ought to exclude it, sort of got on
9 the agenda for discussion.

10 And none of that is clear in the
11 documentation we've gotten. So it's hard to
12 evaluate whether the exclusions look reasonable,
13 but I don't know what they decided has not been
14 excluded or how systematic that review is. So I
15 don't know how good the exclusion process is, and
16 that was the concern I was raising.

17 MEMBER PERLOFF: I would raise a
18 different exclusion issue, sticking with this
19 concept of the episode or bundle of care. Jack
20 is mentioning sort of the exclusions within the
21 construct, things that are not counted when
22 you're thinking about the cost or the quality of

1 care.

2 But another type of exclusion is
3 episodes themselves that get dropped from
4 analysis. And we have seen measures where
5 something like less than 10 percent of the
6 originally-triggered cases remain in the final
7 measure. And we see some where it's small, 5 or
8 10 percent dropout, and some where it's
9 tremendous. And again, not much understanding of
10 what is left on the cutting room floor when you
11 have that degree of dramatic exclusions. So just
12 a different take, the same theme.

13 CHAIR CELLA: This is Dave C. I mean,
14 I confess that I was, you know, when I looked at
15 the exclusions, I kind of had my clinical
16 trialist hat on and thought in terms of, you
17 know, did this exclusion seem reasonable based
18 upon the kind of underlying rules that I might
19 use for deciding whether or not an exclusion from
20 eligibility in a clinical trial or excluding from
21 an outcome determination in the trial made sense.

22 And so, you know, it kind of brought

1 me to that provider control issue, if it seemed
2 like a cost that was legitimately -- either it
3 wasn't a major cost or was something that was
4 outside of the provider control. It seemed
5 reasonable.

6 But I agree, I never saw it spelled
7 out. I was using other sort of internal models.

8 MEMBER NEEDLEMAN: This is Jack again.
9 If I can just -- I totally agree with you that
10 the exclusions we've seen, to me as a non-
11 clinician, have all made reasonable sense. It's
12 more of how systematic is this review -- and how,
13 you know, what didn't get excluded. Again, it's
14 a matter of how the process is done, which --
15 already mentioned. The trials that we've seen
16 all look reasonable.

17 CHAIR CELLA: Right. Yes, yes. So
18 you're not actually concerned about a specific
19 case per se, but the process.

20 And Paul has got his hand up.

21 MEMBER KURLANSKY: So echoing Dave's
22 sort of clinical trials hat, I am just wondering

1 if thinking in terms like a CONSORT diagram, if
2 maybe -- I didn't actually have to review any one
3 of these. But it seems to me that if you had a
4 concept of what was the total population that was
5 potentially theoretically at risk, and then
6 having them demonstrate each exclusion, what
7 percentage or what number were there -- excluded
8 with a reason, and then what was the final study,
9 you know, in sort of the format of a CONSORT
10 diagram which you would do for a clinical trial,
11 it might, to Jack's point, it might make things a
12 lot clearer as to what you're doing.

13 Then you could make a better judgment
14 as to whether or not the exclusion seemed
15 reasonable or not or even if the extent of the
16 exclusion seemed reasonable. But the process
17 would be a lot clearer.

18 CHAIR CELLA: Good suggestion. Any
19 other comments or questions on the evaluating
20 exclusions component of this?

21 Larry?

22 MEMBER GLANCE: So in just listening

1 to this discussion, and I did not evaluate any
2 cost measures, when I saw on the agenda that we
3 were going to be looking at exclusions, I assumed
4 that what we were going to be looking at is if
5 you have outliers in terms of cost and how to
6 deal with those. Are we saying that extreme
7 outliers of costs are being excluded from the
8 risk adjustment model, or are they being excluded
9 from the population -- the patient sample that's
10 -- whose cost performance is being evaluated?
11 One or both? Or none?

12 What are we exactly talking about with
13 respect to the exclusions? Could you make it a
14 little bit more concrete for me?

15 MEMBER PERLOFF: On the high-cost
16 cases, what we tend to see is winsorization. The
17 high-cost outliers aren't excluded. They're
18 truncated and sort of capped at the 99th
19 percentile or the 95th percentile. So that would
20 tend to be the issue there. It doesn't drive the
21 case to be dropped.

22 We're talking about, I think, two

1 kinds of exclusions. One, in counting up the
2 costs of producing a certain kind of care, or
3 measuring the kind of utilization, some kinds of
4 utilization costs are just excluded on
5 theoretical grounds.

6 We couldn't control the costs.
7 Physicians should not be held responsible for a
8 patient who has a car accident on day 60 after
9 knee surgery. That really is beyond anyone's
10 control and should be excluded.

11 CHAIR CELLA: Good example, yeah.

12 MEMBER PERLOFF: And so, yes, anyway,
13 I think that's, Jack, if I've got it right, those
14 are the internal exclusions.

15 MEMBER NEEDLEMAN: Yes, that's right.
16 The measure -- the definition is exclusion of
17 unrelated expenses. And in none of the cases was
18 the car accident three months after the surgery
19 included as one of the excluded cases, the
20 excluded expenses, nor did it exclude the case.

21 So I'm looking. I've got to go back
22 to the -- in my notes, I did not document what

1 the exclusions, examples of the exclusions, and
2 I'd have to go back to the original submission to
3 go see what they did.

4 One of the -- and the appendices that
5 they reference were actually not in our
6 documentation. So there we are. The language
7 showed up in, among other measures, 3564,
8 Medicare Spending per Beneficiary, post-acute
9 measure for home health, as an example.

10 MEMBER PERLOFF: Another type of --
11 (Simultaneous speaking.)

12 MEMBER PERLOFF: -- go ahead, yeah.

13 CHAIR CELLA: And then Larry after
14 that.

15 MEMBER PERLOFF: I just was going to
16 say the other type of exclusion in the skilled
17 nursing facility stage, for example, that
18 concerns me is cases that get dropped. So let's
19 say you have a skilled nursing facility stay, and
20 there is a transfer to a new facility or some
21 other kind of similar event. Those cases as a
22 whole will be dropped.

1 And to me, a concern is whether that's
2 introducing bias into the sample of cases that
3 are left. Is it really a valid measure of
4 skilled nursing stay costs, for example, if I've
5 excluded half of all cases constructed using the
6 logic?

7 So back to -- I think, Larry, you were
8 asking was it high cost. There are other things
9 besides cost that lead to cases being dropped,
10 characteristics of the episode itself besides
11 being an outlier.

12 CHAIR CELLA: Larry?

13 MEMBER PERLOFF: Sorry. I just wanted
14 to --

15 CHAIR CELLA: Sure. Thanks. That was
16 Jen, right?

17 MEMBER PERLOFF: Yeah, that was Jen.

18 CHAIR CELLA: Yeah. Okay. Thanks.
19 Larry?

20 MEMBER GLANCE: And that was exactly
21 the question that I had in terms of maybe some
22 examples of where there was concern about the

1 cases being inappropriately excluded. You can
2 deal with exclusions by just including them as
3 risk factors. So, you know, transferring -- a
4 hospital transfer in, instead of excluding those,
5 you may just want to put it in as a risk factor
6 in your risk adjustment model.

7 And what I'm hearing, it doesn't sound
8 like what you're dealing with is all that
9 different from exclusion in other types of
10 models. Am I missing something? Other types of
11 measures, rather?

12 MEMBER NEEDLEMAN: Yes. What you're
13 missing from me is a concern that I have no idea
14 how things get on the agenda for considering
15 being excluded as an unrelated cost, and
16 therefore, how systematic the process is or how
17 random this is in terms of the validity of the
18 measure.

19 If you're going to start saying we're
20 going to exclude unrelated costs, then you need
21 to tell me how you're making decisions to
22 consider whether costs are related or unrelated.

1 And that's not in the documentation at all, and
2 it's not there how systematic it is.

3 MEMBER GLANCE: Got it. Thank you.

4 MEMBER PERLOFF: I would raise a
5 separate issue, which in cost measures there is
6 tremendous variance, right? The outliers are
7 extreme. And dropping cases really helps a
8 measure with reliability and validity. If you
9 narrow the set of cases to be more homogeneous
10 and similar, you're going to have a better-
11 performing cost measure in terms of the things
12 we've been talking about throughout this day.

13 But, in the process of narrowing that
14 scope, you are leaving a lot of cases behind.
15 And there's -- my concern is little attention
16 given to what's left out and what that remaining
17 set truly represents.

18 If we have 17 percent of cases as SNF
19 care in the country used to assess resource use
20 for SNF care, are we really -- is that really a
21 valid measure? This is a validity question for
22 me in a lot of ways. So I just wanted to raise a

1 different point than the one that Jack's making,
2 which is, also, obviously, important.

3 And I think other measures, obviously,
4 have these problems as well, but, for me, cost
5 measures are very challenging as freestanding,
6 individual episodes of care. They don't lend
7 themselves well to being standalone, highly
8 reliable, highly valid measures.

9 CHAIR CELLA: This is Dave C. I'm
10 sort of torn between whether we're requesting
11 guidance or whether we're nominating ourselves to
12 help with this algorithm, whether a CONSORT
13 diagram or some sort of explicit request for an
14 explicit articulation of the basis for exclusion.

15 MEMBER PERLOFF: One of my thoughts
16 when we met with the standing committee was that
17 it would be helpful to do a white paper on some
18 of the unique features and challenges of
19 reliability and validity of cost measures. So I
20 was hoping to nominate just as sort of a white
21 paper topic which could include diagrammatic
22 examples like we were talking about as one

1 dimension.

2 Because I think we're raising issues
3 that we would like developers to be aware of.
4 I'm not sure there's a short-term action.

5 But, Jack? Bijan? Others?

6 MEMBER NEEDLEMAN: I would just like
7 more documentation of the process by which costs
8 or, you know, services are nominated as unrelated
9 to care and how they're evaluated, and a little
10 bit of whether a decision has been made to not
11 exclude some costs, just to get a better feel for
12 the process here. It's part of my assessment of
13 whether the process for putting the measure
14 together has been valid.

15 CHAIR CELLA: That is Dave C. again.
16 I'm sorry if I missed this. Is there a standing
17 committee for cost measures?

18 MS. WILBON: Yes, there is. This is
19 Ashlie. Yes.

20 CHAIR CELLA: And Bijan and Jen and
21 Jack are on it?

22 MS. WILBON: Bijan and Jack are. Jen

1 we invited as a guest of honor to our webinar a
2 couple of weeks ago, yeah.

3 CHAIR CELLA: So maybe this Committee
4 could weigh in on endorsing the proposal to that
5 standing committee to please do that white paper.
6 It sounds like it's more their purview than ours.
7 But we would appreciate the guidance. Is that
8 fair?

9 MS. WILBON: Hi. This is Ashlie. I
10 actually think it's probably a crossover. I
11 think there are some issues that they are
12 grappling with methodologically that they
13 actually would like guidance from the Methods
14 Panel on.

15 Some were around, I think the main
16 issue that we discussed on the webinar a couple
17 of weeks ago was around validity testing, and
18 particularly for claims-based cost measures and
19 how, you know, developers should be thinking
20 about picking comparators and whether or not
21 there is any kind of systematic bias or error
22 created by using another measure of comparing an

1 administrative claims-based cost measure to
2 another claims-based cost measure to demonstrate
3 validity, and kind of what types of validity
4 they're actually demonstrating by using that
5 approach.

6 So I think there's definitely some
7 methodological questions that have come up at the
8 committee level that I think they are seeking
9 some broader guidance from a group like the
10 Methods Panel.

11 So, Jen, please feel free to add or
12 clarify my explanation if there's -- I'm sure you
13 can probably explain it much more --

14 MEMBER PERLOFF: No, no, I think
15 that's perfect.

16 CHAIR NERENZ: What do people think
17 about maybe some kind of joint committee or
18 subcommittee that would have representation from
19 the Cost Standing Committee and the SMP? And
20 identify what are the four or five issues and, if
21 not a white paper, at least write down some of
22 your recommendations that we can then discuss.

1 MS. WILBON: This is Ashlie. I think
2 that would be great. And I certainly would be
3 happy to help gather folks across those
4 committees and bring you guys together, so that
5 there's a group that's focused on that.

6 CHAIR NERENZ: Sorry about this. Jack
7 and Jen and Bijan -- well, I guess you said Jack
8 and Bijan are members of that standing committee?

9 MS. WILBON: Yes, that's correct.

10 MEMBER BORAH: That's right.

11 CHAIR NERENZ: I think one of you or
12 both of you would be logical leaders of this
13 because you have a foot in both committees, if
14 you would be willing to, I don't know, chair such
15 a subcommittee to get the issues down on paper
16 and convene people that are willing to weigh in
17 on the requests that they have of us and that we
18 have of them. Because it sounds like the
19 requests are going both ways. Is that
20 reasonable?

21 MEMBER PERLOFF: Hear, hear.

22 MEMBER BORAH: Yeah, this is Bijan.

1 I'd be happy to.

2 CHAIR NERENZ: Well, that would be
3 great.

4 MEMBER NEEDLEMAN: Sure.

5 CHAIR NERENZ: So, Ashlie, should we
6 leave this with NQF staff to coordinate a
7 gathering of, you know, I don't know what the
8 number is, but six to eight people or so to come
9 up with identifying the issues and then drafting
10 some position?

11 MS. WILBON: Sure, sure. We can
12 certainly work on getting folks together for
13 that. No problem.

14 CHAIR NERENZ: And then we can decide
15 later whether this is something that we can
16 circulate through email discussion or for the
17 next meeting, depending on its urgency.

18 MS. WILBON: Yes. That sounds good.

19 CHAIR NERENZ: Okay. I don't see any
20 other hands up. Are there any other thoughts on
21 the topic? Or were --

22 MS. WILBON: Oh, Dave, sorry, just

1 real quick, I just wanted to know if -- Jack, did
2 you want to just provide, before we move on,
3 because we're ahead of schedule and we can break
4 early and give folks a longer break. I am
5 sensitive to the start time of Measure Evaluation
6 since we've already coordinated that with the
7 developer. So I'd like to stick to our schedule
8 for Measure Evaluation.

9 But, Jack, if you want to just
10 quickly, since we have a few extra minutes, just
11 explain the second bullet around the risk
12 adjustment? And then if folks have questions, we
13 can, but just understanding that we are -- that
14 can be a subtopic of the paper, if folks were
15 interested in having more in-depth discussion.

16 MEMBER NEEDLEMAN: Sure. The second
17 bullet, oh, this is the tailoring issue. So what
18 we've seen in particularly the CMS cost measures
19 is -- and to some extent in some of the other
20 measures as well -- is they have migrated to a
21 highly stylized, fairly standard way of
22 approaching the risk adjuster. You know,

1 hierarchical HCCs, some specific clinical
2 services, some interactions there. But, then,
3 they're applying -- and it's always a lookback,
4 right?

5 Sometimes they include the diagnosis
6 or the condition that creates the incident event,
7 sometimes not. But the other elements of the
8 risk adjuster are always a lookback based upon
9 review of the full records from the patients. So
10 we wind up with one of the sources of exclusion
11 is we don't have a full year of data before the
12 incident event.

13 But there's not a lot of tailoring.
14 And one of the -- and you keep seeing this
15 language when they're doing the risk adjustment
16 on a million patients, or a hundred thousand
17 patients or several hundred thousand patients,
18 that we don't want to add interactions, and we
19 don't want to do this or that, because we're
20 concerned about overfitting.

21 And even their model with 200
22 variables is not overfit on 100,000 or 200,000

1 patients. There may be specific issues of low
2 cell counts, but it doesn't look like that. And
3 so there's a tendency to not want to do a lot of
4 tailoring to the specific service that's being
5 examined or the specific providers that are being
6 examined. And the question is whether we should
7 expect more tailoring of the risk adjuster to the
8 patients and care circumstances.

9 And in the case of the Medicare
10 spending per beneficiary, in on example, they
11 have month-to-month estimates which they average,
12 but they don't take into account the hit by the
13 bus or the new cancer diagnosis during the period
14 in which things are being located. They don't
15 think about why did patients get into rehab and
16 do we need to make sure we've got specific
17 measures. So it's kind of the variance in rehab,
18 how people get into rehab, that leads to
19 differences in cost downstream from the initial
20 rehab circumstances.

21 And that's the question of how much
22 tailoring we should be expecting versus just

1 saying they're using the standard risk adjuster.
2 We know this. Sometimes it explains 30 percent
3 of the variance, and sometimes it explains 11,
4 and we shouldn't be worrying about what they
5 could do to push the 11 percent of variance up to
6 a higher number.

7 Those were the issues that sort of
8 occurred to me as I was looking across the
9 measures we've been getting as opposed to
10 individual specific measures.

11 CHAIR CELLA: Thanks, Jack. I see
12 that Gene raised his hand, maybe even before you
13 started speaking. And then Eric.

14 MEMBER NUCCIO: Yes, I was just
15 concerned that we're not going to get a chance to
16 talk about risk adjustment. The problem that I
17 saw, and I was part of the cost measure review
18 team, was that there appeared to be a fair amount
19 of what I would call cut and paste that went on
20 across the four measures, the mean spending per
21 beneficiary, that were presented. And perhaps
22 the problem is simply that the developer was not

1 very careful in terms of this cut-and-paste
2 methodology.

3 The one that really upset me had to do
4 with home health, the mean spending per
5 beneficiary for home health care. In that
6 description, they say that the data for the
7 patient is being taken from the MDS instrument.
8 I can assure you, having spent 20 years doing
9 home health analysis, that no patient in home
10 health has been evaluated using the MDS. They
11 use the OASIS instrument. And the items are not
12 the same on those two instruments.

13 And so to claim that the model that
14 they're using for the home health mean spending
15 per beneficiary that takes into consideration the
16 clinical condition of the home health patient
17 using MDS is completely bogus. It just can't
18 happen because those data don't exist. So that
19 obviously upset me.

20 The other piece that I was concerned
21 about, and it didn't have to do specifically with
22 the risk adjustment, was it was not clear what

1 the meaning of the "mean spending per beneficiary
2 value" was supposed to be. They, at the end of
3 their presentation, showed that the data that
4 they generated using their little models were
5 normally distributed. And it looked, you know,
6 like a typical normal distribution.

7 Yet, when they were going to be
8 reporting the results, the results were U-shaped.
9 That is, the lowest percentage of patients or
10 units of performance, whether it's a SNF or a
11 home health or an IRF or a long-term care
12 facility, were U-shaped. That is, there were
13 fewest people, percentage of agencies or
14 facilities that were in the middle, and the
15 largest percentages were either below the normal,
16 below expectations or above expectations.

17 And I found it very confusing because
18 how this setup -- what the criteria that were
19 used to transform the normal distribution into a
20 U-shaped distribution were not quite clear. And
21 I'll end it there.

22 CHAIR CELLA: Thanks, Gene. Eric?

1 MEMBER WEINHANDL: Hi. This is an
2 interesting topic. So I was on the subgroup that
3 did not, to my knowledge or memory, did not
4 evaluate any cost measures. So I'm definitely
5 not speaking to anything that's in front of the
6 panel this cycle, at least in front of my
7 subgroup.

8 I will say that this has been an
9 interesting thing I've observed in watching some
10 of these Medicare cost measures being developed,
11 and not so much through the NQF forum, but, you
12 know, particularly through a variety of the
13 payment mechanisms and models that have been
14 proposed, especially from the Medicare and
15 Medicaid Innovation Center, CMMI.

16 Historically, I've been accustomed to
17 seeing a lot of cost measures being developed by
18 academic groups that are working in contract with
19 the government, with CMS, and so they might be
20 Yale, might be University of Michigan. Some of
21 these big contractors do a lot of measure
22 development.

1 Typically speaking, my impression has
2 always been that they are tailoring to risk
3 adjustment schemes, to the disease stage, or to
4 the application that they are evaluating. What I
5 have noticed with the Center for Innovation is
6 that they are, generally speaking, and I'm making
7 a lot of generalizations, they're gravitating
8 towards this blanket use of the HCC risk score.

9 And that -- the HCC risk score has got
10 different components, right? There's a component
11 for a general Medicare beneficiary. There's one
12 for ESRD. There are ones for people who are a
13 full year prior to eligibility, less than a full
14 year. So there's some level of tailoring to
15 different subsets or phenotypes.

16 But the bottom line is that they're
17 taking this generalized risk score, which was
18 developed for evaluating cost expectations, and
19 it was developed on the fee-for-service data and
20 is typically used for risk-adjusted Medicare
21 Advantage data. But then they're using it in all
22 sorts of applications from general to specific.

1 And interestingly enough, I even
2 encountered an example specific to my disease --
3 dialysis, where the Innovation Center had
4 actually proposed a payment model last summer
5 where the outcome was home dialysis utilization.
6 So we're actually talking about a medical outcome
7 being risk adjusted with the HCC risk score. And
8 I think to myself, well, now this is really
9 daring because this isn't even economic outcome
10 anymore.

11 It seems to me that the question, from
12 my perspective, comes down to a validity
13 question. And so I don't mean to become overly
14 polemical about this. You've got a risk score
15 that has been developed for a specific
16 application, say the HCC risk score. It can be
17 used, as any covariate can be used, in a variety
18 of analyses and risk adjustment models.

19 You know, the child risk score, the
20 Elixhauser scores, or adaptations of Elixhauser,
21 are used in widespread scenarios. We know that
22 those scores weren't necessarily perfectly

1 intended for each specific application, but
2 they're used widely.

3 So I don't mean to say that this
4 should be treated any differently, but I do think
5 that it comes down to a question of validity.
6 Does this risk score that was not tailored for
7 your application provide appropriate resolution?
8 And to my mind, the answer is yes or no,
9 depending on what the nature of the economic
10 outcome is.

11 If it's a general outcome, like total
12 all cost spending across Parts A and B, I'm okay
13 with it in general. You know, it would be good
14 to see evidence before I say I'm okay
15 specifically, but I'm okay in general.

16 When it comes to very specific
17 instances, like episode payments of care, now I
18 think the stakes are higher, and I think that you
19 do want to have some awareness of what was
20 happening before that episode began, what
21 triggered that episode.

22 And my concern then, because of these

1 generalized risk scores not being tailored to the
2 application, are going to explain a lot less of
3 the variation. And as a result, the measure is
4 going to be a lot less valid.

5 So I think it comes down to, if I were
6 to really boil it down, for me, it would be, yes,
7 we should expect tailoring if we're evaluating a
8 very sort of short-term, highly-specific kind of
9 cost endpoint. If it's all costs over a one-year
10 time period, then I'm expecting less tailoring.

11 CHAIR CELLA: Thank you, Eric.

12 Christie?

13 MEMBER TEIGLAND: Yeah, this is a
14 measure that we are going to discuss tomorrow
15 that didn't pass. But I just want to point out
16 inconsistency in using HCC risk models and all of
17 the ICD codes in those models to risk adjust this
18 measure, but then because they wanted to apply it
19 to both Medicare fee-for-service and Medicare
20 Advantage, they elected to only use diagnoses
21 from the discharge claim for a patient, which we
22 all know is in no way going to document every

1 chronic condition that patient has.

2 And then it wasn't even clear if
3 they're actually using history for Medicare fee-
4 for-service patients because they have it, but
5 they're not using it for Medicare Advantage
6 because they don't have it, because they included
7 some adjustment factors for Medicare Advantage.

8 But just the whole point of you
9 developed the model using this huge set of data
10 that assumes that you're going to be accounting
11 for chronic conditions that patients have when
12 you risk adjust, but then when you limit that to
13 whatever diagnoses that were deemed important on
14 that discharge claim, that patient could very
15 well have multiple other chronic conditions that
16 aren't captured. And so then, you know, the
17 results are going to be highly skewed.

18 So, yeah, the measure didn't pass, but
19 just this whole approach of using different data
20 to develop the model, the risk-adjusted model,
21 than you're using to actually calculate the
22 measure seems completely inappropriate. So there

1 should be some kind of, yeah, rule against that.
2 Maybe there is.

3 CHAIR CELLA: Well, thank you,
4 Christie. I don't see other hands up. Wait.
5 Larry just raised his hand. Go ahead, Larry.

6 MEMBER GLANCE: Just a really quick
7 follow-up question to Jack and Christie. When
8 they're using a CMS HCC model in their cost
9 models, and I understand that it was developed in
10 a different dataset, are they estimating new
11 coefficients for the CMS HCC models for the
12 individual categories or are they re-estimating a
13 single coefficient for the entire score based on
14 the old coefficients? I mean, they must be doing
15 some kind of customization. Can you --

16 MEMBER NEEDLEMAN: Yes. The
17 customization is in terms of whether they're
18 including or excluding certain covariates.
19 They're then taking the data, and they're running
20 the regressions with all the covariates that
21 they're including. And you get covariates, you
22 know, you get measure-specific coefficients for

1 each measure. So the risk adjustment is being
2 done there.

3 MEMBER GLANCE: Yeah, so they are
4 customizing the model. And that's a fairly
5 standard approach. I mean, certainly, the CMS
6 HCC model is much, much richer than more
7 traditional models like the Elixhauser
8 comorbidity algorithm that's used repeatedly in
9 the outcomes literature.

10 So can you explain to me why you feel
11 that their approach is not sufficient? I mean,
12 it's a very, very rich model with lots of
13 different --

14 MEMBER PERLOFF: Yes. It's because
15 the model was developed, I think appropriately,
16 as you said, using all of the ICD-10s for the
17 past year of history for that patient. But then
18 when they calculate the measure, in this case
19 they were only using ICDs from a discharge, from
20 an inpatient claim, from an inpatient discharge
21 claim. That in no way is going to capture all
22 the ICD diagnoses for that patient for the past

1 12 months, right? That was the biggest
2 problem --

3 MEMBER GLANCE: The interesting thing
4 is that the CMS HCC model goes back and uses the
5 carrier data as well. So it uses not just
6 inpatient, but also outpatient --

7 MEMBER PERLOFF: That's right. That's
8 right. That's right. It uses a history, a one-
9 year history, of claims to calculate the HCC risk
10 score, yes.

11 MEMBER GLANCE: So what is the major
12 limitation of using the CMS HCC model for cost --

13 MEMBER NEEDLEMAN: Okay. So we looked
14 at measures in this last cycle, and I haven't got
15 the full list in front of me, and I apologize, by
16 name, but we looked at measures for home health,
17 patients who had been admitted to home health,
18 patients who had been admitted to SNF, patients
19 who had been admitted to rehab. And there were a
20 couple of others.

21 They don't always include the incident
22 diagnosis that brought the patient in. Sometimes

1 they do; sometimes they don't. But there's no
2 thinking about what -- the exclusions are an
3 effort to think about what could happen to these
4 patients downstream that are costs that we would
5 want to exclude.

6 But the risk adjustment model, and as
7 I said, I'm not sure those are inclusive enough,
8 but the risk adjustment model doesn't sort of
9 always capture all the things that are unique to
10 the patient's circumstances that brought them
11 into rehab or brought them into a SNF that might
12 affect downstream costs and utilization.

13 And it's this lookback, and it sort of
14 ignores -- there's information of the fact this
15 patient went into a SNF. And patients go into
16 SNFs for different reasons. So it's not always
17 clear to me that they have fully captured the
18 circumstances that brought the patient into care
19 that may affect downstream costs. That's my
20 concern, and it's a concern that's driven by the
21 fact that the models are being standardized, even
22 if the coefficients are different. The models

1 are being standardized.

2 And the question is should there be
3 more tailoring. And I don't have an answer to
4 that. I raised it because I'm torn and uncertain
5 about this.

6 MEMBER GLANCE: Isn't there something
7 about the way the CMS HCC models are created that
8 the categories are hierarchical categories? And
9 so they do look at the full set of ICD codes,
10 both inpatient and outpatient, and they group
11 them in such a way that the ones that are most
12 likely associated with higher costs are given
13 more importance?

14 MEMBER NEEDLEMAN: Yes, but that's
15 exactly right, and that's fairly general. So now
16 we've had a patient who has had a joint
17 replacement and wound up in rehab or wound up in
18 a skilled nursing facility which is providing
19 rehab services. But if the other things that are
20 in that hierarchy are not directly related, you
21 know, in some sense, they get classified out
22 because of something other than the joint

1 replaced. The fact that the condition that
2 created the incident event was joint replacement
3 sort of gets lost.

4 MEMBER GLANCE: Okay. Thanks.

5 CHAIR CELLA: Okay. So this is Dave
6 C. again. So this issue on risk adjustment as
7 well as its exclusions and other topics that have
8 been brought up by the standing committee, will
9 be placed with the subcommittee that anyone can
10 volunteer to be considered for, and we'll do that
11 through NQF. And Ashlie will set that up after
12 the meeting, presumably.

13 We have hit the time where we're no
14 longer ahead of schedule, but we're still on
15 schedule. And it's time to go to public comment,
16 and then we'll take a break.

17 I'm not sure how to open up for public
18 comment, but maybe the operator is listening.

19 OPERATOR: And if you would like to
20 ask a question or make a comment, simply press
21 star then the number 1 on your telephone keypad.

22 MS. WILBON: Thank you. Those who

1 would like to make a comment can also enter your
2 comment into the chat box, and we'll make sure it
3 is read or responded to by the Methods Panel.

4 Thank you.

5 CHAIR CELLA: Okay. So, star-1 or
6 type a note into the chat box, lower left of your
7 screen.

8 MS. WILBON: And if you're on the
9 webinar, you can raise your hand, and we'll
10 acknowledge you that way, too. At least we'll
11 know that you have a question.

12 OPERATOR: And again, in order to ask
13 an audio question, simply press star then the
14 number 1 on your telephone keypad.

15 And at this time, there are no audio
16 questions.

17 CHAIR CELLA: Thank you. I don't see
18 anything in the chat room. I don't see any hands
19 raised, either.

20 MS. WILBON: Okay. Great. Thanks,
21 Dave Cella, for leading us through that
22 discussion. Again, very interesting and

1 thoughtful, and we're looking forward to getting
2 some folks together to write some papers and dive
3 a little bit deeper into these topics and share
4 some guidance going forward.

5 So we are due for our second break.
6 It is another hour, and we will reconvene at 3:30
7 p.m. Eastern Time to conclude our meeting with
8 discussion of two measures.

9 Measure 3559, hospital-level, risk-
10 standardized improvement rate in inpatient-
11 reported outcomes following elective primary
12 total hip and/or total knee arthroplasty, by Yale
13 CORE/CMS.

14 And the other measure is 0715,
15 standardized adverse event ratio for children
16 less than 18 years of age undergoing cardiac
17 catheterization, by Boston Children's Hospital.

18 We expect that the developers will be
19 joining us at that time, and we'll come back to
20 discuss those two measures until the end. And
21 that will conclude our day one.

22 So barring any questions at this

1 point, we will go ahead and break and reconvene
2 at 3:30.

3 CHAIR CELLA: Ashlie, this is Dave C.
4 again. Just a note that Colette Pittson
5 (phonetic) has typed in a comment. It doesn't
6 require a response, but just to let people know
7 there is a comment that has been added.

8 And, Dave N., can you just hang on for
9 a minute?

10 MEMBER KAPLAN: This is Sherrie. Can
11 I ask one quick question?

12 CHAIR CELLA: Sure.

13 MEMBER KAPLAN: Given the difficulties
14 in redialing in, is it better to hang up or stay
15 on the line?

16 CHAIR CELLA: You can stay on the
17 line.

18 MEMBER KAPLAN: Okay. Thanks.

19 CHAIR CELLA: You can stay on.

20 MS. WILBON: Just if you stay on, just
21 make sure that your phone is muted, please.

22 (Laughter.)

1 MEMBER KAPLAN: Yes. Got it.

2 MS. WILBON: Yes.

3 MEMBER KAPLAN: Okay. Thank you.

4 MS. WILBON: Yes, you're welcome to
5 stay on and stay on the webinar as well. Thank
6 you.

7 CHAIR CELLA: Okay. Bye, everyone.

8 (Whereupon, the above-entitled matter
9 went off the record at 2:29 p.m. and resumed at
10 3:30 p.m.)

11 MS. WILBON: Hi, everyone, it's Ashlie
12 Wilbon from NQF again. Welcome back to our third
13 and final session of the day. This session will
14 be focused on reevaluating two measures by
15 Subgroup 1 that were submitted this cycle. And
16 we're going to dive in here real shortly.

17 We are working through a couple of
18 technical for folks trying to get on the phone,
19 so we'll continue to do that. We do have a
20 little bit of slides to go through, and we're
21 going to do a voting test as well for those of
22 you in Subgroup 1 who will be voting. So a

1 couple of administrative things before we dive
2 in.

3 I also just wanted to check in to see
4 if the developers were on the phone from Yale
5 CORE and CMS? If you want to speak, you will
6 need to hit star one. And you can also chat us
7 through the chat boxes. Please let us know if
8 you've having any trouble getting through on the
9 audio.

10 I don't hear anyone. I see Lisa Suter
11 on the webinar. Lisa, can you raise your hand if
12 you see me -- I mean if you hear me, sorry. Oh,
13 I see a note from Victoria, you guys are on. Are
14 you dialed into the phone number?

15 PARTICIPANT: Some people have been
16 joined this way.

17 MS. WILBON: Can you just chat us and
18 let us know if you're dialed into the phone
19 number. So you won't be able to speak if you're
20 just dialed in through that.

21 So we'll go ahead and get started, and
22 we'll have our teams work with them, the

1 background, to make sure we can hear them and
2 they'll be able to participate in the discussion.
3 Just a couple of notes, as I mentioned. The
4 process we'll be using for measure discussion
5 will be the same as we used last cycle, so just a
6 quick refresher.

7 We'll have an NQF staff person who
8 will introduce the measure, myself or Sam will be
9 doing that today. And we'll have then the lead
10 discussants to summarize some of the key concerns
11 that were outlined in the discussion guide as
12 well as the PAs that were submitted by the
13 subgroup. And then we will invite other subgroup
14 members to provide comments.

15 We'll then open it up for developers
16 to give a couple minutes of initial response. At
17 that time, we'll ask for the developers to
18 provide a summary of their response, which has
19 been included in the discussion guide in Appendix
20 B. And then we will open it up to the full panel
21 for discussion.

22 So again, all members can -- all

1 members of this panel can discuss the measure,
2 but we'll only be collecting the final vote from
3 the subgroup. Any questions about that? And we
4 will, as staff, be noting any folks who will need
5 to be recused from the discussion, and that we
6 have everyone on the line and staff can establish
7 quorum before we vote and discuss.

8 CHAIR NERENZ: And Ashlie, just one
9 additional small point, Dave Nerenz here. I'll
10 take care of watching the hands up and calling
11 out people. I know Sherrie and Joe are leading
12 the discussion, but they may not be able to see
13 that function, so I'll take care of that for
14 them.

15 MS. WILBON: Okay. Thank you for
16 that. The voting is going to be done via our
17 Poll Everywhere software, which Hannah just sent
18 an email to all of the Subgroup 1 members to make
19 sure the instructions were at the top of your
20 email. So if you all could kind of direct
21 yourselves to your email and make sure you find
22 that.

1 There's a link in there for you to
2 click and make sure that you can get into the
3 voting software. You may not see anything right
4 now, but we'll be running a test here shortly to
5 make sure that everyone can vote and that the
6 software is working, and it's ready for the time
7 in the discussion that we'll be ready to vote.

8 Just also noting that we will over the
9 next -- the rest of today and the remainder of
10 the meeting tomorrow, our discussion today will
11 be focused on measures that were consensus-not-
12 reached, and measures where they did not pass but
13 have submitted -- the developers have submitted
14 additional information for the Methods Panel to
15 consider prior to submitting a final vote on the
16 measure.

17 So we will not be discussing all
18 measures. Again, just seven measures that will
19 be discussed as part of this meeting. The
20 remainder of the measures that are not being
21 discussed have all passed based on the initial
22 preliminary analysis and will not be -- and have

1 not been pulled for discussion and will not be
2 re-adjudicated over this call.

3 Those measures, by virtue of not being
4 pulled for discussion by the Methods Panel
5 members, have passed by consent calendar by the
6 Methods Panel, and the vote submitted for the
7 preliminary analysis will stand as the final vote
8 for reliability and validity for the measures.
9 That is until the standing committee evaluation.

10 And just a note here that we will be
11 considering transitioning to a full panel vote
12 next cycle. If you recall, last cycle we did the
13 shadow vote and found that there was actually
14 quite a bit of consistency among subgroup members
15 and those members who weren't assigned to the
16 measure the subgroup members.

17 So we're looking into that, and it's
18 a process change that we're looking into
19 potentially making in the future. But for now,
20 it will just be the subgroup. So I would
21 definitely encourage members of the panel who are
22 not on the subgroup to try tune into the

1 discussion.

2 Again, some of the issues are
3 overarching. And even though you were not a part
4 of the subgroup, we would still like to hear any
5 input that you have on the measure based on your
6 review of the discussion guide and listening to
7 the discussion.

8 So with that, I'm going to hand it
9 over to Hannah to do a voting test for subgroup
10 members, and we'll make -- we'll move into the
11 measure. I'm going to hand it over to Sam after
12 that to get started. And in the meantime, we'll
13 work on making sure the developers are able
14 speak.

15 MS. INGBER: Okay. Thank you, Ashlie.
16 This is Hannah, can everyone hear me?

17 CHAIR CELLA: We can.

18 MS. INGBER: Wonderful. Okay, so
19 we'll be doing a voting test first. I'll be
20 opening the test vote now. If you have the link
21 open on your desktop or your phone, you should
22 see the question: during your morning commute,

1 what is your preferred method of transportation?

2 Okay, so I see six votes. So before
3 we move forward, I'd like to confirm that --
4 which Subgroup 1 members are on the line. I'm
5 going to read through your names, if you could
6 just reply and let us know if you're here.

7 Daniel?

8 MEMBER DEUTSCHER: Yes, I'm here.

9 MS. INGBER: Dave Cella.

10 CHAIR CELLA: Here.

11 MS. INGBER: Matt Austin.

12 MEMBER AUSTIN: Here.

13 MS. INGBER: John Bott.

14 MEMBER BOTT: Here.

15 MS. INGBER: Joe Hyder. Okay, Joe's
16 not in. Patrick Romano?

17 DR ROMANO: Here.

18 MS. INGBER: Thank you. Sherrie?

19 MEMBER KAPLAN: Here.

20 MS. INGBER: And Terry.

21 MEMBER WARHOLAK: Here.

22 MS. INGBER: Michael Stoto? Oh, Mike

1 is not available at this time actually. And
2 Larry.

3 MEMBER GLANCE: Here.

4 MS. INGBER: Okay. Wonderful. Thank
5 you, everyone. So we should be getting eight-
6 something.

7 CHAIR CELLA: This is Dave Cella, I
8 just have a quick question. So when it says
9 clear last response, if you click that, does that
10 mean it registered the response, or it clears it
11 and didn't register?

12 MS. INGBER: That means it clears it
13 and it didn't register. So don't clear your last
14 response.

15 CHAIR CELLA: So when you vote it just
16 -- the vote just stays up on the screen. It
17 doesn't clear.

18 MS. INGBER: That's right.

19 CHAIR CELLA: Is that right?

20 MS. INGBER: It will only change once
21 I shift it on the back end.

22 CHAIR CELLA: Okay. Thank you.

1 MS. INGBER: I'm registering nine
2 votes. But is there -- did Joe or Mike join us?
3 I'm not hearing any response.

4 CHAIR CELLA: This is Chicago. Maybe
5 somebody voted twice.

6 MS. WILBON: Hannah, maybe try doing
7 another test, then --

8 MS. INGBER: Okay. Okay, yes. I'm
9 going to clear the responses, and we'll ask you
10 to fill in your vote again.

11 Hi, sorry for that delay. I'm still
12 registering nine votes. The team is just going
13 to take a minute just to adjudicate this.

14 DR. ROMANO: This is Patrick. I might
15 be the guilty party. So if --

16 MS. INGBER: Okay.

17 DR. ROMANO: It doesn't prevent me
18 from -- in other words I'm on my phone just as a
19 backup, in addition to being on the laptop. But
20 it didn't seem to block the second vote. So is
21 that -- that's the way the system works, it
22 allows two votes?

1 MS. INGBER: Yes. That is possible.

2 DR. ROMANO: Oh, okay, I'll do that
3 again.

4 MS. INGBER: Okay, maybe we should try
5 one more time. Oh, go ahead. Oh yeah, that is
6 confusing. Sorry about that. Okay, we'll try
7 one more time, and we'll get -- we'll hope for
8 eight. Thank you for your cooperation.

9 MS. BALESTRACCI: Hi, this is Katie
10 Balestracci. Can you hear me?

11 MS. INGBER: Yes, we can.

12 MS. BALESTRACCI: Wonderful, I am on.
13 Thank you, hi. I will be the lead discussant for
14 Yale CORE for this measure. Thank you for your
15 patience, I was having trouble being heard.

16 PARTICIPANT: Thank you for joining
17 us. Apologies for the difficulty.

18 MS. INGBER: Okay, I'm registering
19 five votes now.

20 MS. WILBON: Hannah, can you tell who
21 the votes are from? Like if you got a double
22 vote from someone, would you be able to tell who

1 it was, or?

2 MS. INGBER: No, unfortunately not.
3 Waiting on one more vote. Okay, we have eight
4 votes now. Thank you so much for your
5 cooperation and your patience with that. I'll
6 hand it over to Sam.

7 MEMBER SIMON: Excellent. Thank you
8 so much, Hannah. I'm glad that we've got our
9 testing up and going, and hello friends and
10 colleagues. It's been a little while since I've
11 had the pleasure to be with the Scientific
12 Methods Panel.

13 We've -- Ashlie has been riding solo
14 for a bit here, and it's undoubtedly to my
15 detriment. I don't get to interact with you
16 nearly as much as I'd like to, so big thanks to
17 Ashlie for inviting me to join you today to
18 introduce this measure.

19 Just a quick reminder in order of
20 operations. I'm going to introduce the measure.
21 Lead discussants will then summarize the key
22 concerns. We'll invite the subgroup members to

1 comment, and then we'll hand it over to the
2 developer to do two to three minutes of initial
3 response. And then we'll open it up to the full
4 panel.

5 Once we've gotten through that, we'll
6 of course move to voting. And then we'll move on
7 to our next measure.

8 And just to let, to remind everyone
9 where we're starting from, this is Measure NQF
10 3559, hospital-level risk standardized
11 improvement rate in patient-reported outcomes
12 following elective primary total hip and/or total
13 knee arthroplasty. So the initial results of
14 this is that the measure passed under liability,
15 but consensus was not reached on validity.

16 So when we hand it over to our lead
17 discussants, Sherrie and Joe, we'll ask them to
18 focus primarily on the validity concerns that
19 were expressed by the panels who reviewed this
20 measure.

21 Now, as was mentioned, the developer
22 for this measure is Yale CORE. And you'll find

1 inside of your discussion guide a summary of the
2 issues that were causes for concern amongst the
3 panelists.

4 Now, big thanks to Yale CORE for
5 putting together a very robust response to the
6 concerns that were identified by the panel. That
7 was attached to your meeting materials as well,
8 and I hope that you have all reviewed that. But
9 I imagine that we'll be going through that in
10 some detail.

11 Just as a couple of highlights about
12 the measure, the testing that was conducted --
13 excuse me just one second. The testing that was
14 conducted for reliability was both at the measure
15 score and the data-element level. So looking at
16 the test-retest reliability of the hip
17 dysfunction and osteoarthritis outcome score for
18 joint replacement or HOOS, JR., as well as the
19 knee injury and osteoarthritis outcome score for
20 joint replacement, KOOS, JR. ,as it were.

21 They also did assess consistency, and
22 those produced some pretty good results overall,

1 hence the panel not identifying too many problems
2 with liability. Signal to noise analysis was
3 conducted at the score level.

4 I won't go to the main concerns
5 associated with reliability as those were the
6 past reliability, and those are largely addressed
7 by the developer. But we can wade into those
8 during discussion if the panel wishes to do so.

9 Now, on validity, as I mentioned,
10 consensus was not reached. This was, as is
11 appropriate for all PRO-PMs, this measure was
12 tested at both the data element and score levels
13 for validity. Looking at responsiveness,
14 external validity, and floor and ceiling effects
15 for both the HOOS, JR., and KOOS, JR.
16 instruments.

17 I won't go through the results in too
18 much detail because I think our lead discussants
19 will likely want to get into that themselves. So
20 at this point, I'll hand it over to Sherrie and
21 Joe to lead our discussion.

22 MEMBER KAPLAN: Who wants to go first?

1 MEMBER HYDER: You can arm wrestle on
2 that one, Sherrie. As you chimed in, why don't
3 you go ahead.

4 MEMBER KAPLAN: Oh, dear. Okay, so
5 one of the first questions I had for the measure
6 developer and for NQF was it -- this is created
7 as a composite score, and I am always concerned
8 that I'm getting NQF's definitional things
9 incorrect. Because when you're creating a
10 composite across multiple items that are still
11 the same construct, does NQF count that as a
12 composite? In this case, knee and hip function.

13 MS. WILBON: Yeah, this is Ashlie. I
14 think that's a good question. It's actually a
15 question that we have that I think Dave Cella
16 brought to our attention and is actually at the
17 bottom of the slide about whether or not this
18 measure qualifies as a composite.

19 I think, and Sam, I'm going to ask for
20 your help a little bit on this, because I think
21 we have had this question come up before with
22 programs that have multiple items. And I -- do

1 we also sometimes classify them as both or can it
2 be both? Or, I'm going to lean on you a little
3 bit for this at this point, Sam.

4 MEMBER SIMON: That's really tricky
5 question, I wish I had a better answer for you.
6 And I can't think of examples of where we've had
7 multiple items that could potentially roll up
8 into a single score that I've used -- I've used,
9 as in this case, to effort scoring instrument.
10 So I unfortunately don't have a good answer.

11 MEMBER KAPLAN: Well, here's why it's
12 relevant. Because, and it would be a little, it
13 would -- for people like me, it would be weird to
14 have data-element reliability.

15 For example, in these multi-item
16 things that are supposed to assess an underlying
17 construct like knee function or hip function, so
18 you wouldn't go after, that would -- you wouldn't
19 go after data element and reliability anyway.
20 And so you're only doing score-level reliability.

21 And then this, there's the patient and
22 the hospital or whatever facility level,

1 reliability questions too. And that was of
2 concern when I was thinking about the reliability
3 piece of this. You know, what happened to the
4 across patient -- across items within patient
5 part of the -- in the denominator.

6 And so when you're thinking those
7 things through, now that, because we haven't had
8 that discussion yet and it would be unfair to
9 apply those new, you know, criteria around those
10 things. But if we're creating composites, that
11 piece of the error term, when you're aggregating
12 it up to the next unit, it becomes very relevant
13 for the error term and how you're comparing
14 things to things like validity variables.

15 So that's probably, if we can't answer
16 for this round, then we have to just ignore it.
17 But that's something probably we should put in a
18 parking lot and come back to in future
19 discussions.

20 So having said that, there is concern
21 raised, and I'm reading this from the notes from
22 others and the compiled notes on concerns raised

1 by the S&P on validity. One is attribution, and
2 it's relevant to this business about well, where
3 is the error variance and where is the real two-
4 score variation.

5 Attributing joint function, changes
6 differences in joint functions at a hospital
7 versus rehab services, versus something that can
8 happen in the interval as long as nine months to
9 a year following surgery.

10 So which piece of the variance belongs
11 to the hospital in terms of attribution, versus
12 whatever else they got after the surgery with
13 that long of a time interval. So that's one
14 concern that was raised. Shall I go on, or do
15 you want -- shall I just blast through these and
16 then have, ask the developer to respond, or do
17 you want to do them one by one?

18 MS. WILBON: Sure, Sherrie, this is
19 Ashlie. Go ahead and we'll see if Joe has
20 anything to add, and then we can open it up to
21 the developer.

22 MEMBER KAPLAN: Okay, there's a

1 concern raised that suggests the exclusion of
2 staged procedures made up to 43% of the
3 procedures. And the measure should include, from
4 unstaged procedures. I'm not exactly clear what
5 that refers to, but, and it wasn't, I didn't
6 bring that one up. But that was another concern
7 raised.

8 The exclusion analysis noted that data
9 weren't provided in the same way that there was -
10 - a concept diagram would have helped on how much
11 the exclusions affected the performance scores.
12 There were questions raised about the 25-case
13 volume threshold and what that based on, and what
14 happens when a facility falls below the 25-case
15 recommendation. Were they excluded or did you do
16 some other kind of analysis on those data, and
17 did you examine the inclusion/exclusion of those
18 20, you know, the smaller volume hospitals.

19 Another concern that came up was about
20 risk adjustment. The model was including
21 hospitals wasn't used for reliability, validity,
22 and missing data, for example. And I'm not

1 reading this one right. Hospitals with low
2 caseloads were not recommended from the measure.
3 Did the developers -- oh, did the developers do a
4 sensitivity analysis, which is related to the
5 issue I just read, that tests the impact of
6 including hospitals from risk adjustment, the
7 risk adjustment development sample.

8 And then another concern was
9 meaningful differences. There was some question
10 about how much of the variation could be --
11 establish meaningful differences between
12 hospitals in the top quartile for example.

13 And finally, there's an issue about
14 missing data. Two people raised concerns about
15 missing data, and that only the complete data
16 were analyzed without accounting for what's
17 likely very, fairly extensive missingness. And
18 whether that's actually missing at random or
19 missing not at random. And so that's kind of the
20 gist.

21 And I got the -- it says measure
22 developer response in the piece I'm looking, but

1 I didn't get the robust response that Sam was
2 talking about, so I don't know where that lives.
3 But apologies for not having read that in
4 advance.

5 One other question, one other comment
6 is the data-element validity presented the first
7 of studies in the literature at the patient
8 level. But again, I'm not concerned about that
9 because this is supposed to be a composite
10 measure.

11 The end.

12 MEMBER SIMON: Ok, Joe, did you have
13 anything else that you would like to add?

14 MS. WILBON: Hi, Sam, I think we're
15 trying to figure out if Joe was on or not. I
16 thought I heard him, but Hannah was saying she
17 thought he was not on. So if that's the case,
18 then we can open it up to other subgroup members.

19 MEMBER SIMON: Okay now, so let's go
20 ahead and open it up.

21 CHAIR CELLA: Okay, well, this is Dave
22 Cella. Maybe I'll start then. I'm one of the

1 subgroup members. And Sherrie really focused on
2 the measure, measure validity and wasn't
3 concerned about data element. But I'm actually
4 quite concerned about the data element, and maybe
5 I can explain why.

6 So, and so I'm wondering if I should
7 talk in the weeds or up some 30,000 feet. Now,
8 let me start at 30,000 feet and then get into a
9 little bit of the weeds.

10 At the data-element level, a little
11 background for those of you who don't know the
12 HOOS and KOOS very well. The HOOS and KOOS, JR,
13 were developed kind of off the grid of the
14 developers of the HOOS and the KOOS as
15 (telephonic interference). They combined pain
16 and function into one measure, so, and they do
17 that I guess to have one score and a short
18 measure.

19 And by doing that, given that this is
20 a performance measure that really relies upon
21 patient self-report, by doing that, they conflate
22 pain and function. And in some -- in many cases,

1 particularly with knees, the recovery is
2 different for pain as it is for function.

3 And although they used a rush
4 measurement technique to create (telephonic
5 interference) that would hold together well at
6 least in the sample they tested, that's not
7 necessarily how they'll perform later.

8 So there'll be a lot of error
9 introduced. And it's a short measure with a
10 pretty good sized ceiling effect, so it's not
11 clear that it'll work very well for people that
12 come in at the relatively high function or low
13 pain level. Again, mixing the two.

14 So one of the things that the HOOS and
15 KOOS developers did in collaboration with the
16 late Barbara Gandek was they went ahead and
17 developed short versions of the HOOS and the KOOS
18 that keep pain and function separate. But those
19 short versions were developed and published after
20 CMS had allowed the JR to qualify for bundle
21 payment. So JR kind of got in the hopper.

22 But there are these, I would think

1 from a PRO person's perspective, better measures
2 that are available, and actually in the fourth
3 data set, that the developers could use to allow
4 pain and function to remain separately measured
5 with still short measures. The reason they went
6 with the very short measure was because the TEP
7 recommended it.

8 But there's, and another, you know,
9 maybe less important issue but I'll mention it is
10 that the JR versions, the ones that are being
11 proposed, are really only using orthopedics and
12 only in the subset of orthopedics. Not using
13 rheumatology, for example, where there are
14 clinical quality measures that rely on the same
15 issues of pain and function in the hips and knees
16 for osteoarthritis.

17 So I think there's a real strong case
18 to be made for reconsidering using these 12-item
19 versions that are, you know, they take two
20 minutes per person as opposed to one minute per
21 person, so it's not that much more of a burden.
22 And I'm not sure how much the TEP was included,

1 was asked about using the 12 versus the six-to-
2 seven item JR version.

3 But one of the other benefits, and
4 this is getting a little bit into the weeds, and
5 I'll remind everyone about my conflict, that at
6 the beginning of the meeting, I am on the board
7 of a nonprofit, PROMIS Health Organization. But
8 one of the other benefits of having pain and
9 function separately measured at the patient level
10 is you can then allow the orthopedic community
11 flexibility in what they use.

12 They can use the 12-item version or
13 the full HOOS and KOOS. They could use a PROMIS
14 measure. And many of them have already converted
15 over to PROMIS measures because they don't have
16 that problem with the ceiling effect.

17 So you know, I think it's a good
18 submission and I came down it on low on validity
19 because I think there's a much more valid way to
20 get information from patients about pain and
21 function, reduce ceiling effects, and leave more
22 assessment available to the community, so that

1 they can use the 12 or they can use PROMIS, or
2 anything that can be linked. WOMAC, including
3 WOMAC, that could be linked to these pain and
4 physical function measures.

5 We'll make a happier orthopedic
6 community, make for better registry connectivity,
7 and better understanding down the road.

8 Otherwise, what's going to happen is
9 that everyone will converge on the JR mixing pain
10 and function together and this opportunity will
11 be lost. So that's why I came in where I came in
12 on this. There are other, you know, minor
13 comments I might chime in with based upon where
14 the discussion goes, but I'll leave it at that.

15 MEMBER SIMON: Thanks, Dave. I've got
16 Matt, Larry, and Sherrie in that order. And I
17 almost will check with Sherrie as the discussion
18 leader if you want to stay at the spot in the
19 queue or if you have some immediate response.

20 MEMBER KAPLAN: Well, I kind of --
21 this is Sherrie, I kind of do have an immediate
22 response, because it seemed like, Dave, you were

1 raising some separate, some separable issues.
2 One is dimensionality within the hip and knee
3 osteoarthritis outcomes measures.

4 So there's dimensionality because for
5 example, the knee includes a stiffness dimension,
6 that's a single item, that's its stiffness, plus
7 pain and daily function. And the dimensions are
8 differentially, you know, represented with item
9 content. But are you raising a concern -- I was
10 kind of under the impression that we were
11 evaluating what we're seeing, not what we could
12 see.

13 And that's a question for NQF, are we
14 evaluating the measure as we're staring at it, or
15 are we evaluating it in a larger context of how,
16 what would you choose if you were, you know,
17 opting for the ideal measure for, of hip and knee
18 function post-intervention and recovery.

19 Go ahead, Ashlie, it's all right.

20 MS. WILBON: No, no, no, sorry, I was
21 just going to say we're evaluating the measure as
22 is and as it has been presented to us.

1 MEMBER KAPLAN: Okay, and then so my
2 question back to Dave Cella is are you raising
3 concerns about multi-dimensionality within the
4 knee survey and whether those have been, are
5 accurate for reflecting in terms of content
6 validity, reflecting all the content. Is that
7 the concern?

8 Or is it -- because if you shorten
9 some of these measures as we did for the SF-12,
10 for example, you destroy the internal
11 dimensionality, but you still have a, have
12 construct validity at the overall score level.
13 I'm a little bit confused about --

14 CHAIR CELLA: Yeah, I, my vote was low
15 on validity, and it was four reasons, really, one
16 of which was this missed opportunity. But three
17 reasons that I gave before that are the concerns
18 about the missing data, the proxy reporting
19 issue, and the ceiling effect of the data
20 element.

21 MEMBER KAPLAN: Okay, great, I just
22 wanted some clarity. Thank you.

1 CHAIR CELLA: Yeah.

2 MEMBER SIMON: Okay, Matt.

3 MEMBER AUSTIN: Yeah, good afternoon,
4 everyone. So I have maybe a couple of questions
5 for maybe NQF staff more than the measure
6 developer. And that's just to sort of interpret
7 maybe two sort of rules or guidelines.

8 One is for the validity testing, they
9 provided those measures, score validity testing
10 and data-element validity testing. If we're
11 comfortable with one but not with the other, how
12 should we proceed?

13 And the second question is when we
14 talk about data-element validity testing and
15 needing to look at all critical data elements,
16 does NQF have a definition in what's included and
17 not included as a critical data element?

18 MS. WILBON: Hi, Matt, this is Ashlie.
19 So given the different types of -- for your first
20 question on the different types of validity
21 testing, I would say, you know, if there is a
22 concern with one kind of, one of the kinds of

1 validity testing, that you should incorporate
2 that into your evaluation, similar as you would
3 of considering, you know, all the various
4 components of validity, you know, risk
5 adjustment, inclusion, missing data.

6 All of those components are also kind
7 of subsets or subsections of validity. So we,
8 you know, we don't have any specific guidance on
9 how those should be weighed, but you certainly
10 should take into consideration how all those
11 different components kind of, you know, weigh
12 against each other and whether or not that
13 concern is significant enough to impact your
14 vote, you know, one way or the other.

15 MEMBER AUSTIN: Okay.

16 MS. WILBON: So the second question
17 around critical data elements, I was actually
18 looking for the specific language. But it's
19 essentially, I mean, we consider, you know, the
20 critical data elements, those data elements
21 required to compute the measure, so essentially
22 all of them would be critical. But definitely

1 the numerator data element.

2 And I'm sorry, I can't quote it off
3 the top of my head, but give me a second to find
4 it and I can find it for you.

5 We don't have any specific
6 requirements on, you know, if they did five of
7 the six or, you know, how we, you know, we
8 certainly have submissions where, you know,
9 they've done, you know, maybe five of the ten
10 data elements and those ten reviewers have found
11 that to be sufficient.

12 I think the word critical is somewhat
13 subjective and our language is not quite
14 definitive on that, although we do provide some
15 examples in our description of how we define
16 critical data elements. And I'll find that
17 language for you in just a second, and I can
18 share that fact with the group.

19 MEMBER AUSTIN: Okay, that'd be
20 helpful. I just want to make sure I'm being fair
21 in how I'm applying that term, critical. Okay,
22 thank you.

1 MS. WILBON: Sure, thank you.

2 MEMBER SIMON: Okay, Larry's up.

3 MEMBER GLANCE: Hi, everybody. So the
4 caveat here is patient-reported outcome measures
5 are not something that I know an awful lot about.
6 And I'm sure Sherrie will point that out at some
7 point. Hi, Sherrie.

8 But a couple thoughts. One, when I
9 looked at this measure, it struck me that -- I
10 think this is a CMS measure, correct?

11 MS. WILBON: Yes, I believe Yale was
12 contacted by CMS.

13 MEMBER GLANCE: Right. So it struck
14 me that if you look at the measures that are
15 currently being used in the comprehensive joint
16 replacement program by CMS, that I think the only
17 outcome measure that they have currently is the
18 risk standardized complication rate.

19 And I think that when I evaluate
20 measures, a couple things that I look at, and I
21 know this is not typically what we, you know, the
22 typical schema. But I look at things like how

1 much of a need do we have for a measure like
2 this.

3 And my understanding of most of the
4 episode-based payment, the bundled care programs
5 that CMS has, as well as the accountable care,
6 the qual metrics that'll be used for ACOs, I
7 don't know of very many, if any, patient-reported
8 outcome measures. So there's a barely a need for
9 this kind of a measure in my mind.

10 The second thing that I think of when
11 I evaluate a measure is, you know, we talk a lot
12 about cutoff values, criteria that we would like
13 to be able to use. And I think that's kind of
14 hard.

15 But one of the things I do is I sort
16 of compare our measures when I'm evaluating
17 compared to all the other measures that I've
18 looked at for the last couple years, both on this
19 Methods Panel, as well as the standing committee
20 that I used to serve on.

21 And so I look at the quality of the
22 measurement. I know that that's sort of a gut-

1 level thing, but to me that's important because I
2 just sort of put it into context.

3 So when I looked at this measure
4 again, it occurred to me that there's a need for
5 this type of a measure in the performance metrics
6 that are being used by CMS. Because what we need
7 to look not just at complication -- and costs and
8 process measures, we also need to look at patient
9 reported outcome measures.

10 And secondly, I looked at the quality
11 of the measure, and I kind of thought it was at
12 least as good if not better than the majority of
13 the measures that I've looked at. And I think
14 the one that consensus not reached was on
15 validity, and I'll sort of limit my specific
16 comments on validity.

17 So even though this is a composite
18 measure, it boils down to it's an all-or-none
19 measure. So it's a, essentially ends up being a
20 logistic regression model. And they used the
21 standard approach to looking at the validity of
22 the prediction model in a validation data set,

1 and they found reasonably good discrimination
2 with a P-value of 0.69. Not terrific, but it's
3 not uncommon to see C-stats in that area for
4 models for any kind of, anything other than
5 mortality. Mortality models typically have C-
6 statistics that are better. But other models
7 that are not mortality models, and this is not
8 unusual.

9 And then the calibration, they looked
10 at calibration using calibration plots, and those
11 seemed pretty good. And they also used another
12 standard approach as well, and the calibration
13 there was good as well in the validation data.

14 So to me, at least that the score-
15 level validity seemed to be good. And I think we
16 were all agreed that score-level reliability was
17 okay. So that was the reason that I voted to
18 pass this measure. And again, I don't think it
19 really matters whether it's a high or moderate.
20 But in my mind it's sort of a binary decision,
21 and I voted pass for those reasons.

22 MEMBER SIMON: No hands up. Back to

1 Sherrie and Joe again.

2 MEMBER KAPLAN: I always have to be
3 careful that I don't hit the off button while I'm
4 trying to hit the unmute button. So, yeah, I
5 think the big issue I think for me is the missing
6 data. And I think Dave, at least Dave Cella,
7 raised this question, that more than 50% of
8 hospitals with more than 25 eligible patients and
9 about 70% of all hospitals had missing either PRO
10 and/or risk variable data.

11 And so despite their propensity for
12 analysis where they compared those with and
13 without missing data, there still remains concern
14 about a pretty substantial bias in the data
15 presented. And so that was, that I think is a,
16 remains a big concern of mine.

17 And then I was also concerned that
18 there's the association with the risk-
19 standardized complication rate was the NQF 1550
20 was described in the text as a correlation. But
21 the data presented were, figure 1, for example,
22 had a box plot. So, and it wasn't clear the, I

1 may have missed it, but it wasn't clear the
2 analysis that generated these data was provided
3 in detail.

4 And so there's considerable
5 variability at the mean and a plot of the
6 association of sort of a pass/fail of each one of
7 these measures at the hospital level would have
8 been really helpful, along with the standard
9 error bar. Even in the 123-hospital sample, if
10 we could just have seen the magnitude of the
11 error there, it would have helped sort of figure
12 out how hospitals compare to each other and how
13 this might be used or not used.

14 And again, I did miss the response
15 from the measure developer. So if that was
16 addressed in that response, I apologize.

17 CHAIR CELLA: This is Dave Cella
18 again. I think we're supposed to turn to the
19 developer since there are no more comments. But
20 just to say that my, you know, I share the
21 concern about missing data. I also think there
22 shouldn't be proxy reports used.

1 But the other thing is the orthopedic
2 community is really getting on board with patient
3 -reported outcome data. So I'm optimistic that
4 in the future there will be better quality data
5 collection, because at present there is compared
6 to what, to the data that were analyzed for this
7 submission.

8 One of the problems is that, you know,
9 what's being used isn't just this one particular
10 set of questions. And this one particular set of
11 questions is not going to be easily be mapped to
12 others. Whereas a different choice that could be
13 done with the same data that were used here in
14 the FORCE-TJR registry could be linked to other
15 things that are being mentored now.

16 So it's, you know, maybe a somewhat
17 out-of-order suggestion to the developers that a
18 change in the actual element could bode very well
19 for a good participation rate in the orthopedic
20 community and we move that missing data problem
21 downstream. That otherwise I think we'll still
22 be there because people are committed to other

1 measurements.

2 MS. WILBON: Thanks, Dave. Yes, let's
3 open it up to the developer. And I did want to
4 just point out, because I think perhaps there was
5 a question, the developer's response is included
6 in Appendix B of the discussion guide. It starts
7 on page 38.

8 We would ask the developers, if you
9 could, you know, summarize your responses in
10 Appendix D. I think many of the subgroup members
11 reviewed it, but I think some may have not had an
12 opportunity. So if you could do that, that would
13 be very helpful.

14 MEMBER KAPLAN: Actually, Ashlie,
15 could I also ask that the developer speak to the
16 issue of attribution to the hospital, given the
17 time window following surgery is a fairly broad
18 nine to twelve months, is quite wide. And that
19 could have a lot to do with rehab and other
20 things. Can they also address that, thanks.

21 MS. WILBON: Sure, thank you.

22 MS. BALESTRACCI: Hello, this is Katie

1 Balestracci from Yale CORE, can you hear me?

2 MS. WILBON: We can, thank you.

3 MS. BALESTRACCI: Wonderful. So thank
4 you for this opportunity to speak. I would like
5 to start by just giving the context with which
6 this measure was developed, specifically in terms
7 of stakeholder input.

8 This measure was developed, testing
9 results were presented to, and a great deal of
10 input was provided by, our technical expert
11 panel. We had a technical working group that has
12 worked with us over the life of the development
13 of this measure. There were stakeholders versus
14 public comments.

15 During the creation of the CJR model
16 under CMMI, which was the comprehensive care for
17 joint replacement model, which was the mechanism
18 by which these patient-reported outcome data were
19 collected and submitted, required and developed a
20 great deal of input from our TEP, but also from
21 the hip and knee societies in terms of data to be
22 collected, data elements to be included for risk

1 adjustment, and the PROM survey instruments used.

2 I noted earlier a question by one of
3 the panel members about the choice of PROMs.

4 There was a great deal of discussion early on
5 from the TEP about different PROMs. There was an
6 evaluation of -- including the WOMAC, including
7 HOOS and KOOS the full version, etc. So these
8 decisions, the decisions around PROMs, the
9 decisions around the data elements chosen went
10 through a particularly rigorous stakeholder
11 examination evaluation. And we received a great
12 deal of input.

13 Likewise, there is for this measure a
14 particularly important feedback and input from
15 patients. Not only did we have patients on our
16 technical expert panel, but we engaged a patient
17 working group that would allow us to get input
18 specifically from a larger number of individuals
19 who have undergone either a total hip or a total
20 knee arthroplasty, and in several cases multiple
21 such procedures. So I did want to put this in
22 that context.

1 As I listened I've heard a number of
2 different concerns around the validity of this
3 measure. I will say that each one that was
4 mentioned in the last half-hour was addressed in
5 the 12-page response we provided to the panel.
6 But I'm happy to try to quickly address them
7 here. And then ask that, you know, if someone
8 needs even more detail, I'm happy to provide it.

9 I heard concern about attribution of
10 this measure. This is a hospital-level measure
11 because we are hoping with this measure to attain
12 the following goal: To really capture the full
13 spectrum of care and to incentivize collaboration
14 and shared responsibility.

15 I think we note that a surgeon can do
16 a terrific job, but if there is not a
17 coordination of care around other providers
18 within the hospital, around discharge planning,
19 etc., then a patient may not receive the positive
20 outcomes that they are expecting and that their
21 surgeon is expecting.

22 So we are really expecting that this,

1 as a hospital measure, will allow patients to
2 then receive a high quality of care across that
3 spectrum. It is a follow-up. The follow-up
4 post-assessment is a nine to twelve month post-
5 assessment, because we do want to make sure that
6 patient has had the time for a full recovery,
7 whether it's a knee or a hip replacement.

8 And our technical expert panel and
9 other consultant experts indicated to us that
10 they thought that follow-up would sufficiently
11 cover that.

12 I heard a concern about staged
13 procedures. I will tell you that we are unclear
14 where the 43% number came from in terms of the
15 panel. It is our experience in our data that the
16 number of patients who may have these type of
17 procedures, staged procedures within a year of
18 each other, is about seven percent. We noticed
19 also globally there are some studies coming out
20 of Sweden that mirror this exact percentage.

21 I will say that in our data, 4.17% of
22 the patients with complete PRO and risk-variable

1 data were removed because of the staged
2 procedures. And we did not do a sensitivity
3 analysis for this reason.

4 Our very concern about the staged
5 procedure within a second procedure within a year
6 of the first is that we don't know how to
7 interpret that outcome because of the overlap of
8 the recovery period.

9 I heard a concern about a 25K volume
10 threshold. This threshold was chosen because we
11 expect that in public reporting, such a threshold
12 would be applied, and certainly it is applied in
13 many of the claims-based measure with which this
14 measure is intentionally harmonized. So this is
15 not an exclusion, this is in fact a reporting and
16 expected or recommended reporting threshold.

17 I will say that from our data, while
18 33% of hospitals conducted fewer than 25 elective
19 primary hip or knee procedures, the number of
20 procedures that this represents for the overall
21 number of hip or knee procedures that occurred
22 across the country in hospitals during that

1 measurement period is 3.14%.

2 So while hospitals with fewer than 25
3 procedures appears to be around 33%, it was only
4 three percent of procedures themselves that then
5 did not get included in the measure.

6 I heard a concern about the choice of
7 HOOS, JR, and KOOS, JR, and I will simply
8 reiterate what I said as I began speaking, which
9 is that both of these PROMs went through a
10 rigorous examination by our technical expert
11 panel, as well as a public comment period when
12 the CJR model was being proposed. And they
13 continued to be the measure that was supported
14 through the development and final testing of this
15 measure.

16 I heard a concern about missing data.
17 In this measure, one of the things that we
18 recognize as developers of a patient-reported
19 outcome-based performance measure is that unlike
20 claims-based measures, the data need to be taken
21 directly from or gathered directly from patients,
22 so that there is a voluntary nature to this.

1 We have proposed in our responses, and
2 certainly as we continue to consider PRO-PMs,
3 there is certainly ways to improve the response
4 rate. And we believe that the CJR model has
5 really provided a proof of concept of how this
6 can be approached. We do have for this measure,
7 as you note, an approach to response bias.

8 We recognize that as the collection of
9 PRO-PMs increase as hospitals get better about
10 collecting them, as providers get better about
11 collecting them, you know, likely that will never
12 be or hard to get to 100%. So we do believe that
13 that has to be something we pay attention to, and
14 so we did do a statistical approach to address
15 potential response bias.

16 You will note in our results that we
17 did not find a large difference in measure
18 results when we applied this response-biased
19 approach statistically, but we believe it is an
20 important consideration and recommend that that
21 be part of the measure.

22 I will also note that we did, in the

1 response-biased approach, identify and deal
2 differently with both cases in which no PRO data
3 were provide, and cases in which incomplete data
4 were provided. So addressed both missing and
5 non-response, which are of course two different
6 issues.

7 Let me just address what I think are
8 the two other things that I heard. There is a
9 concern about proxy reporting. We expect in an
10 elective procedure, such as this elective primary
11 hip or knee replacement surgery, that proxy
12 responses will be quite low. They were certainly
13 low in the data that we used for the development
14 of this measure.

15 However, because of the nature of
16 volunteer reporting, we did, and this is part of
17 the requirements around the CJR final rule and
18 data that will be collected, we did allow for
19 proxy responses because it did provide us with
20 additional information for patients undergoing
21 this procedure.

22 And lastly, let me address critical

1 care elements. We also provided some detail in
2 our response when the Scientific Methods Panel
3 noted this concern. We have, as you saw,
4 provided the data-element reliability and
5 validity information on the HOOS JR and the KOOS
6 JR.

7 The claims data that are used both to
8 identify procedures in the denominator and also
9 are used for some of the risk variable co-
10 morbidities are those which are regularly audited
11 by CMS.

12 We have other claims-based measures in
13 which we have done medical chart review in order
14 to validate this type of data. So there have
15 been -- there are many ways in which we can have
16 confidence in these claims data.

17 With reference to the data elements
18 that are risk variables in the model that comes
19 from CJR hospitals through the collection of
20 patient-reported outcome data, those particular
21 risk variables were vetted by a thorough
22 literature review by our technical expert panel.

1 We did a medical chart review that
2 looked at the reliability and the feasibility of
3 these variables in hospital data collection. So
4 given those inputs as well as continued support
5 from our TEP clinical experts and our patients,
6 we feel confident that those variables are in
7 fact valuable choices here.

8 I am going to ask if Lisa Suter has
9 anything to add before I conclude my comment.

10 MS. SUTER: Can people hear me?

11 CHAIR CELLA: A little faint but yes.
12 Okay, I will turn up my volume. Is that better?

13 CHAIR CELLA: Better, yes.

14 MS. SUTER: Great, thank you. First
15 of all, I want to thank you all for the
16 opportunity to comment. Katie addressed very
17 robustly the issues raised. I wanted to provide
18 just a little bit more historical context about
19 the concerns with -- I'm getting a lot of
20 feedback and background noise.

21 But I just wanted to let people know
22 that this measure, the CMS embarked on this

1 measure many years ago, even before the
2 comprehensive care for joint replacement model.

3 It actually, the initial technical
4 expert panel didn't have a short form version and
5 made a decision to go with the HOOS and KOOS full
6 form version. The technical expert panel
7 recommended those, given the other limitations
8 and proprietary nature of other surveys at the
9 time.

10 Public comments and orthopedic
11 stakeholder feedback actually were the ones that
12 identified the short form versions that were
13 developed at the hospital for specific -- the
14 Hospital for Special Surgery, where they actually
15 created the short form -- the surveys with the
16 actual joint replacement patients undergoing
17 joint replacement, as opposed to the HOOS and
18 KOOS, which were developed in knee osteoarthritis
19 patients broadly.

20 And the patients were deeply involved
21 in the development of those short forms. Those
22 short form surveys were brought back to CORE and

1 CMS with a request that we consider shorter forms
2 to minimize burden. And through a tremendous
3 amount of stakeholder input, as Katie already
4 alluded to, the decision was to move forward with
5 those short form versions.

6 I want to say in addition to a patient
7 work group and patient technical expert panel
8 members and two public comments, we have also had
9 multiple orthopedic societies, including the AAOS
10 and American Academy for Hip and Knee Surgeons
11 and the Hip Society and the Knee Society, comment
12 on this measure, provide feedback on this
13 measure, have representatives engaged in this
14 measure.

15 And each of those organizations, you
16 know, supported the measure moving forward with
17 shorter forms, acknowledging that there are some
18 limitations. But you know, there were individual
19 orthopedic surgeons with communication, with the
20 leadership of those organizations involved in
21 providing advice to us as developers.

22 I'm not saying that those societies

1 endorsed these measures. I would not, you know,
2 be so bold as to say that. But they have engaged
3 in the development and provided us feedback
4 throughout.

5 So we are very appreciative of all the
6 engagement that the orthopedic community has
7 given us throughout the development of this
8 measure, including a summit where the orthopedic
9 community came together and recommended the
10 limited number of high value risk variables to
11 collect prospectively as part of the joint
12 replacement model.

13 So I just, it's hard to reflect how
14 much went into building this measure, and you
15 know, I'm sure all measures can be improved, and
16 we are very happy to hear the committee's
17 feedback about how to improve this measure and we
18 want to make it better.

19 But recognizing that this measure has
20 had a, you know, almost a ten-year arc from its
21 inception through having data collected
22 prospectively through a voluntary model that

1 incentivized hospitals to collect the data, not
2 require them to participate in, you know, in a
3 proprietary registry or other, you know,
4 treatment-requiring process.

5 But to submit the data in, you know,
6 in many different ways that allowed them that
7 flexibility has been a -- it's been a privilege
8 to be a part of that. And I just wanted to ask
9 people to have a little additional context to
10 what went into the development of this measure.
11 Thank you.

12 CHAIR CELLA: We appreciate that.
13 Just a very important time check here. We're 25
14 minutes to the hour, we have one more measure yet
15 to get in before the scheduled adjournment.
16 Sherrie, do you see a path to getting your group
17 to voting pretty quickly here?

18 MEMBER KAPLAN: I think so. I have
19 two remaining, and it's just a remaining concern,
20 because I have now had a chance to go over the
21 response by the developers and listen to their
22 presentation. I have two remaining concerns.

1 One is attribution, because even
2 though the TEP is a very useful thing to have for
3 face validity terms, it would have helped a lot
4 to have a within versus between facility variance
5 -- inter-class relation coefficient.

6 That would have helped a lot with the
7 attribution issue, because I think a year out, a
8 lot of things have happened that can contribute
9 to the patient's outcome that may or may not have
10 anything to do with the hospital, including
11 social support and other things and so on.

12 So, and I do remain concerned about
13 missing data, because HCAHPS has been around for
14 a long time and now patients are getting more and
15 more surveys. So you know, using these things on
16 the ground has to be held in context with a 15-
17 30% response rate that HCAHPS remain stuck at.

18 So those are just two remaining
19 concerns, and I don't have anything further to
20 add. I don't know if Dave Cella or Joseph or
21 anybody else has anything remaining.

22 CHAIR CELLA: Well, if I could, this

1 is Dave, I just want to say I have a lot of
2 respect for the Yale group, and Lisa and Katie in
3 particular. And I've worked with them in other
4 contexts.

5 And so, and I understand probably more
6 than most what it's like to have a seven- or a
7 ten-year arc of development work. And so, you
8 know, I said what I said, you know, with that
9 knowledge and not to take it lightly.

10 I wouldn't have said anything if it
11 was just a matter of is it good enough. Yeah,
12 it's good enough, it's probably going to go fine.
13 But the downstream implications of not doing what
14 I think can be done with existing data are
15 significant, and it's unfortunate. That was
16 really, you know. And I think the committee just
17 has to decide if that's what it wants to vote on
18 or the missing data issue or not.

19 I just, I think this can be fixed in
20 a way that keeps it much more open for the
21 orthopedic community. They're going to be a much
22 happier group.

1 And maybe I'll put it to you a
2 different way. Is there, can you see any way
3 two, three years down the road, to be able to
4 say, okay, you don't have to administer the HOOS
5 KOOS, JR. You could administer the 12-item short
6 forms and the, or the PROMIS and approximate the
7 same benefit. And you know, let's link those up.

8 I don't have a lot of optimism that
9 that can work or that it would ever be done. And
10 that'll, you know, it just changes the landscape
11 forever. Although I do, you know, listening to
12 Lisa's description, I can see what happened all
13 along the way and it made sense.

14 But it's a little bit now like, you
15 know, like I'm saying there's a better drug. And
16 are we going to go ahead and say this is the drug
17 that's going to go in the formulary, or are we
18 going to put the better drug in the formulary
19 because it's right there and it can be shipped.

20 So it's, you know, I don't know if
21 that's in or out of scope, frankly, and that's
22 part of why I wanted to have this discussion.

1 This was actually going to be one of the general
2 topics for discussion, but we decided since it
3 was only related to this particular submission
4 that we would have it here in the submission.

5 MS. SUTER: So this is Lisa Suter
6 again. I'll just acknowledge the -- and I don't
7 know if CMS is on the line. I could not possibly
8 speak for, you know, what is going to happen with
9 this measure two or three years down the road.
10 But all CMS's measures are maintained with
11 contractors that do annual review and update the
12 measure that reflect the, you know, science that
13 is out there.

14 And I think this, you know, I would
15 assume that measure would go into reevaluation on
16 a regular basis as well. I don't know how, you
17 know, it's a lot different to make a code update,
18 you know, when the ICD-10 codes are expanded or
19 changed than it would be to change an entire
20 patient-reported outcome.

21 CHAIR CELLA: Yeah. The only example
22 I have, Lisa, is the PHQ-9, and I can tell you

1 there it has not been possible to modify. The
2 use of the PHQ-9 is the only measure that
3 qualifies for that particular quality measure,
4 even going through maintenance cycles.

5 It's part of why I am -- anyway. I
6 think, let's be optimistic that CMS will look at
7 differently than the developer of the PHQ-9
8 measures, but I don't know.

9 MS. WILBON: Hi, this is Ashlie. I'm
10 wondering does Subgroup 1 feel ready to vote? I
11 just want to be respectful of the time, and we
12 have another developer group on the line.

13 I'd like to make sure we have -- we do
14 due diligence for that measure. If there are any
15 other kind of quick, lingering issues we could
16 mention, or if the subgroup feels ready to vote
17 based on the additional information submitted the
18 developer in the discussion today.

19 MS. BALESTRACCI: Ashlie, I'm so
20 sorry, this is Katie Balestracci from Yale CORE.
21 If I can just note one thing in response to the
22 comment we just heard. There was a concern about

1 ICD testing or the lack of it. And in fact, the
2 measure score is based on an ICD which about
3 0.25, my analysts are telling me. So we do want
4 to note that in fact we have that data.

5 MS. WILBON: Thank you. Okay,
6 Subgroup 1, can we call a vote?

7 MEMBER KAPLAN: I think so.

8 MS. INGBER: Okay, wonderful, thank
9 you, everyone. Voting is now open on Measure
10 3559, hospital-level risk standardized
11 improvement rate in patient-reported outcomes
12 following elective primary THA and TKA.
13 Reminder, this is a rating for validity.

14 Okay, I will now share my screen to
15 show the results. Okay, as you can see we had
16 five ratings for moderate and three ratings for
17 low. This means the measure passes on validity.

18 MS. WILBON: Thank you, Hannah. So we
19 are running behind. We had scheduled to review
20 another measure during this time, 0715,
21 standardized adverse event ratio for children
22 younger than 18 of age undergoing cardiac

1 catheterization from Boston Children's Hospital.

2 But I know they have holding on the
3 line, and I want to be respectful of folks' time
4 and make sure that we give them an opportunity to
5 review, an adequate opportunity to review and
6 present their measure. Is it Lisa, are you
7 there? Can you hear us?

8 MS. SUTER: Can you hear me?

9 MS. WILBON: Yes, yes.

10 MS. SUTER: Okay, good.

11 MS. WILBON: Can I just ask, are you
12 guys, I know this is a tough position for us all
13 to be in, and I apologize for running over, would
14 you guys be able to join us tomorrow for a
15 discussion of your measure, or is today, are you
16 locked in for today?

17 MS. BERGERSEN: We're happy to do
18 whatever works for the committee.

19 MS. WILBON: Okay. I'd like to, let
20 us take some time as a team and with the co-
21 chairs to look at the agenda for tomorrow, and we
22 will get back to you this evening. And we're

1 going to add you to the agenda for tomorrow.

2 I just want to make sure there is
3 enough opportunity for the committee to consider
4 your measure, as well as for you to give, you
5 know, a response and engage in some discussion,
6 while also being respectful of folks' time and
7 ending our day today at five.

8 So I really appreciate your
9 flexibility, and we'll be in touch very shortly
10 after the close of the call to work out a time
11 that you guys can join us tomorrow.

12 DR. ROMANO: Ashlie, this is Dr.
13 Romano. I guess there isn't any way to go past
14 five? Because pushing to early tomorrow morning
15 would be 6:00 a.m. on the West Coast.

16 MS. WILBON: Right. We did actually
17 move Subgroup 1's measures to the afternoon for
18 that reason. So we'll kind of rejigger things
19 around a bit. We have developers who have some
20 kind of restrictions on what time they can
21 attend. And so we'll take a look at things and
22 move things around, and we're definitely keeping

1 that in mind (telephonic interference).

2 Dave and Dave, do you have any other
3 comments or thoughts about that for the group
4 before we wrap up for today?

5 CHAIR NERENZ: No, it's a tough spot.
6 I mean, I feel very badly about asking the
7 developers particularly to adjust schedule, but I
8 also don't want them to feel shortchanged in
9 terms of the opportunity for discussion and for
10 them to talk through some of the responses.

11 So I think all of us will just have to
12 remember tomorrow to keep the discussion focused,
13 keep the comments as brief as possible, because
14 we'll be squeezing in one more thing beyond what
15 we had originally schedule.

16 DR. ROMANO: And this is Patrick
17 again. I just, for the benefit of other folks,
18 the developers provided quite a detailed and
19 lengthy response to the comments on pages 49-59
20 of the discussion guide. So everyone should take
21 a look at that material in advance of our
22 discussion.

1 CHAIR CELLA: Thanks, this is Dave
2 Cella, nothing to add, that sounds good. Let's
3 try to keep the same time parameters, start and
4 end time parameters tomorrow and we can just be
5 efficient.

6 MS. WILBON: Okay, the team will take
7 a look at the agenda and we'll touch base with
8 the co-chairs and with the developers this
9 evening to make sure we're on track for tomorrow.
10 And we're at about ten minutes before the top of
11 the hour, and I think we're going to go ahead and
12 open it up for public comment for a few minutes,
13 and then we'll go ahead and adjourn for the day.

14 And at this time, if you would like to
15 comment, you can enter them into the chat box of
16 the webinar or press star one, although I think
17 we've been having some difficulty with that. But
18 if you're able to raise your hand if you're on
19 the webinar or enter your comment in the chat
20 box, we'll be sure to relay your comment and find
21 a way for you to (telephonic interference).

22 Okay, I think, hearing none, I think

1 we'll go ahead and adjourn for the day. I did
2 just want to thank everyone for being such
3 troopers and being engaged for such a marathon
4 webinar for today.

5 I do think this having been over
6 webinar I don't think that we lost very much by
7 not being in person. So I really appreciate
8 that, and we look forward to more discussion
9 tomorrow and getting through all the measures.

10 So thanks, everyone, and have a good
11 evening, and we'll talk to you tomorrow morning.

12 (Whereupon, the above-entitled matter
13 went off the record at 4:51 p.m.)
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