

NATIONAL QUALITY FORUM

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SCIENTIFIC METHODS PANEL

SPRING 2020 MEETING

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THURSDAY

APRIL 2, 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:

ASHLIE WILBON, MS, MPH, FNP-C
SAM STOLPE, PharmD, MPH

MIKE DiVECCHIA, PMP

HANNAH INGBER, MPH

CAITLIN FLOUTON, MS

ALSO PRESENT:

SUPARNA BAGCHI, CDC

NAOMI BARDACH, UCSF

JENEITA BELL, CDC

ANDREA BENIN, CDC

LISA BERGERSEN, Boston Children's Hospital

CLAUDIA DAHLERUS, University of Michigan

ELIZABETH DRYE, Yale CORE

JONATHAN EDWARDS, CDC

JACK KALBFLEISCH, University of Michigan

JOE MESSANA, University of Michigan

CRAIG PARZYNSKI, Yale CORE

DORIS PETER, Yale CORE

JONATHAN SEGAL, University of Michigan

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

2 9:01 a.m.

3 MS. WILBON: Good morning, everyone.

4 Welcome back to day two. And I see that we've
5 got just about everyone back. So, thanks again
6 for joining us.

7 We're looking forward to jumping right
8 in. We're going to do our best to keep things
9 brief and on time today, so that we can make sure
10 that we get the tasks at hand completed.

11 Just a quick agenda review and update
12 from yesterday, based on where we landed. We did
13 run out of time and were not able to get to the
14 second measure that was slated for review
15 yesterday. We have slotted that measure in the
16 measures we'll review after the break this
17 morning.

18 In order to accommodate that, we did
19 have to shorten the morning break, which is
20 scheduled for 11:00 a.m. We will still take that
21 break, but instead of a 30-minute break, we're
22 going to shorten that to 15 minutes. So, I

1 realize it's not long, but we want to make sure
2 that we can get done the tasks at hand and make
3 sure that all the measures have adequate time for
4 review. So, our 11:00 a.m. break will now be 15
5 minutes. It will be from 11:00 a.m. to 11:15.
6 We'll come back at 11:15 and wrap up measure
7 review for the remaining three measures.

8 Our goal is still to try to adjourn by
9 1:00 p.m. And we'll do our best, myself and the
10 two Chairs, to keep us on task. We'll just ask
11 developers as well as SMP members to try to keep
12 your remarks brief and concise. Obviously, we'll
13 make sure there is adequate time for discussion,
14 but we want to make sure we're being as efficient
15 as possible as well.

16 A couple of kind of housekeeping items
17 about the webinar. For those of you that are
18 already on the webinar, I think you've figured it
19 out, but there is a separate link to get into the
20 webinar for day two. So, if you're on the phone,
21 if you haven't gotten to the webinar yet, it
22 probably says you have to click on the day two

1 link.

2 Also, keep in mind, for those of you
3 who dialed into our speaker line, your lines are
4 open. So, please make sure your lines have been
5 muted if you're not speaking, so we don't get the
6 background music or background noise and
7 feedback.

8 If you are dialed into the other line,
9 which the public and some developers may have
10 that line, we will choose you when to speak and
11 you can hit *1 when muted. If you need operator
12 assistance, please hit *0. We can add reminders
13 as well to the staff about that.

14 If you're having issues speaking and
15 you're dialed into the speaker line, if you're a
16 Methods Panel member and for some reason you're
17 not able to get unmuted, or you should be able to
18 speak and are not able to, the best workaround
19 for that is just to dial back in. We do have an
20 operator that is assisting us and who is with us
21 for the duration of the day who should be able to
22 assist you in getting back into the call in a

1 timely manner.

2 I think those are the main reminders,
3 and I just wanted to open it up to Dave and Dave
4 to see if you have any opening remarks before we
5 jump in.

6 CHAIR CELLA: This is Dave C. No,
7 just to say I thought yesterday was a good
8 meeting. We had lots of great discussion. I'm
9 sorry that we didn't at the end keep on schedule,
10 but we'll catch up today.

11 Dave N.?

12 CHAIR NERENZ: Yes, Dave N.

13 Thanks, everybody, for all the hard
14 work yesterday and the staff for putting things
15 together. It was really, really good.

16 Please, please, folks, today stay on
17 point. We have a lot to try to get in. We have
18 to squeeze these discussions in and stay on time.

19 As I look at what ground we have to
20 cover, if for a given measure, say reliability
21 passed but validity is the question, please limit
22 the discussion, then, to validity. Let's not re-

1 discuss or re-legislate things that have already
2 been settled.

3 Thanks.

4 MS. WILBON: Thank you both.

5 What we're going to do, one other
6 thing for the Methods Panel, you should have
7 received an email by now, an email from our team
8 with voting instructions again, so that they're
9 at the top of your mailbox, as well as the
10 revised agenda for today.

11 Please also keep in mind we will be
12 voting by Subgroup. As we get to your Subgroup,
13 we will check in with those who we are expecting
14 to be voting to make sure you're logged in and
15 that we can achieve a quorum for voting. So,
16 we'll do that when we get to it. We won't do
17 roll at this time.

18 We're going to dive right into measure
19 evaluation. I did want to check in, particularly
20 with developers for our first measure that's up
21 for this morning, 3556. And that's the National
22 Healthcare Safety Network Nursing Home-onset CDI

1 Outcome Measure from the CDC. The developer is
2 Dr. Jeneita Bell.

3 Dr. Bell, I think you may have the
4 other line. If you would hit *1 to speak and let
5 us know if you're there or enter chat in the chat
6 box, and you can let us know if you're able to
7 speak.

8 MS. BELL: Hello. Can you hear me?

9 CHAIR CELLA: Yes.

10 MS. WILBON: Yes.

11 MS. BELL: Okay. Great. I was
12 actually provided a number that gave me access to
13 the speaker line.

14 MS. WILBON: Okay. Great. Okay.
15 Perfect.

16 MS. BELL: Yes, so I'm here and I'm
17 joined by two subject matter experts on my team
18 who will be here to assist with the conversation.
19 Thank you.

20 MS. WILBON: Okay. Great. Thank you
21 so much.

22 So, just a quick process overview

1 again. I'll start out with a brief introduction
2 of the measure. I'll hand it over to the lead
3 discussants who are John Bott and Larry Glance
4 for this measure. We will, then, open it up to
5 the other Subgroup members to comment. And then,
6 we'll hand it over to the developers to provide a
7 response to any questions raised. We'll then
8 open it up to the full panel for any comments.
9 And then, we'll bring it up for a final vote.
10 Okay.

11 I'll just start out with a brief
12 introduction here. I will direct you to page 10
13 of the discussion guide where the measure is
14 summarized. There's also links there to the
15 measure information form and the testing
16 attachment, if you need to reference that.

17 I will just ask, if you're on the
18 phone and on the computer, if you could turn the
19 volume down on your computer, so you don't get
20 the feedback, and then, if you could mute your
21 line, so we're not getting feedback.

22 So, again, this is a new measure

1 submitted for consideration. It's the
2 standardized infection ratio of a nursing home
3 facility-onset incident, a CDI; laboratory-
4 confirmed events among residents in the facility.
5 Nursing home-onset CDI is defined as laboratory-
6 confirmed cases that develop four days after
7 admission. It's assessed at the facility level.
8 It is risk-adjusted.

9 For this measure, they submitted data
10 elements validity testing. And so, the focus,
11 particularly for this measure, is, again, based
12 on our criteria, data element validity testing
13 can be submitted. If it is submitted, therefore,
14 they don't need to submit additional reliability
15 testing. So, the focus should be on the data
16 element validity testing and whether or not that
17 was adequate. The vote for validity at that
18 point would, then, stand for the reliability
19 vote.

20 And so, I'll focus on the data element
21 validity question here. I'll just give a really
22 brief overview, and then, hand it over to the

1 lead discussants.

2 The developers performed sensitivity,
3 specificity, PPV, and NPPV populations. We do a
4 comparison of validators' and facilities'
5 determination of the presence of a reportable CDI
6 testing, it was based on three states
7 encompassing 14 nursing homes. The results are
8 summarized here on the discussion guide. I won't
9 read those aloud.

10 But again, I'll hand it over to Larry
11 and John at this point to give a summary of some
12 of the concerns identified by the reviewers, and
13 we'll go from there.

14 Larry and John?

15 MEMBER GLANCE: I'm happy to start
16 off, if you'd like.

17 So, as you said, validity was
18 conducted at the data element level. The results
19 of the validity testing, sensitivity and
20 specificity, I thought were problematic. Because
21 we're looking at the validity of the outcome
22 itself as opposed to the elements for risk

1 adjustments. And although there are no strict
2 criteria for what represents acceptable
3 sensitivity/specificity, the values here seem
4 unacceptably low, given the fact that we're
5 looking at data elements for the outcome itself.

6 Differences in measure performance
7 between nursing homes may reflect differences in
8 the accuracy of the data conversion rather than
9 true differences in nursing home performance.

10 And finally, the results in data
11 validity are based on a convenient sample of
12 nursing homes which may not be representative.
13 So, I thought data validity was a real problem.

14 The other main threat to validity was
15 the risk adjustment model itself. The model is
16 based on data from 2700 facilities, but includes
17 no patient-level risk factors, and therefore,
18 can't account for any differences in case mix
19 between facilities.

20 And what the measure developer says,
21 quote, "Social risk factors make up for the
22 differential incidence of CDIs resident-level,

1 but we were unable to assess these factors
2 because of the methods of data collection."

3 The other problem with validity,
4 again, a major threat to validity, was in their
5 risk-adjusted model they included facility
6 characteristics, things like percent skilled
7 nursing and a number of the patients were
8 admitted for C. diff treatment. Now, admittedly,
9 that's going to be an important risk factor. And
10 the problem is that, if you remove the portion of
11 patients that were admitted for C. diff treatment
12 in the risk-adjusted model, you will adjust away,
13 potentially, differences in performance. So, if
14 you have more of these patients, your own
15 patients are at higher risk for infection and, in
16 theory, you should be taking steps to try to
17 mitigate that. And instead, you sort of get
18 credit for having a sicker patient case mix, and
19 you're not asked to make any adjustments.

20 So, overall, I thought that data
21 validity was a major issue. I thought that the
22 risk adjustment model was poor. In terms of

1 guidance to the measure developers, I think they
2 need to include the validity of the outcome data
3 elements before this measure can be used for
4 public reporting. I think they need to consider
5 including a more representative sample of nursing
6 homes around the country in the data validity
7 testing. I think they need to include patient-
8 level risk factors such as age, sex,
9 comorbidities, ADLs in the model itself. And
10 finally, I think they need to exclude facility-
11 level risk factors in the model.

12 MS. WILBON: Thank you, Larry.

13 John, would you like to add anything
14 to that?

15 MEMBER BOTT: Well, the notes I had
16 were really all covered very articulately by
17 Larry. So, I just really absolutely second
18 everything Larry said. Well said and I
19 completely agree.

20 Thanks. And thanks for that great
21 summary, Larry.

22 MEMBER GLANCE: Thank you.

1 MS. WILBON: Okay. I wanted to see if
2 there are any other Subgroup members that wanted
3 to identify any additional concerns maybe that
4 Larry didn't touch on for the developer to
5 respond to.

6 MEMBER AUSTIN: Yes, this is Matt
7 Austin. Good morning.

8 I mean, to sort of follow up on the
9 conversation from yesterday in terms of critical
10 data elements, one of the gaps I identified was
11 that they did not seem to provide any data around
12 the data element validity for the values in the
13 denominator, things like residents' age, et
14 cetera. And so, I think that was a gap in their
15 analysis.

16 MS. WILBON: Anyone else from Subgroup
17 I have anything to add?

18 Okay. Dr. Bell, I'll hand it over to
19 you.

20 I did just want to make one comment
21 that the measure did not pass reliability and
22 validity. We wouldn't have added the measure to

1 the agenda, but, given the timing of the COVID
2 crisis, many of our developers have been busy
3 responding to the crisis. And so, people were
4 not able to submit a written response. So, we
5 pulled the measure for discussion in order for
6 Dr. Bell and her team to be able to respond
7 verbally. So, there is no written response to
8 any of these questions that we have. Obviously,
9 we'll allow time for them to respond verbally.

10 So, Dr. Bell, thank you for joining
11 us, and we'll open the floor to you and your team
12 to respond to the panel's concerns.

13 MS. BELL: Hello. Good morning, and
14 thank you so much. I appreciate the opportunity
15 to engage in this discussion because you may know
16 this by now, that I was actually out in the field
17 helping with the coronavirus response. Our team
18 actually pulled away today to be able to
19 participate in this discussion.

20 I have with me at least three other
21 subject matter experts, two of which who led the
22 risk adjustment work. And I also have our

1 subject matter expert who leads data validation
2 within our branch, which is consistent across the
3 branch for other components within our
4 surveillance system.

5 But, first, I want to say I appreciate
6 and understand the comments that were provided by
7 the panel members. I hear that there's two
8 things primarily. One, there's some issues that
9 you are all concerned about concerning the
10 validity of the measure, the data elements that
11 are associated with the measure itself, and the
12 representativeness of the sample. And also,
13 there's some concerns about the factors that were
14 included in the risk adjustment model.

15 So, if I may, I'm going to ask for my
16 colleagues, Jonathan Edwards and Elizabeth
17 Mungai, to see if they can speak to some of the
18 concerns regarding the risk adjustment. And
19 then, I'll pivot over to Dr. Suparna Bagchi to
20 see if she has comments relating to validity.

21 MR. EDWARDS: Hi. This is Jonathan
22 Edwards. Good morning, everyone, and thank you

1 for the summarized input.

2 The thing I want to start with is that
3 we definitely hear the comment about the need for
4 patient-level data quite often in the data we
5 collected in NHSN. And I'll just editorialize
6 here just real briefly and say that we are trying
7 to move in directions where we can capture data
8 electronically at the patient or patient
9 admission level for new type data collection, not
10 necessarily related to this measure or this
11 population yet.

12 So, that's something we want to move
13 in the direction of, but we have to pay attention
14 to the data collection burden. So, given that,
15 the way the data are collected in the NHSN are
16 they are ecological or summarized data. And
17 while we have information on the infection events
18 themselves that are at the detail level, the data
19 are still summarized. And so, we do not have
20 patient-level data on the entirety of the
21 population, only those that have the events.

22 And so, what we have to rely on are,

1 basically, factors that might be collected in a
2 manual survey to be able to be used as surrogates
3 for differences in acuity. And we have had many
4 discussions and have had many occasions where
5 there are our own internal discussions about how
6 well those particular factors from an annual
7 survey may serve to distinguish differences in
8 acuity of patients.

9 And it is not a new point that some
10 may not be willing to accept some of the factors.
11 And it also is not a new point to have folks that
12 were reviewing our models to say, well, we want
13 patient-level data and we want patient-level
14 factors, and I'm not satisfied with particular
15 annual survey surrogates.

16 That said, what we do, and what we
17 did -- Elizabeth Mungai and myself and then the
18 team -- is we used the data reported into NHSN
19 and we used this measure to be able to understand
20 where are there differences in the outcomes. And
21 so, to the extent that we understand where there
22 are differences in the outcomes, we, then,

1 capture those differences.

2 And again, it's a fair point to say
3 that we can't adjust for certain factors. I
4 believe that the best that we can do is to use
5 these factors that are collected in an annual
6 survey to say: are the outcomes different or is
7 the outcome different across those levels of
8 those factors?

9 So, in the end, the measure is based
10 on a regression model that is the best
11 characterization of differences in the outcome,
12 being the CDI incidents.

13 And I'll just stop there and see if my
14 colleagues have anything further they want to add
15 in there.

16 MS. BELL: This is Jeneita.

17 I would just add, you know, Jonathan
18 mentioned that we rely on facility-level factors
19 because very limited information is available for
20 a patient level. At the most, you can collect
21 age and sex, but there is no comorbidity
22 information or information about patient case mix

1 to include into the model.

2 Should we proceed with our remaining
3 comments? I don't know how dynamic the
4 conversation is expected to be. Sorry.

5 MS. WILBON: Yes. Hi, Dr. Bell. This
6 is Ashlie.

7 Go ahead and have everyone from your
8 team respond, and then, we'll have the follow-up
9 questions from the Methods Panel follow that.

10 MS. BELL: Okay. Jonathan, do you
11 have anything else to add?

12 MR. EDWARDS: No, no. I'm happy to
13 respond to further questions, but I think I've
14 said everything that we can say.

15 MS. BELL: Yes.

16 MR. EDWARDS: Again, our preference is
17 that we would have better risk adjustment. We
18 always want to seek that out. We always have to
19 bear in mind the data collection burden.

20 And I would just add, in NHSN, in
21 terms of using these measures, we want the
22 measure to be based on the data that are readily

1 available. And so, another point that may seem a
2 little bit astray, but I think it's still
3 relevant, is that sometimes people can share
4 ideas of, oh, well, why don't you get these data
5 or why don't you have use of these other data
6 sources? Well, in the NHSN, we need to have the
7 data available at the time. And so, the
8 completeness and the data availability and the
9 timeliness, certainly, there are factors there.
10 And so, we have to weigh the burden of data
11 collection also together with the completeness
12 and timeliness of data.

13 That's all I'll say for now. Thanks.

14 MS. BENIN: Jeneita, it's Andrea. I
15 can also add to Jonathan's discussion about how
16 we're often needing to weigh the pros and cons of
17 how we approach the metrics by, I think,
18 emphasizing also that this particular disease we
19 think is of enormous importance in these
20 facilities. And without being able to get a
21 start on a metric to quantify that and understand
22 it better, it really inhibits our ability to

1 understand the landscape and move forward with
2 the prevention activities.

3 And I think the recent events around
4 infection control in these facilities highlights
5 some of the general urgency around being able to
6 get at some of the feasible approaches to
7 understanding these types of facility-acquired
8 infections.

9 And so, just to underscore what
10 Jonathan is saying about why some of the
11 approaches that we have chosen at this point are
12 what we have at our fingertips.

13 MS. BELL: Thanks, Andrea.

14 And continue on with our comments,
15 I'll pivot over to the validation portion of this
16 discussion. And I heard the comments that there
17 is concern about the representativeness of the
18 samples and there's concern about the essence of
19 the denominator data and the validity or
20 validation testing.

21 The methods that we use were developed
22 in-house and consistent with what we use for

1 other quality measures that are already NQF-
2 approved. We did understand that there may be
3 some concern regarding the three state
4 validations that we presented. And we debated
5 whether or not to include all three, but, for the
6 sake of transparency, we decided to include
7 Wisconsin and Minnesota, in addition to Nevada.

8 Nevada was our pilot state. They
9 worked with us once we finalized the methodology
10 and they have requirements for all their long-
11 term care facilities to report to NHSN. So, we
12 knew that invariably these facilities have some
13 opportunity and some training and education about
14 how to report to the surveillance system and do
15 it with some level of consistency, because of the
16 requirement that's there.

17 But I want to allow Suparna Bagchi the
18 opportunity to give some explanation about the
19 validation methods. Hopefully, that will provide
20 some deeper understanding as to why there may be
21 some discrepancy here.

22 Suparna, I want to see if you have any

1 comment.

2 MS. BAGCHI: Sure. Good morning,
3 everyone.

4 Thank you, Jeneita.

5 So, as Jeneita mentioned, we have
6 developed an in-house validation methodology for
7 the long-term care CDI validations conducted by
8 the states. And this was developed in
9 collaboration with the Nevada Department of
10 Public Health, primarily because Nevada is one of
11 the states which has a mandatory requirement for
12 reporting. So, Nevada was the State that pilot-
13 tested our methodology around 2018.

14 But around the same time, prior to our
15 development of this methodology, around the same
16 time, Massachusetts was already conducting long-
17 term care validations. So, they had the criteria
18 for the facility selection was different than
19 that that's proposed by NHSN. And Wisconsin
20 followed the suit pretty soon.

21 So, the general methodology that NHSN
22 follows is like it's trying to maximize the

1 resources we suggest for states with greater than
2 50 long-term care facilities. They would select
3 facilities with at least greater than a hundred
4 bed size.

5 And the idea was to maximize the
6 possibility of the validators being able to
7 identify an adequate number of charts which would
8 provide us with a fairly good sample size to have
9 some precision and accuracy and the precision of
10 the estimation.

11 So, the methodology of Wisconsin and
12 Massachusetts was different, and that could
13 attribute to some of the reasons why the sample
14 sizes are significantly smaller than Nevada.
15 However, we did, when we started putting together
16 the package, we wanted to be transparent that,
17 even though we definitely worked with Nevada, and
18 we are concerned about the methodology and the
19 results, we still wanted to go ahead and provide
20 the results.

21 And we cautioned the leaders about the
22 results that we have identified, the Wisconsin

1 and Massachusetts validation. And we definitely
2 understand that the smaller number of charts that
3 were sort of viewed could lead to accuracy
4 estimations with lesser precision.

5 As far as the denominator validation
6 is concerned, definitely, that has been on NHSN's
7 list. However, because of the lack of resources,
8 our current focus has always been on the
9 numerator validation. At some point, we
10 definitely hope that we would be able to conduct
11 denominator validation, too.

12 That concludes my summary --

13 MS. BELL: Yes, and I think along
14 those lines, it might be helpful to understand
15 that there is no specific funding dedicated to
16 any of this. So, all the states and all the
17 nursing homes and staff that have contributed to
18 this validation have been voluntary. And we are
19 grateful for their participation, but it also
20 limits our ability to control all the factors
21 that come into bringing this all together.

22 CHAIR CELLA: Hi. This is Dave Cella.

1 MS. BELL: I think that concludes our
2 remarks.

3 CHAIR CELLA: Yes. Thank you. This
4 is Dave Cella. I'm one of the Co-Chairs, but
5 also on this Subgroup.

6 Just to move things along, does the
7 Subgroup or anyone on the Committee have any
8 questions in response to this response from the
9 developers?

10 Thank you for that, by the way.

11 MS. WILBON: I think there's several
12 hands raised. I didn't catch the order.

13 CHAIR NERENZ: Christie, Larry,
14 Patrick, at least as they appear on the list I
15 have.

16 CHAIR CELLA: Yes. Okay. Go ahead,
17 Christie.

18 MEMBER GLANCE: I have a really quick
19 question to the measure developers. You said
20 that you are very concerned about the data
21 collection element piece and that was why it was
22 difficult to do more patient-level risk

1 adjustment. My question is, why not use the data
2 that is available that is already being collected
3 by CMS for Nursing Home Compare and use that data
4 for patient-level risk adjustment?

5 MR. EDWARDS: This is Jonathan.

6 I would just add in here that the
7 timeliness and completeness of data is definitely
8 an issue we have encountered on a number of them
9 where we have attempted the idea of can we bring
10 in data from other data sources. One of the
11 challenges we faced -- and I definitely
12 understand the idea that, theoretically, you
13 ought to be able to just have data on all
14 facilities and be able to easily move that in. I
15 don't know all the particulars of that myself
16 specifically, but one of the issues is timeliness
17 of the data and, then, the other one is the
18 completeness.

19 And when I say "completeness," one of
20 the things I'm bringing up is the ability to
21 actually merge and match data from other data
22 sources with those that report into NHSN. And

1 so, one of the things that I'll report on is, in
2 general, not with the Nursing Home Compare data,
3 but in other data sources we've looked at for
4 this population of health care delivery, is to
5 basically have to confront a 80 percent or lower
6 match rate.

7 So, there are problems and technical
8 challenges in trying to align with how data might
9 be reported from another data source with how it
10 is reported in NHSN. Largely what we try to
11 promote is a brick-and-mortar structure,
12 identification of a facility. And I think that
13 we would need the data to be timely in NHSN.

14 And I'll just stop there, if other
15 colleagues have something to add.

16 CHAIR NERENZ: Thank you. We're
17 trying to move through on schedule.

18 Patrick, do you want to go from here?
19 Patrick, and then, Christie, if your hand was up
20 and you want it back up. I don't see it now. Go
21 ahead, Patrick.

22 MEMBER ROMANO: Yes, thank you.

1 I think a big stumbling block for me
2 is the actual data that you've recorded on
3 validity testing. And I'm wondering if you could
4 help us interpret this. I did look at the
5 ancillary documents that you provided.

6 So, it appears, if I understand
7 correctly, that the sampling for your validation
8 study is based on positive laboratory reports of
9 C. difficile. You can correct me if I'm wrong.
10 And then, your auditors do a further evaluation
11 of that.

12 Now your report from Massachusetts, of
13 course, is very, very low sensitivity of 26
14 percent. It's higher in Nevada of 90 percent.
15 So, maybe you could help us understand that for a
16 second. I understand that only Nevada has a
17 mandatory reporting via NHSN, but I assume that
18 Massachusetts also has some state-level reporting
19 or something going on that led them to
20 participate in this pilot in the first place.
21 So, maybe you could explain that variation in
22 sensitivity between 26 percent and 90 percent.

1 And then, I'm also concerned about the
2 variation in specificity rate as there seems to
3 be a fair amount of over reporting going on, and
4 you explain that. But normally, specificity of
5 even 80 percent in Nevada would be considered
6 unacceptable because that really, depending on
7 the prevalence of the events, that could lead to
8 a very large number of false positives.

9 So, maybe if you could just help us
10 understand a little bit the sampling for the
11 validation study and the wide variation and,
12 overall, what you're doing to respond to that?

13 MS. BAGCHI: Sure. This is Suparna
14 then.

15 So, as I mentioned earlier, yes, we
16 understand the concerns about the differences in
17 the findings between the states. So,
18 Massachusetts was not a part of the pilot
19 testing. So, they conducted their validation
20 prior to the validation guidance being provided.

21 I have received the results from the
22 state validation. They identified 10 facilities

1 for validation that had complete data in the six
2 months prior to their validation timeframe, which
3 probably was, given the concerns about the data
4 completeness, already narrowed down the sampling
5 pool. And from the facilities that were
6 identified to have the complete data in the
7 timeframe of six months prior to the validation,
8 possibly could have less from smaller facilities
9 with the lesser number of medical records
10 available for validation.

11 So, a response from the Massachusetts
12 Department of Health, from the facilities that
13 they selected, the number of charts that they
14 were able to identify ranged from like zero to 19
15 across these facilities. And that supplies the
16 reason why they have such a small sample size.

17 But given the smaller sample size of
18 the charts that were reviewed, any assessment of
19 the accuracy for the 26 percent sensitivity, it
20 makes us question the precision. So, it is, as
21 you've mentioned, it is not a really good
22 presentation of the long-term care settings

1 within even the State of Massachusetts. So, it
2 would not be correct to compare the results of
3 Massachusetts with even Nevada --

4 MEMBER ROMANO: Thank you.

5 MS. BAGCHI: -- in terms of any
6 accuracy estimates.

7 CHAIR CELLA: Okay. Christie Teigland
8 had her hand up. She got disconnected. I think
9 I don't see any other hands up.

10 MEMBER TEIGLAND: I'm here. Can you
11 hear me?

12 CHAIR CELLA: Yes, if you have a quick
13 question? We're trying to move very quickly.

14 MEMBER TEIGLAND: A really quick
15 question. Yes, I just was curious if you
16 attempted at all to link to the Minimum Data Set
17 where you could get a lot of those
18 characteristics that you would need to
19 appropriately risk adjust the measures with the
20 demographic characteristics about the patients.

21 MR. EDWARDS: So, the answer is --
22 this is Jonathan Edwards -- no, we did not link

1 to the Minimum Data Set. I think to go back to
2 the concerns that I was mentioning prior about
3 the timeliness and the completeness of data, and
4 when I mention "completeness," I'm really
5 primarily thinking of the ability to have
6 complete data to match and merge in. If we have
7 a match rate of anything less than 100 percent,
8 then that would mean that we would get skewed in
9 the facilities based on the lack of matching
10 within that data set. And that does not even
11 bring in the fact that there is a timing issue.

12 Thank you.

13 CHAIR CELLA: Thank you. I want to
14 thank the developers and make sure there are no
15 final comments from the Subgroup or the
16 developers.

17 Otherwise, I think it's time to move
18 to a vote.

19 MS. WILBON: So, we will be voting on
20 validity only. This will be based on the
21 discussion that we've had around their data
22 element validity testing. The voting results

1 from the validity testing will also serve as the
2 reliability vote because of our pass criteria
3 regarding data element validity testing.

4 So, those Subgroup 1 members, we're
5 just going to do a quick roll call here to see
6 who's on.

7 Daniel Deutscher, are you there?

8 MEMBER DEUTSCHER: Yes, I'm here.

9 MS. WILBON: Okay. All right. Dave,
10 I know you're here.

11 Matt, I heard you.

12 John, I heard you.

13 Joe Hyder, are you there? Okay.

14 Patrick, I heard you.

15 Sherrie, are you there? I think I saw
16 Sherrie.

17 CHAIR CELLA: She's been on the chat.

18 MS. WILBON: Okay.

19 CHAIR CELLA: She asked for the ballot
20 to be sent to her.

21 MS. WILBON: Okay. Terri, are you
22 there?

1 MEMBER WARHOLAK: I am.

2 MS. WILBON: All right. Mike Stoto?

3 MEMBER STOTO: Yes, I'm here.

4 MS. WILBON: Okay. And, Larry, I know
5 you're there.

6 So, we'll have one, two, three, four,
7 five, six, seven, eight, nine voting.

8 Okay, Hannah.

9 For those of you in Subgroup 1, if you
10 will try to make sure you clicked on the voting
11 link in the email, and the survey should be up
12 for you, and we'll display the voting results
13 when everyone has voted.

14 MEMBER STOTO: Are you sending an
15 email now with voting?

16 MS. WILBON: It got sent maybe about
17 20 minutes ago.

18 MS. INGBER: At roughly 9:02.

19 MS. WILBON: Thank you.

20 It should be toward the top of your
21 email.

22 MEMBER STOTO: Okay.

1 CHAIR NERENZ: But it doesn't say
2 "voting link" in your subject line. It starts
3 with the agenda. The voting link is further
4 down. You just have to scroll down.

5 MEMBER STOTO: Okay. Thank you.

6 PARTICIPANT: The link that she sent
7 yesterday also works. That's the link I used.

8 MS. WILBON: Yes. We were just trying
9 to put it at the top of the email. Whichever you
10 get to first is fine. It's the same one. Hannah,
11 could you just give us an update? Are you seeing
12 votes coming in? Do we have a sense of who has
13 voted at this point, how many --

14 MS. INGBER: Yes, I have eight votes
15 in and I'm waiting for one more.

16 MEMBER STOTO: This is Mike. I'm
17 having trouble finding the link. I'm not sure
18 I'm looking --

19 MS. WILBON: That's okay.

20 MEMBER STOTO: Where is it in that
21 email?

22 MS. WILBON: All the way at the

1 bottom. I can send it to you again.

2 MEMBER STOTO: All the way at the
3 bottom? Okay. No, I'll go. Voting. I got it.

4 MS. WILBON: Thank you.

5 MEMBER STOTO: Okay. I think I've
6 voted now.

7 MS. INGBER: Okay. Yes, I see your
8 vote.

9 One minute while we adjudicate the
10 results. I'm going to share the results on my
11 screen.

12 Okay. You should be able to see the
13 results for validity on Measure 3556.

14 We have eight votes for low and one
15 vote for insufficient. Therefore, the measure
16 does not pass on validity.

17 MS. WILBON: So, I just do want to
18 thank the CDC team for joining us and for,
19 obviously, all the work you're doing in the
20 current crisis. We do hope that you are able to
21 take the feedback from the Methods Panel and
22 consider some other approaches to potentially

1 improving the measure. We, again, want to thank
2 you for your time and engagement in the process.

3 MS. BELL: Thanks for your
4 consideration.

5 MS. WILBON: And with that, let's go
6 ahead and keep things moving. We'll be moving on
7 now to Subgroup 2 and the evaluation of Measure
8 2496, Standardized Readmission Ratio for dialysis
9 facilities.

10 And if you want to check to see if the
11 developers are on the line? I believe that is
12 Casey Parrotte, Joe Messina, Jesse Roach, Joel
13 Andress, Wilfred Agbenyikey, and Jennifer
14 Sardone.

15 Is anyone from the team on the phone
16 before we get started?

17 MS. INGBER: I see Casey's name in the
18 webinar, but I don't hear you. I'm not sure if
19 you guys got the speaker line, but if you hit *1,
20 the operator should be able to connect you and
21 open your line.

22 MR. MESSANA: This is Joe Messina from

1 UM-KECC. Am I audible?

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

3 MR. MESSANA: Okay. So, I'm not the
4 principal discussant from our group. I believe
5 Dr. Jack Kalbfleisch and Dr. Claudia Dahlerus
6 were and they received the same speaker line
7 information that I did. So, hopefully, they're
8 on and just being shy.

9 MS. WILBON: Okay. Maybe unmuting
10 your phone?

11 MR. KALBFLEISCH: Yes, this is Jack
12 Kalbfleisch. Yes, I'm on the line. I'm trying
13 to get over my shyness here.

14 (Laughter.)

15 MS. WILBON: Okay. Okay. Great.

16 CHAIR CELLA: Okay. This is just a
17 reminder, everyone, we barely made it under the
18 wire on time with the previous discussion. So,
19 to calibrate, please try to make your comments
20 concise. A friendly reminder.

21 MS. WILBON: Okay. Thanks. We'll
22 dive in here.

1 So, we're now on Measure 2496. This
2 is a maintenance measure. Its most recent
3 endorsement was in 2016. It's a Standardized
4 Readmission Ratio for dialysis facilities. It
5 looks at the ratio of the number of index
6 discharges from acute care hospitals to that
7 facility that resulted in an unplanned
8 readmission to an acute care hospital within 4 to
9 30 days of discharge to the expected number of
10 readmissions given the discharging hospitals and
11 the characteristics of the patients, and based on
12 a national norm.

13 It's based on claims and registry
14 data. It's measured at the facility level. It
15 is risk-adjusted.

16 For this measure, there was consensus
17 not reached for reliability and not passing a
18 vote for validity.

19 I'll just do a really high-level
20 overview of what they did for reliability and
21 validity, and then, hand it over to our lead
22 discussant. I'm not sure that Susan is on. So,

1 it will be Gene who will, hopefully, be leading
2 us in identifying some of the concerns.

3 For reliability, they did four-level
4 reliability using the IUR and the PIUR that we
5 spent a great deal of time discussing, and the
6 notes are there in the discussion guide. Again,
7 we're on page 12 of the discussion guide.

8 For validity, they presented testing
9 for data elements and measured four-level
10 testing. They did present some data element
11 validity testing, but this does not meet our
12 requirement. So, we are going to ask the panel
13 to focus on the measure for empirical validity
14 testing, which they compared this measure to four
15 other measures using Pearson's correlation.

16 So, with that, I'm going to hand it
17 over to Gene Nuccio to give us a summary of some
18 of the concerns raised by the Subgroup for this
19 measure.

20 MEMBER NUCCIO: Yes. Thank you.

21 There are several concerns about the
22 use of IUR and PIUR. We discussed much of that

1 yesterday. Let me just do a quick summary.

2 By the way, the developers provided a
3 very lengthy response, beginning on page 76 in
4 the detailed discussion guide. We thank them
5 very much for that. That was informative.

6 One of the concerns was that in their
7 previous presentation the IUR values for the
8 measure were on average 0.55. I couldn't find a
9 PIUR number for the previous one. However, in
10 the new presentation with more recent data, the
11 IUR value dropped to 0.35 and the PIUR value
12 dropped to 0.61. Both of these are below that .7
13 value that we discussed yesterday with Adams.
14 So, that was a concern.

15 The developers did provide several
16 reasons regarding why they think that this drop
17 was expected; notably, dealing with the fact that
18 these are publicly-reported values now and, also,
19 part of a value-based purchasing program, which
20 would suggest that people are getting better.
21 And I suspect the assumption is that there's less
22 variation going on. Nonetheless, the values for

1 reliability are rather low.

2 There was another set of questions
3 regarding bootstrapping and a bootstrapping
4 methodology. And this had to do with the size of
5 the agencies where the agencies that are
6 delivering dialysis service were small and didn't
7 have sufficient information. And so, they used a
8 bootstrapping method.

9 In their response, they talk about
10 patient years, which I believe is patient-years
11 at risk. And just out of curiosity, you know,
12 why can't you just use age, given that people
13 would develop these sorts of needs for dialysis
14 perhaps at a later age, and prior to that there
15 was no need for this? So, age of the patient.

16 But if the developer could explain
17 their response to issue No. 3, that bootstrapping
18 deals with the size of the agency, but they
19 reported the information based on the age of the
20 patient. And then they say in their notes that
21 they noticed that a lot of other developers are
22 doing this.

1 But again, let me just do the validity
2 real quickly here. The Pearson correlations are
3 notably low, down in the .1 level, and this is
4 not an r-squared. It's just an r. So, that was
5 a concern there.

6 Also, one of the interesting things,
7 what they did -- I think a positive thing -- is
8 that they allowed for the Medicare Advantage
9 patients to be calculated by looking at claims
10 data for inpatient claims because you can
11 aggregate both the Medicare fee-for-service and
12 the Medicare Advantage on the inpatient claims,
13 but you can't do it for outpatient. So, this is
14 a change from the previous measure, and perhaps
15 that's accounting for some of that difference.

16 Also, they did make a positive change
17 in looking at excluding patients who were only in
18 service on dialysis from zero to three days.
19 Given the lack of stability, they excluded those
20 patients from the data set, and they should be
21 applauded for that.

22 The final thing that I want to mention

1 -- two things. One was that they did make use of
2 the sociodemographic variables, and they are to
3 be congratulated on the use of sociodemographics.

4 The one last thing that was of some
5 concern was the power of the model. The
6 C-statistic for the logistic was only 0.6359,
7 which is rather low. And so some of the
8 discrimination characteristics of the lower-than-
9 expected, as-expected, and worse-than-expected,
10 basically, the numbers of patients that performed
11 poorly, as I'm understanding the last table that
12 they provided in their response. For the group
13 flagged as better-than-expected, that was 136
14 patients. They had the same number of facilities
15 -- the same number of facilities showed up in the
16 as-expected in terms of worse-than-expected. The
17 number of facilities in the as-expected group was
18 204, and in their flagging the number of
19 facilities was 245. So, again, there seems to be
20 a lack of discrimination, perhaps due to the risk
21 model.

22 I'll stop there.

1 MS. WILBON: Thanks, Gene.

2 This is Ashlie.

3 I just wanted to point out one thing.

4 Our discussion yesterday about thresholds, that
5 was more of a forward-thinking discussion. And I
6 just want to make sure that we're not applying
7 any kind of new rule, based on discussions
8 yesterday, to the measures we're evaluating
9 today. So, I think the .7 threshold is desirable
10 for many, but it's not kind of a new rule or
11 anything that we're imposing. But, certainly, in
12 terms of consistency from the reviews that were
13 done by the Methods Panel, the cycle that the IUR
14 reported is lower than other measures that
15 passed.

16 I see we have a hand raised from Jeff.
17 Did you want to make a comment?

18 At this point, I guess we should open
19 it up to other Subgroup members.

20 Jeff, go ahead.

21 MEMBER GEPPERT: Sure. Just quickly,
22 I think in a lot of respects their methods that

1 are used are not position exemplary and the
2 results are presented with a lot of integrity, as
3 Eugene mentioned.

4 So, for a mature measure like this, I
5 think a more compelling demonstration of validity
6 is warranted. Demonstrating validity with
7 correlations among more measures seems like a
8 circular argument, in that each measure is
9 essentially used to demonstrate the validity of
10 the others. And a more compelling demonstration
11 might be to give evidence that the quality
12 construct itself is causally related to the
13 likelihood of experiencing these outcomes of
14 interest. For example, if there's something that
15 better dialysis centers do or have that worse
16 dialysis centers do not do or do not have, you
17 know, that is causally-related. So, that would
18 be simply a more compelling demonstration for a
19 very mature quality measure.

20 Thank you.

21 MS. WILBON: Hi, Christie. Go ahead.

22 I see your hand.

1 MEMBER TEIGLAND: Hi. I'll try not to
2 disconnect myself this time.

3 So, I had a concern, and to make sure
4 I understood this correctly, that the model was
5 developed using a year's worth of data, and I
6 believe just from Medicare fee-for-service
7 patients. And this model is being applied to
8 Medicare Advantage, which we know is a little bit
9 different. And I know you just have adjustments
10 for that.

11 But, then, the model, the way it's
12 implemented is it gives you the only diagnoses on
13 discharge claims. So, having extensive
14 experience working with claims data, I know that
15 discharge claims only contain very few diagnoses.
16 Obviously, the primary diagnosis for those is the
17 hospitalization stay and maybe a secondary
18 diagnosis that's also related to the stay. But
19 in no way do they document all the chronic
20 conditions. So, that means if you have less
21 patients who were discharged for some type of
22 inpatient stay that didn't involve their heart

1 failure or their diabetes, or their whatever else
2 is in the model, they're going to not get
3 properly risk-adjusted.

4 So, I'm concerned that you developed
5 the model using a year's worth of data which it
6 does take significant time to document all the
7 conditions that patients have. But the way it's
8 implemented, it's only using a subset of that,
9 which could have resulted in some of those very
10 small validity findings.

11 CHAIR CELLA: I think we should move
12 to developer discussion if there are no other --
13 oh, wait. Bijan and Jack. Sorry. Go ahead,
14 Bijan.

15 MEMBER BORAH: Hi. Good morning.

16 So, I think this is something that
17 has been pointed out earlier. So, there was a
18 significant drop in IUR from the prior submission
19 to the last submission, from .55 to I think .35.
20 The only difference was that we are using more
21 outdated data. And I think as was pointed out
22 earlier, we also had Medicare Advantage data. I

1 guess it could be a good question as to what is
2 the rationale or what was the thinking behind
3 what is dropped.

4 And my other sort of question was, the
5 initial analysis they have used, taken here, as
6 opposed to the number taken, and I guess in terms
7 of how Medicare patients are penalized. I mean,
8 particularly the unique age of the patients. I
9 think it would be really helpful to understand
10 how including patient-years versus simply the
11 number of patients, I mean, how would the results
12 change? It would be insightful if they would
13 present the results both ways, including patient-
14 years as well as simply patients.

15 Thank you.

16 CHAIR CELLA: Jack? Yes. Okay. Thank
17 you for lots and lots of comments.

18 MEMBER NEEDLEMAN: This is Jack.
19 Sorry, it took me a while to get to my mute
20 button.

21 I just have like three comments, some
22 of them responding to the response of the

1 developers. I, again, want to echo we're getting
2 excellent documentation of these measures, and
3 nothing is nefarious about the documentation.

4 With respect to the IUR versus PIUR,
5 I think the IUR is low, lower than we should
6 expect. And given that centers will be evaluated
7 across the distribution of experience, not simply
8 the outliers, the IUR for me is the relevant
9 measure, unless we're being told we're only
10 looking for outliers in this measure, which we
11 have not been told.

12 Second, the developers make a specific
13 comment in their response about the IUR going
14 down because we're getting better risk
15 adjustment. But I'd simply point out that, if
16 we're getting better risk adjustment, that means
17 that we're getting a more accurate measure of the
18 expected. And when we do that, the range of
19 distribution across the facilities is narrowing.
20 So, it's harder to find differences across the
21 providers, but the conclusion that a lower IUR is
22 an indication we're doing a better job of

1 discriminating across providers is simply wrong.

2 The third thing is, there's a comment
3 on the analysis comparing to other measures
4 about, while the correlations have gone down, the
5 directions are right, which is terrific, but they
6 are very precise. The estimates are very
7 precise. The statistical significance is -- the
8 p-values in the statistical significance are
9 very, very low.

10 All that means is you've got precise
11 estimates. And what really matters is the
12 magnitude of the correlations, not the p-values.
13 You can't point to a p-value and say, because the
14 p-value is so good, it's showing that these
15 measures are correlated.

16 The question is, what's the level of
17 correlation? And you noted the correlations are
18 low.

19 I'm done.

20 CHAIR CELLA: Okay. Now to the
21 developers. Thank you for your patience. I know
22 that's a lot of questions.

1 MR. KALBFLEISCH: Okay. So sorry, there are two
2 Jacks around obviously.

3 CHAIR CELLA: Yeah, sorry about that.

4 MR. KALBFLEISCH: This is Jack
5 Kalbfleisch. I'm a professor of biostatistics
6 and statistics at the University of Michigan.

7 I'm going to talk about -- mostly
8 about the reliability issues and a few other
9 things. And I think that Dr. Dahlerus will talk
10 more with regard to the -- with regard to
11 validity. And we'll also kind of pick up a
12 number of other comments as well.

13 And one of the first ones, one that's
14 frequently asserted a change in the IUR this time
15 from the last time which, of course, was of
16 considerable concern to us too, to see that
17 change so large.

18 And we really don't know why that
19 happened. There's been a lot of changes since
20 the last time. And I think a number of you have
21 already mentioned in the discussion there's sort
22 of been changes in the data, changes in measuring

1 instruments, and to some extent, changes in the
2 response that we use now. We don't use the first
3 three days which had been used before in the IUR
4 measure.

5 So there are a number of changes in
6 there. One which I think is substantial is that
7 there has been involvement of a measure in
8 equipment and in the five-star ratings and also
9 in Dialysis Facility Compare presentations. So
10 there's more attention paid to this measure by
11 facilities than there was in the past. And
12 that's a good thing, of course.

13 I think we also more completely
14 account for comorbidities in that we changed the
15 way we measure comorbidities from CMS
16 hierarchical condition categories to the AHRQ CCS
17 diagnostic categories.

18 There are more measurements of
19 comorbidities than there used to be. And we've
20 expanded the number of measures that would be
21 used. So all of these have some impact on
22 reliability.

1 I certainly agree that reliability
2 goes down doesn't mean necessarily that you're
3 doing a better job of accounting for facility
4 differences in a model. Reliability can go down
5 for two reasons.

6 One is because the facility -- the
7 adjustment in facility, the differences are
8 smaller, that you get a smaller variance
9 corresponding between facilities. Or the other
10 is that you get more variation among patients
11 within a facility. And either of those can
12 account for change in reliability -- in the IUR
13 rather.

14 I guess one sort of general concern,
15 I think, is with IUR itself in that IUR is inter-
16 unit reliability. It was called that for some
17 reason. I don't know. It's really just a
18 correlation.

19 It's an inter-class correlation
20 between the -- with respect to the measure rather
21 than the individual, so that the individual gives
22 you the ICC, the inter-class correlation; the IUR

1 is with respect to the measure. And so it's a
2 measure of signal to noise or correlation.

3 It's given the name reliability, and
4 I think one gets a transfer then to everyday
5 language -- from everyday language to the
6 technical language that one needs to worry about.
7 I think the original technical report by Adams,
8 which led to the 0.7 which again the committee is
9 considering, it prefaces the comments in that
10 technical report that his arguments are based on
11 the assumption that inter-facility differences
12 are entirely due to the quality of care.

13 But I think this is seldom the case
14 that there typically are unmeasured confounders
15 like genetic differences or diet, socioeconomic
16 factors that we really can't measure very well
17 and that affect the responses and that also
18 differ in their distribution between facilities.

19 So IUR should be interpreted with some
20 care, I think. And even with relatively large
21 IURs, one should be cautious about making
22 comparisons of facilities, especially in the

1 center part of the distribution. There's always
2 the possibility on unmeasured confounders
3 affecting the variability.

4 Also as you pointed out, a low IUR
5 doesn't mean that the measure is not useful for
6 profiling because there can be a relatively
7 smaller subset of providers that are extreme and
8 of interest. This is partly because the IUR is
9 to be based on normal of function. And it
10 doesn't really recognize what's going on the tail
11 very well.

12 So you can have an ultimately smaller
13 group be extreme and certainly of interest
14 because they're actually likely to get a faulty
15 improvement program in. But the IUR doesn't pick
16 that up as something the measure is capable of.

17 And so that's the motivation of the
18 PIUR. And it's really based on the rather simple
19 idea that a measure can be viewed as reliable if
20 the probability will be reidentifying the same
21 facilities in the same category and perhaps an
22 extreme category -- those that are verified

1 outside the range in the upper 2.5 percent, 5
2 percent, or 10 percent -- reidentifying those
3 facilities in a new sample under the same
4 conditions. If that probability is relatively
5 high with that, it could be taken as a measure of
6 reliability.

7 I think in the introduction actually
8 to the form, on reporting on the measure to the
9 NQF panel, it actually describes reliability in
10 terms like that, basically the ability to repeat
11 the classification.

12 So unlike the IUR, if the IUR is not
13 based on normal assumptions, if the probability
14 of reidentification is estimated based on data
15 splitting, and it doesn't really involve normal
16 assumptions at all. And I think that's something
17 of an advantage. But it does concentrate on
18 specific things like the tail area.

19 The standing committee made, I think,
20 a comment that there's an indication of the
21 measure are useful for identifying extremes is
22 quite true. But on the other hand, I would argue

1 that that's an important aspect for information
2 too.

3 You could standardize the PIUR in
4 various ways. Although we use the properties for
5 the IUR under a normal model to calibrate the
6 PIUR so that we basically calibrate the PIUR by
7 picking a value of IUR that we give the same
8 probability of reidentification. So the same
9 probability of reflagging individuals.

10 So that's done -- in the IUR, it's
11 done in a very normal assumption. And it's
12 really just way of trying to get something which
13 is trying to get at a way of calibrating the PIUR
14 that relates to measures of some of the claims.

15 The PIUR would give has a reference to
16 a tail area of 2.5 percent which you can get
17 similar results with other fill areas as well at
18 5 percent or 10 percent. But it's focusing
19 basically on tails of the distribution.

20 I think the higher PIUR, and it's
21 still I think 0.7 is a very high bar. But the
22 high PIUR I think indicates that it is very

1 useful in identifying facilities that are
2 relatively extreme compared to the central part
3 of the distribution.

4 It's less useful, I think, for ranking
5 facilities closer to the center of the
6 distribution. Although I think it should be
7 recognized that ranking facilities in the center
8 of the distribution is a difficult task for most
9 measures, even moderate or even high IUR,
10 especially if you account for the likely
11 existence of unmeasured confounders.

12 So I think basically the PIUR
13 indicates that the measure is quite useful for
14 identifying extreme values.

15 MS. WILBON: Hi, Dr. Kalbfleisch.
16 This is Ashlie from NQF. I apologize for
17 interrupting, but we want to try to make sure
18 that we have enough time for you guys to finish
19 your response for validity as well as allow the
20 methods panel to ask any additional questions.
21 And we still have one more measure review during
22 this time frame.

1 So if I can just encourage you guys to
2 be succinct in your remarks, and then we can try
3 to stay on time.

4 MR. KALBFLEISCH: Okay. I think that
5 was basically what I wanted to say about IUR, I
6 think at this stage. So I could pass it on to
7 Dr. Dahlerus to talk about validity or take
8 questions. I don't know.

9 MS. WILBON: Yes, we'll hear from your
10 colleague about validity. Thank you.

11 MS. DAHLERUS: Hi, this is Claudia
12 Dahlerus from University of Michigan. Can you
13 hear me? I want to make sure that I'm connected.

14 CHAIR CELLA: Yes, we can hear you.

15 MS. DAHLERUS: Wonderful. Thank you.
16 Good morning. Okay. I will be concise in our
17 responses regarding the validity testing we did
18 for the SRR. So we do recognize that the
19 correlation coefficients were a little lower than
20 in the prior submission from 2014.

21 What I would reiterate that the
22 hypothesized association for the direction of the

1 correlations are very consistent and in the
2 expected direction for all of the other outcome
3 and intermediate outcome measures that we
4 validated the SRR against.

5 I did want to highlight that there has
6 been some changes to the underlying data source
7 since the original submission six year ago which
8 used actually 2009 data. And here, we're using
9 more current data that includes ICD-10 diagnostic
10 codes versus ICD-9. So that's one substantial
11 change.

12 Given that, we felt it was reassuring
13 to see a consistency in the direction of the
14 correlation coefficients and that the declines
15 weren't huge, so we sort of stand by what we
16 report in terms of our validity results.

17 Also the measures that we validated
18 the SRR against have also undergone some
19 definition changes. This would include all of
20 the measures, so the hospitalization and
21 mortality measures in the prior round did not
22 include adjustment for prevalent comorbidities

1 and now they do. And the SMR is also underlying
2 the population change where it was restricted
3 down to the Medicare-only population.

4 So this likely may have influenced
5 potentially some change in the correlation
6 coefficient. But at least, again, we maintain
7 that the direction of those associations were
8 very consistent and still very statistically
9 significant.

10 There are two intermediate outcome
11 measures that really reflect the delivery of care
12 by the dialysis facility. And so I think this
13 may address one is the panel member's concerns
14 about using sort of measures to validate against
15 reflecting what the dialysis center can do to
16 help manage outcomes in their patients.

17 And so the fistula measure and the
18 catheter measure both reflect care that is
19 delivered directly by the dialysis center where
20 they have some control over outcomes that may
21 help them manage hospitalization readmission in
22 their patients.

1 Both of these measures were correlated
2 with the SRR in the expected direction. The
3 measures that we used however have undergone
4 changes since the original submission. So that
5 would account for some of the changes that we're
6 seeing in the correlation coefficient.

7 So the other change that was made was
8 how we handle Medicare Advantage patients. They
9 were included in the measure before. But they
10 were not accounted for in a way that makes sure
11 we are capturing all available comorbidities that
12 are used for a risk adjustment. So we've
13 modified that in the current SRR model.

14 So given sort of the range of changes
15 and, both to measure specifications as well as to
16 underlying data source, we do feel very
17 comfortable with the correlation coefficients and
18 the empirical validity testing results.

19 And we think that this really
20 demonstrates quite good stability from the
21 previous submission in 2014 to this current
22 submission and think that the results represent

1 both stability and robustness in light of those
2 changes that were made.

3 I will stop there because I know we're
4 short for time, unless there were other specific
5 issues in validity that you would like addressed
6 regarding Medicare Advantage -- the inclusion of
7 Medicare Advantage patients.

8 CHAIR CELLA: Thank you very much, and
9 thank you for being concise. Any other questions
10 or comments from the committee, from the
11 subgroup?

12 MR. MESSANA: If I may respectfully
13 ask, this is Joe Messina. I would add one last,
14 final comment. The -- one of the discussants at
15 the beginning of this section talked about or
16 questioned the use of inpatient claims only.

17 I think it's important to know that
18 both for Fee-for-service and Medicare Advantage
19 patients, the average number of claims-based
20 diagnoses identified from inpatient claims as in
21 the 12 to 14 range in this population and didn't
22 differ between Fee-for-service and Medicare

1 Advantage, differed by single-digit, small
2 percentage.

3 So we feel very comfortable with the
4 decision to use inpatient-only claims as a
5 reasonable compromise between the possibility of
6 excluding Medicare Advantage patients entirely
7 from the measure which would be, we think, an
8 overreaction. And we're comfortable with the use
9 of inpatient claims as a reasonable source for
10 identification of claims-based comorbidities
11 here. Thank you.

12 CHAIR CELLA: Thanks. Jack Needleman,
13 your hand is up.

14 MEMBER NEEDLEMAN: Yeah, hi. Thank
15 you. That's actually very relevant information
16 and very helpful in thinking about how well the
17 risk adjustment is performing from the hospital-
18 only data.

19 But was any analysis done for the
20 Medicare Fee-for-service population comparing the
21 risk adjustment estimated expected patient and
22 then by facility using just the inpatient data

1 and also using the look-back on the outpatient
2 claims as well?

3 CHAIR CELLA: Response?

4 MS. DAHLERUS: So do you mean just
5 including -- so excluding Medicare Advantage
6 patients and just --

7 MEMBER NEEDLEMAN: Basically yeah. So
8 you're making this change in method and you have
9 an old method and you have new method. And
10 you're applying the Fee-for-service patients, and
11 I get that. But did you do the comparison of
12 what would be of value from the Fee-for-service
13 patients using the old method? What do we get
14 using the new method? And how comparable are the
15 results?

16 MS. DAHLERUS: Okay. So I'd have to
17 check with our analyst. I don't think we did an
18 analysis that's just restricted to Medicare Fee-
19 for-service patients. We did compare the
20 predictability of using -- of outpatient versus
21 inpatient claims with respect to how well they
22 predict the outcome.

1 And as expected, use of inpatient
2 claims were far more predictive than outpatient
3 claims. And because we do get inpatient
4 comorbidities for Medicare Advantage patients, we
5 felt very comfortable again with the decision to
6 include them.

7 But in terms of the availability of
8 comorbidities for Medicare Advantage patients,
9 it's quite similar to the Fee-for-service
10 population. So we don't think that we are
11 missing a lot by excluding the outpatient claim.
12 We did not -- but I don't think that we compared
13 Fee-for-service versus Fee-for-service plus
14 Medicare Advantage.

15 MR. MESSANA: Claudia, I'll add a
16 general observation that may help in response or
17 may provide some information in response. So in
18 other measure evaluation, we have compared the
19 impact of inpatient only versus inpatient and
20 outpatient in the Fee-for-service population for
21 mortality measure development. And we saw a very
22 small effect -- a very small difference in the

1 modeling and in the C-statistic using inpatient-
2 only claims.

3 And I think that's generally
4 consistent with the approach that many in the
5 nephrology field use, including United States
6 Renal Data System, who basically apply a premium
7 to inpatient claims.

8 The way they score inpatient -- excuse
9 me, score claims-based diagnoses is that if it's
10 present on an inpatient claim, they consider it
11 identification of a comorbidity. For outpatient
12 claims, they have a different threshold that has
13 to be -- it has to be present on more than one
14 outpatient claim separated in time and/or venue
15 to be considered evidence of a comorbidity.

16 So they take the general approach of
17 putting less emphasis on outpatient claims in
18 this population, if that helps the answer.

19 CHAIR CELLA: Thank you.

20 MR. KALBFLEISCH: It may also be
21 relevant to note that Hospital Compare also uses
22 just inpatient claims has made that change as

1 well. So they also looked at that question.

2 CHAIR CELLA: Thank you, again. I
3 think it's time to move to a vote unless there's
4 any final urgent comments.

5 MS. WILBON: Hi, Dave. It's Ashlie.
6 I did just want to just -- before we vote on
7 validity, just a point of consistency. The
8 approach used for demonstrating validity in
9 terms of a correlation with other measures using
10 experiments was used on for this measure as well
11 as for a couple of others submitted from U of M:
12 1453, 0369.

13 Both had kind of similarly low
14 correlations but seemed to be all statistically
15 significant and also in the direction that the
16 developers hypothesized.

17 So I just want to make sure, from my
18 understanding and perhaps for others from a
19 consistency perspective, what may be different
20 about this measure and the parts that were
21 reported versus the other two that passed. And I
22 just want to make sure we're being consistent.

1 If there's something different, then certainly
2 let's make sure that's clear.

3 CHAIR CELLA: Can somebody address
4 that? Were all three of these with Subgroup 2?

5 MEMBER NEEDLEMAN: This is Jack. I
6 believe so. And we haven't used -- we have
7 accepted those correlations, that methodology for
8 establishing empirical validity before, not only
9 in this cycle but in prior cycles.

10 And the issue is whether the
11 correlations are high enough given that they're
12 measuring different things. And I actually found
13 the correlations high enough. My complaint was
14 not with the correlations, per se. It was with
15 the leaning on statistical significance rather
16 than on the magnitude of the correlation.

17 MS. WILBON: So sorry, this Ash. I do
18 want to say that Measures 1463 and 0369 were
19 reviewed by Subgroup 3. So there was kind of a
20 different set of panel members reviewing those.
21 But again, for the sake of consistency, I just
22 want to make sure that we're consistent across

1 all of the subgroups in that way.

2 CHAIR CELLA: Well, I think on the one
3 hand, Jack is clarifying that he's focused not on
4 the methodology but on the use of statistical
5 significance over magnitude or scientific
6 correlation.

7 I don't know that anyone can speak to
8 whether that's the basis for Subgroup 3 passing
9 the other two submissions, but it sounds like
10 it's independent. Can anyone else comment on
11 that?

12 I mean, Subgroup 2 members didn't dig
13 into Subgroup 3 measures. And Subgroup 3 members
14 didn't dig into Subgroup 2 measures. So you're
15 raising something that might not be that easy for
16 anyone to speak to.

17 MS. WILBON: Right. I wonder if some
18 members of Subgroup 3 which we're going to be
19 moving to them shortly. So hopefully, there's a
20 few on the phone might be able to just talk about
21 their consideration of the correlations that were
22 submitted for the other -- those two measures:

1 1463 and 0369.

2 Hopefully, I'm not putting anyone on
3 the spot. But if we could, if there is anyone
4 that could speak to that and we could just -- I
5 just want to make sure that before we move
6 forward with a vote, that we are just being
7 consistent so it doesn't -- it's not something
8 that we have to come back and rectify. ZQ, I see
9 your hand raised.

10 MEMBER LIU: Yeah, I think it was in
11 the past cycle and also in this cycle including
12 the measure in this subgroup, I have seen other
13 measures and correlations to validate reason for
14 validity test. I think our focus should not be
15 on, again, the scientific association, right?
16 It's based on your hypothesis whether you think
17 there should be what kind of association.

18 So it's not just, like, you really
19 need to have some really strong association.
20 Sometimes it's a negative association. Sometimes
21 there's no association. As long as you expect --
22 a reason to expect that, I think that's fine.

1 MS. WILBON: Thanks. That's actually
2 really helpful. I think that will help and
3 certainly for us in writing up summaries that we
4 will be able to explain that.

5 MR. KALBFLEISCH: And if I could just
6 comment on that briefly. We certainly take the
7 point that it's the value of the coefficient that
8 matters, not the significance. If we gave a
9 different impression, we didn't mean to.

10 CHAIR CELLA: And Gene, would you like
11 to comment? You have your hand up.

12 MEMBER NUCCIO: Yes, sorry. Just I
13 mean, the values, with all due respect to Jack,
14 and for standardized mortality rate, the R-value
15 is 0.1. For long-term catheter, 0.04. And for
16 fistula, it's -0.06.

17 So I mean, there's only one that's
18 above 0.1. And I did not find that as
19 demonstrating a meaningful difference or
20 potentially creating how these things are
21 meaningfully related, the statistical
22 significance to p-value notwithstanding. And I

1 did consider those and didn't find them
2 persuasive.

3 CHAIR CELLA: Ashlie, do you feel like
4 you have enough information to differentiate this
5 from the two that are in Subgroup 3?

6 MS. WILBON: I think so. I think so.

7 CHAIR CELLA: So then we should vote.

8 MS. WILBON: Yes. So Subgroup 2
9 members, I do just want to do a quick check. I
10 think I've heard or seen most everyone on the
11 webinar at this point. I've heard Bijan. I've
12 heard Christie. I've heard Gene. I've heard
13 Jack. I've heard Jeff. Jen, I've seen you, but
14 I didn't hear you. Are you there?

15 MEMBER PERLOFF: Yes, I'm here.

16 MS. WILBON: Okay. John, I think I've
17 seen you --

18 (Simultaneous speaking.)

19 MEMBER BOTT: I'm here.

20 MS. WILBON: Okay, perfect. ZQ just
21 commented. I think the only one missing from
22 Subgroup 2 is Susan, unless she joined us since I

1 last checked.

2 Okay. So we'll have eight Subgroup 2
3 members voting. If you could find the voting
4 link in your email that was sent this morning.
5 And click there, you should see we're going to be
6 voting on both reliability and validity.

7 MS. INGBER: Right. So voting is now
8 open for reliability on 2496.

9 Okay. I'm just going to share my
10 screen real quick. Okay. So as you can see, for
11 2496, we have zero votes for high, five votes for
12 moderate, and three votes for low, and zero votes
13 for insufficient. The measure therefore passes
14 on reliability.

15 MS. WILBON: Okay. Thanks, Hannah.
16 So the next vote we'll be making will be on
17 validity, and Hannah will give you the process
18 forward.

19 MS. INGBER: Okay. So voting is now
20 open on validity for Measure 2496. Your options
21 are high, moderate, low, and insufficient.

22 Oops. I'm sorry. I was on mute.

1 Okay. I'm going to share my screen again to show
2 the results. Okay. So you can see here for
3 2496, for validity, there was zero for high,
4 three for moderate, five for low, and zero for
5 insufficient. Therefore, the measure does not
6 pass on validity.

7 MS. WILBON: Okay. Thank you to the
8 University of Michigan development team and for
9 joining us and for engaging the discussion today.
10 And I hope that the feedback from the panel was
11 helpful and that you will continue to engage in
12 the process and that we will be in touch.

13 The next measure up for discussion I
14 think may also be some of the same team members.
15 It is Measure 3566, Standardized Ratio of
16 Emergency Department Encounters Within 30 Days of
17 Hospital Discharge for Dialysis Facilities.

18 Can someone from University of
19 Michigan let us know? Is it the same team, or
20 will be a different set of colleagues?

21 MS. DAHLERUS: Hi, this is Claudia
22 Dahlerus from University of Michigan. It'll be a

1 subset of the same team. So it will be myself
2 and I believe that Dr. Jonathan Segal is also on
3 the line --

4 MS. WILBON: Okay.

5 MS. DAHLERUS: -- and also Dr.
6 Kalbfleisch.

7 MS. WILBON: Okay. I think Dr. Segal,
8 I don't know if we spoke to him. Do you want to
9 just test to make sure we can hear you?

10 MR. SEGAL: Yes, this is Jonathan
11 Segal. Can you hear me?

12 MS. WILBON: We can; great. Thank
13 you. So I wanted to thank you guys for joining
14 and just give a brief overview of this measure,
15 3566. It's a new measure that was submitted by
16 the University of Michigan team. It is a measure
17 initially that we made an error in the tally of
18 the reliability vote.

19 So initially, we communicated that it
20 had passed reliability. And we identified the
21 error as we were preparing for the meeting and
22 finalizing materials. So the developers did not

1 have an opportunity to submit a written response.
2 So we did ask them to join in order to provide a
3 verbal response to the panel's concerns.

4 And I think we may find some
5 efficiencies because they used very similar
6 methodology for reliability that we just
7 discussed with the IUR and the PIUR. But we'll
8 get into that shortly. But again, just wanted to
9 thank you all for joining us and for being
10 accommodating.

11 So I'll just briefly review the
12 description of the measure, and we'll hand it
13 over to the lead discussants, Eric and Marybeth,
14 to discuss some of the concerns with reliability
15 before we open it up for discussion and conclude
16 with a vote.

17 So again, this is a new measure. It's
18 the Standardized Ratio for Emergency Department
19 Encounters Occurring Within 30 Days of Hospital
20 Discharge for Dialysis Facilities. It's a ratio
21 observed to affected events. And it is based on
22 claims and registry data measured at the facility

1 level. It is risk-adjusted.

2 Again, the concerns for this measure
3 were with the reliability. The developer used
4 the IUR with bootstrapping as well as presented a
5 PIUR value which is listed here in the discussion
6 guide. And I think there were a couple of
7 concerns here, both with the results and some of
8 the specifications. But I'll hand it over to
9 Eric and Marybeth to review some of the concerns
10 in more detail.

11 MEMBER WEINHANDL: All right. This is
12 Eric. Can you hear me?

13 MS. WILBON: Yes, we can.

14 MEMBER WEINHANDL: All right.
15 Excellent. So this is the Standardized Ratio of
16 Emergency Department Encounters 30 Days after
17 Hospital Discharge. I will say that my initial
18 reaction to this measure was extremely positive.
19 I think that this is the measure that fills an
20 obvious gap that exists in readmission metrics
21 from dialysis facility landscape.

22 Just to give a little bit of a

1 background, as the group just discussed, the
2 measure around hospital readmission during the 30
3 days after discharge, what there has been in the
4 dialysis population over the last approximately
5 five, seven years is a pretty steady increase in
6 emergency department encounters to the point
7 where they're occurring essentially as frequently
8 as hospital admissions are.

9 So during the 30-day readmission or
10 post-discharge period, a patient could present
11 for any number of acute care needs. They may go
12 to a hospital, be admitted as an inpatient. Or
13 they may go to an emergency department and be
14 discharged to home.

15 So I think that thinking about it from
16 that perspective helps to clarify what the
17 rationale or need is for this metric. And I
18 think it's obvious to me.

19 And so that dovetails into the exact
20 specifications of this measure. Very much of
21 this measure is very analogous and perfectly
22 harmonious to the standardized readmission ratio

1 that we just discussed.

2 Insofar as patients are discharged
3 from the hospital, the first three days of
4 follow-up during the post-discharge are not
5 tracked by the metric, but instead emergency
6 department encounters are included from days 40
7 to 30 plus discharge.

8 Now because these outcomes, the
9 emergency department encounters, are truly not
10 just emergency department and then immediate
11 transfer into a hospital bed, the outcomes that
12 are tracked are only those are taken from
13 outpatient claims insofar as the patients is in
14 the emergency room or observation status and then
15 is discharged back home.

16 Because of that difference with the
17 standardized readmission ratio, that does
18 necessitate that the measure is limited to the
19 Medicare Fee-for-service population. And that
20 may be something for the subgroup and for the
21 panel to consider insofar as it is a subset of
22 the denominator that's tracked in the

1 standardized readmission ratio. Those would just
2 be for service.

3 And to give you a qualitative sense of
4 what we're talking about, I would say that
5 approximately 80 percent of the dialysis
6 population is either in Fee-for-service or
7 Medicare Advantage. And of those 80 percent,
8 about three in four are Fee-for-service. So
9 we're dealing with about 75 percent if not more.

10 The measure is risk-adjusted -- a wide
11 variety of factors, demographic factors, comorbid
12 factors. As was discussed with reliability and
13 validity, reliability was the domain in which
14 this measure did not have.

15 And I'll specifically note that the
16 inter-unit reliability to 0.451. The profile
17 inter-unit reliability was 0.570. That is the
18 number. It's the 0.570, even for detecting
19 outliers but probably caught the attention of
20 many reviewers within the subgroup.

21 To the extent that there are forces
22 moving around the dialysis population,

1 particularly with respect to potential Medicare
2 Advantage enrollment in coming years, it's
3 reasonable to think that the number of index
4 discharges per dialysis facility may actually
5 decrease so long as this measure is restricted to
6 the Fee-for-service population.

7 And so I would encourage the group to
8 consider whether these profile inter-unit
9 reliability values are likely to remain stable or
10 potentially decrease with some erosion of sample
11 size in the future. Not a guarantee but a
12 potentiality.

13 And as far as validity is concerned,
14 the measure did pass. I won't speak a lot to it,
15 but I do want to pay attention in the discussion
16 guide to some of the values that are in Table 2
17 where the standardized measure was correlated
18 with respect to other measures.

19 I actually found this to be quite
20 heartening in many regards and quite positive.
21 You'll notice that there is a modest but notable
22 correlation with the standardized mortality

1 ratio. As one would expect, the higher mortality
2 during the post-discharge period would be
3 associated with any demand for acute care.

4 I'd also point out that that
5 correlation between this measure and the
6 standardized transfusion ratio which is the
7 second one in Table 2 is quite a positive thing.

8 The dialysis population is
9 approximately 20 percent of transfusions occur in
10 the emergency department setting. And you would
11 expect patients to generally be relatively more
12 anemic, potentially blood loss, during the post-
13 discharge period.

14 So to see that difference in the
15 standardized transfusion ratio between better
16 than expected and worse than expected facilities,
17 that's an extremely positive sign with respect to
18 the validity -- face validity of this measure.

19 And then I'll also point out the
20 second to last row, which is an interesting thing
21 in its own right, the standardized readmission
22 ratio takes the value of 1.00 on average in those

1 facility with a better or as expected. And it
2 also takes the value 1.00 in those worse than
3 expected.

4 To the extent that these two outcomes,
5 the standardized readmission ratio taking
6 hospital readmissions, this measure is taking
7 emergency department readmissions so to speak,
8 emergency department visits in the post-discharge
9 period but the patient goes home instead. One
10 might hypothesize that these measures ought to be
11 sort of orthogonal and that they should reflect
12 differences in disease severity.

13 So actually, to see the absence of
14 correlation for me -- it may not be the case for
15 every other person in the subgroup -- but for me,
16 the absence of correlation was actually a strong
17 feature of the measure as it demonstrated that
18 this really does fill an information gap that the
19 readmission ratio is currently not filling.

20 So I think that when it comes down to
21 it, the validity for me was quite strong.
22 Obviously, most of the grades were medium. But

1 reliability and the nature of the profile inter-
2 unit reliability being 0.57 is definitely a
3 concern for the panel to consider.

4 MS. WILBON: Were there other subgroup
5 members -- Subgroup 3 members who wanted to
6 comment on the reliability in particular. I know
7 we had a very similar discussion with the prior
8 measure. But if there's anything you or any
9 comments that you would like --

10 (Simultaneous speaking.)

11 OPERATOR: Pardon me. Pardon me.
12 Hello? Hello? Can you hear me?

13 MS. WILBON: Hi, yeah.

14 OPERATOR: Hi. My name is Gigi. I'm
15 the lead operator for today's call.

16 MS. WILBON: Yes?

17 OPERATOR: Yes. Okay. Can you hear
18 me, all?

19 MS. WILBON: Yes, we're on a call.

20 Hello?

21 CHAIR NERENZ: Let's go ahead.

22 OPERATOR: Wait one moment. Never

1 mind. Sorry. Disregard. Disregard. Never
2 mind.

3 MS. WILBON: Hello?

4 CHAIR CELLA: Go ahead, Ashlie. Go
5 ahead, Ashlie.

6 MS. WILBON: Hi. Sorry about that.
7 I'm not sure what happened.

8 CHAIR CELLA: She made a mistake.

9 MS. WILBON: Oh, okay. I wasn't sure
10 if I hit a button something. Okay. So we'd
11 already discussed reliability with the previous
12 measure. And so I just wanted to open up to the
13 subgroup to see if there's any additional
14 comments regarding reliability that might be new
15 or different for the developers to respond to
16 before we give them an opportunity to comment on
17 that.

18 Again, I'm not sure if there's
19 anything different. But I do want to give the
20 developers an opportunity to respond if there are
21 any additional comments about that.

22 CHAIR NERENZ: Yeah, Dave Nerenz here.

1 And I appreciate the great similarity between the
2 issues in front of us here and what was discussed
3 in the last one since we turned to the
4 developers.

5 So I would appreciate it if they would
6 focus on anything that might be different in the
7 realm of reliability between this measure and the
8 one we just discussed. Otherwise, I think we had
9 a very clear and very thorough presentation just
10 a few minutes ago.

11 MR. KALBFLEISCH: This is Jack
12 Kalbfleisch. It seems to me that the issues are
13 quite similar here with the IUR and PIUR. I
14 think that the level of the IUR and PIUR
15 certainly within the bounds of things depicted
16 and have been approved before, although don't
17 meet the very high threshold that the Commission
18 talked about recently.

19 MS. WILBON: Thanks. I did want to
20 just check in with other Subgroup 3 members or
21 anyone else from the panel who may have comments.
22 And if there are no further comments given the

1 conversation we had for the previous measure, we
2 can call the vote.

3 I do just want to do a quick check-in
4 before we do that with Subgroup 3 members to make
5 sure we have a quorum for the voting. Alex, I
6 see you. Can you hear us?

7 MEMBER SOX-HARRIS: Yes.

8 MS. WILBON: Dave, I know you're
9 there. Eric, I know you're there. Joe Kunisch,
10 are you there?

11 MEMBER KUNISCH: I'm on.

12 MS. WILBON: Okay, great. Lacy?

13 MEMBER FABIAN: Yes, I'm here.

14 MS. WILBON: Okay. Marybeth?

15 MEMBER FARQUHAR: Yes, I'm here.

16 MS. WILBON: Hi. Paul? Paul, are you
17 there? Okay. Sam?

18 MEMBER SIMON: Yes, I'm here.

19 MS. WILBON: Okay. And Sean, I think
20 I saw or heard you.

21 MEMBER O'BRIEN: I'm here.

22 MS. WILBON: Okay. We'll have eight

1 people voting. Hannah, Subgroup 3 members, if
2 you could locate the email from this morning that
3 was sent from our team with the voting link in
4 there. If you could locate that, Hannah will be
5 pulling up the vote for reliability for Measure
6 3566.

7 MS. INGBER: Thanks, Ashlie. The vote
8 for 3566, rating for reliability is now open.

9 We're just waiting for one more vote.

10 Okay. I'm going to share my screen to
11 show the results. Okay. You can see here for
12 Measure 3566, the overall rating for reliability,
13 we received zero votes for high, three votes for
14 moderate, five votes for low, and zero votes for
15 insufficient. Therefore, the measure does not
16 pass on reliability.

17 MS. WILBON: So this is Ashlie. I
18 just want to, again, call a point of consistency.
19 So we just reviewed another similar measure with
20 an IUR and PIUR that was lower. So I think it is
21 a little problematic in terms of consistency for
22 us to make the case for the voting results.

1 Can someone speak to that? Or
2 potentially if we might revote, I just want to
3 make sure we're being consistent, and it doesn't
4 appear that we are kind of in sequential order.

5 Also, considering that it is a
6 different subgroup. But subgroups, we're part of
7 a whole. And the votes represent the whole
8 panel. So I just want to make sure that we are
9 being consistent and we have a discussion about
10 that.

11 CHAIR NERENZ: Ashlie, Dave Nerenz
12 here. I fully appreciate that concern and
13 problem. One possible task, if both of these
14 measures can make their way onto the standing
15 committee, it seems to be the reason we had this
16 discussion for the past hour or so and the reason
17 that things came out the way they did is this is
18 a really, really close call on both these
19 measures in terms of whether the reliability is
20 acceptable or not. Part of it is just simply the
21 numeric values of these two statistics on each
22 one.

1 But also part of it is the idea that
2 when we endorse a measure, when ultimately NQF
3 does, it's not for specific use like identifying
4 outliers. It's for a whole range of uses,
5 including building in the star ratings and things
6 like that.

7 It's, in my mind, very, very
8 problematic. I'm right teeter-totter on this on
9 whether, at least in our hands, this or the other
10 one should go forward or not. And it's perhaps
11 that ambiguity or that close call nature could be
12 passed on to the standing committee.

13 Eventually, we end up these pass-fail
14 distinctions. But at least in my mind, both of
15 these are just teetering right on the edge. It's
16 really hard.

17 MS. WILBON: Thanks for that, Dave.
18 Any other comments from the subgroup? Or I will
19 say that with our current criteria that issues
20 around threshold values strictly for reliability
21 is grounds for the standing committee to
22 reconsider the measure and revote. So the

1 measure could and likely would be reconsidered by
2 the standing committee.

3 But I do think it's an important point
4 of consistency for the panel as well because
5 certainly again while we do divide the group, the
6 panel and the subgroup vote on that, we do want
7 to maintain some cohesiveness as a panel and what
8 the votes and recommendations are for the panel.
9 So if there are any other comments about that, I
10 think it would be really helpful.

11 MEMBER SOX-HARRIS: So this is Alex.
12 I would just add that this highlights the
13 importance of our discussion yesterday and the
14 planned future work to try to tighten our
15 understanding and consensus on standards.

16 Prior to that discussion, there had
17 been a very loose consensus. Lots of different
18 interpretations about what constitutes that
19 reliability coefficient. So I think what we're
20 seeing here is a reflection of that state of
21 affairs.

22 MS. WILBON: Hi, Joe. I see your

1 hand.

2 MEMBER KUNISCH: Yeah. Just I kind of
3 second Dave and the comments that it has to be
4 consistent because experience coming from the
5 same measure developer. If you pass one and
6 they're very similar in results. And then they
7 go back to say, okay, how do we get this one
8 passed through the second round?

9 And it was really failed on -- just
10 dependent on who reviewed it. I struggled with
11 this and the low scores too, but I did from the
12 very beginning when we started this in our very
13 first round of not really having clear direction
14 on thresholds. Because when I first started,
15 anything that I thought was too low a threshold,
16 I was failing right away. And then had a lot of
17 offline discussions with Karen at the time.

18 And I still struggle with it because,
19 yeah, I see some of these results and I just
20 think they're very low. But again, unless we
21 have something to say this is the cut point, you
22 have to give a pass.

1 So if you get a pass on one measure
2 with similar results, it just wouldn't be good to
3 not pass the second measure again because they
4 have to go back and prove it. And it may depend
5 on who's going to review it in the second round.

6 CHAIR CELLA: This is Dave Cella.
7 Just to chime in, I want to return to what Dave
8 Nerenz suggested which is to bring this to the
9 standing committee and educate them about how
10 this really is right on the brink.

11 It would've been interesting if we did
12 the shadow voting this cycle to see if there
13 would've been a consistent up/down if the whole
14 committee weighed in because to some extent there
15 is this issue of different reviewers in
16 subgroups. And when you're at 5-3, 3-5, that's
17 all it really takes to see it go one way one time
18 and another way the other.

19 So I would endorse kind of moving on
20 from here. The vote is vote. Pass it along to
21 the standing committee and let them deal with the
22 issue, looking at both submissions or all three

1 of them.

2 MS. WILBON: I see a hand from
3 Sherrie. But I'd like to just push back a little
4 bit because I think it presents an issue I think
5 for the methods panel, right? Because the vote
6 that moves forward are from the methods panel.
7 So it doesn't say subgroup. It says methods
8 panel.

9 And so I think the signal that it
10 sends from -- an inconsistent vote coming from
11 the methods panel I think is probably one that we
12 should try to rectify. I'd like to just put out
13 a suggestion that we revote and see how folks
14 feel about that because it is a little
15 disconcerting.

16 And I just want to -- and certainly
17 I've heard responses from several folks about
18 that. But I just want to kind of put it out
19 there and we do have a mechanism in place. But I
20 think the signal that it sends, I think -- which
21 we talked about before with the signal that it
22 sends when we can't vote on risk adjustment or

1 social risk factors.

2 Again, I think the vote coming out of
3 the methods panel as a whole I think makes a
4 difference. So I'll just stop there. There's a
5 couple hands from Eric and Sherrie. I think
6 Sherrie was first.

7 MEMBER KAPLAN: Ashlie, can you hear
8 me?

9 CHAIR CELLA: Yep.

10 MEMBER KAPLAN: So I agree and sitting
11 on another steering committee. And so the signal
12 would be very confusing and it would really, I
13 think, cause confusion in the steering committee.
14 I mean, if you send it back with this kind of
15 inconsistency, it'll be very disconcerting to
16 those sitting on the committee.

17 And I do think being valid but not
18 reliable is another signal we've got -- issue we
19 have to address. Because if you're accurately --
20 if you're inconsistently accurate, it's a very
21 curious kind of -- from a measurement standpoint,
22 it's a very curious situation to be in.

1 So I think that the issue, I think
2 you're absolutely right. I think we should
3 probably revote.

4 MS. WILBON: Eric and then Alex.

5 MEMBER WEINHANDL: Yes. So this is
6 Eric. I think that revoting is reasonable.
7 However, I think that there's a bit of a
8 cognitive bias to the extent that Subgroup 3 is
9 being asking to revote in light of the results of
10 Group 2's evaluation of readmission.

11 So I wonder if we should be doing a
12 bit of a crossover, and this my perspective,
13 where Subgroup 3 has a chance to vote on the
14 reliability of the readmission metric and
15 Subgroup 2 has a chance to vote on the
16 reliability of this metric.

17 MS. WILBON: Okay. That's a
18 discussion we'll put on the table. I think it
19 was Alex, Jack, and then Lacy, I think.

20 MEMBER SOX-HARRIS: I was going to
21 suggest a version of what was just suggested,
22 either having the entire panel vote or have both

1 subgroups vote on both measures instead of just
2 having Subgroup 3 revote or just Subgroup 2
3 revote.

4 MS. WILBON: Okay, thanks. Jack and
5 then Lacy.

6 MEMBER NEEDLEMAN: Yeah, I suspect
7 what we're seeing in -- the two votes are not
8 that far apart. They just work in opposite
9 directions. And I think what we're seeing here
10 is real disagreement among the two groups of
11 eight about what level of reliability is
12 acceptable.

13 I suspect if we had both groups voting
14 on both measures, we'd wind up 4-4, consensus not
15 reached. And I think the fact that consensus is
16 not being reached with a pass on reliability for
17 one of the measures and not passed on reliability
18 on the other measure just reflects the fact that,
19 as somebody said, the reliability number here is
20 different. It makes some people uncomfortable
21 and less people less uncomfortable.

22 So I have no suggestion other than I

1 think if we revote, we're going to wind up with
2 the same results.

3 MS. WILBON: Okay. Lacy and then
4 Alex.

5 MEMBER FABIAN: My thought was just to
6 second that we either revote as a whole group on
7 the couple of measures or we -- the subcommittees
8 vote on -- revote on the measures because
9 otherwise really the only option is to default to
10 the prior vote of the other subcommittee to
11 address the issue which presents the bias.

12 MS. WILBON: Okay, thanks. Alex, did
13 you have a -- I saw your hand go down. I wasn't
14 sure if you had any comment.

15 MEMBER SOX-HARRIS: No, I put my hand
16 down.

17 MS. WILBON: Okay. Dave and Dave, do
18 you have any thoughts on this?

19 CHAIR NERENZ: Yeah, just a couple of
20 things. One thing, just watching the time and
21 also just thinking about kind of make these kind
22 of decisions on the fly. The one that's easy to

1 do is just have a Subgroup 3 revote right now.

2 Go ahead then and take the break. And
3 depending on how that comes out, we may want to
4 pick out the different strategy that we could do,
5 like, at the end of the day today or something.
6 I assume people will still have the issues
7 reasonably fresh in mind. But I don't think we
8 have the opportunity here to try two or three
9 different variations and sort of make them up on
10 the fly as we go on.

11 MS. WILBON: Sure. Fair enough. Dave
12 C., do you any thoughts?

13 CHAIR CELLA: Well, I think the
14 options that we have, also looking at the time,
15 I'm actually least comfortable with just having a
16 Group 3 revote and going with that. Having a
17 Group 3 revote to come to a discussion would work
18 better for me.

19 But I do think that in a sense it's
20 like asking people in Group 3 to reconsider and
21 go with the direction of Group 2 which is really
22 just an order effect on something that's -- I

1 guess I don't necessarily agree that it would be
2 terribly difficult for a standing committee to
3 understand that this was just where we are at
4 this point in time in terms of this issue, unless
5 you want to try to resolve it later in the day if
6 we can move through the other reviews.

7 MS. WILBON: Okay. Let's do that.
8 Also, there's a lot of options on the table. And
9 given that we're already into our break time, I'm
10 inclined to table this. We'll talk offline and
11 come back with another plan to see how we can
12 resolve this before the end of the day.

13 So thanks to all. We'll break now.
14 Oh, sorry. Let me do a brief public comment.
15 Thank you to the developers again, all of you for
16 going overtime. But is there anyone who'd like
17 to make a comment, press *1 for the operator to
18 open your line and we'll take that now. Or you
19 can enter a chat into the chat box.

20 Okay. Seeing none, we'll go ahead and
21 break. We'll return from break at 11:15. I
22 realize the slide says 30 minutes, but it's

1 actually 15. We're squeezing in an additional
2 measure on the second half of the discussion. So
3 a short break. We'll see you back in 10 minutes.
4 Thanks, all.

5 (Whereupon, the above-entitled matter
6 went off the record at 11:05 a.m. and resumed at
7 11:18 a.m.)

8 MS. WILBON: Hi, everyone; welcome
9 back from a very short, brief, break. We are
10 here to convene and put our heads together, and
11 we're going to share our path forward here.
12 Essentially, since the panel seems to have not
13 reached consensus on reliability for these two
14 measures, we'd like to put these forward to the
15 Standing Committee; put the vote for reliability
16 for both 2496 and 3566 as consensus not reached.

17 That kind of eliminates kind of re-
18 voting and getting the same inconsistencies. And
19 so essentially what the Standing Committee would
20 need when they look at these measures for
21 reliability for both would be consensus not
22 reached from the SMP. We would not share

1 individual votes per se, for high, moderate, and
2 low.

3 What we're going to do in order to
4 solidify that decision is, after you guys do
5 respond to a brief survey that is going to be
6 opened up via the survey link that you all have
7 access in the last two minutes, if you could open
8 that up, I think Hannah is going to have it open
9 for you. And we're just asking whether or not
10 you agree that these measures will be put forward
11 as consensus not reached in the Standing
12 Committee; just a yes or no response.

13 So I do just want to, before we do
14 that, if there's questions from the Message Panel
15 members or others before we cast votes. Can you
16 guys hear me?

17 Are we in the full --

18 MEMBER AUSTIN: Yes, this is Member
19 Austin, so I can --

20 MS. WILBON: Oh, okay. There was
21 radio silence; I wasn't sure if I was actually
22 speaking to everyone --

1 MEMBER AUSTIN: That sounds like a fine
2 solution, Ashlie.

3 MS. WILBON: Okay, perfect; absolutely
4 perfect.

5 CHAIR CELLA: This is Dave Cella. I'm
6 back Ashlie, hi.

7 MS. WILBON: Hi, hi. Okay, great. So
8 if everyone could click on the link for voting,
9 there will be a survey there for you to respond
10 to. We just want some acknowledgment from the
11 group, and this will be a full-panel vote, not
12 just Subgroup 2 and 3 members. It will be all
13 Message Panel members will vote on whether or not
14 you agree that these measures will be put
15 forward, consensus not reached for reliability to
16 the Standing Committee.

17 MS. WILBON: You should have 25 votes,
18 Hannah.

19 MS. INGBER: Right. I'm reporting 20.

20 CHAIR CELLA: If you have 13 in one
21 direction, you could probably close it, if the
22 number of voting members is 25.

1 MS. WILBON: It still looks like we've
2 got unanimous agreement there; I think Hannah
3 will show it briefly. But thanks to all for that
4 quick resolution, and these measures will be put
5 forward to the Standing Committee as this is not
6 reached for reliability.

7 Thanks again, and we'll dive back into
8 evaluating the remainder of the measures on the
9 docket for this afternoon. For this morning,
10 we're starting with Measure 2539, Facility 7-Day
11 Risk-Standardized Risk Hospital Visit Rate after
12 Outpatient Colonoscopy, presented -- this
13 involved the Yale CORE team and CMS. They just
14 want to check in to make sure the Yale CORE team
15 is on the line.

16 MS. PETER: Hi, this is Doris Peter.
17 Yes, I think we're all on the line. Elizabeth,
18 are you there?

19 MS. DRYE: Hi, yes, thanks.

20 MS. WILBON: Hi, great. We can hear
21 you. So we will get started here; let me find my
22 place. Okay. So this is a maintenance measure.

1 Again, I'll just give a brief overview here, and
2 I'll hand it over to the lead discussion, Alex
3 and Sean, also noting that DQ is recused from
4 this measure, and we'll file through here.

5 So maintenance measure, last
6 endorsement was in 2014 at the Facility level
7 Risk Standardized Rate of acute, unplanned
8 hospital visits within seven days of a
9 colonoscopy for a hospital outpatient department
10 or ambulatory service center among Medicare Fee-
11 for-Service stations 65 years and older.

12 The claims-based facility-level
13 measure is risk reduced. The measure did pass
14 reliability, so we will not spend time there.
15 The focus of discussion will be on the one with
16 validity where consensus was not reached.
17 Because this is a maintenance measure, the
18 developer is asked to submit empirical validity
19 testing at this point. They did re-share the
20 base validity assessment they had done before and
21 also provided a rationale for why they were
22 unable to do empirical validity testing and

1 provided a description of their analysis and
2 consideration of other measures.

3 I did just want to note also that you
4 should be looking at the version of the
5 discussion guide that was attached to the viewing
6 meeting invitation, whereby the five measures
7 that they considered as potential comparators are
8 listed in the discussion guide under Action
9 Items.

10 With that, I would hand it over to
11 Alex and Sean to walk us through the methods
12 panel concerns, and we'll focus here on validity.

13 MEMBER SOX-HARRIS: Great, thank you.
14 This is Alex. So I wanted to commend the
15 developers for the methodology and results and
16 their face validity analysis, because it's really
17 well done and, as far as face validity goes,
18 pretty compelling, although as Ashlie just
19 mentioned, the NQF criteria for maintenance
20 measures are that there's a requirement to submit
21 empirical validity testing at the time of
22 maintenance or a rationale.

1 So the rationale provided for not
2 doing empirical validity testing was mostly
3 focused on the inability to find a relevant
4 measure to correlate with that also had adequate
5 sample size within entities, because different
6 entities do single procedures and therefore
7 wouldn't be able to calculate both measures of
8 the same site and so forth.

9 So I'm going to, for the purposes of
10 this discussion, cede that point and say, Okay,
11 there's not another measure to correlate with.
12 So that particular form of empirical validity
13 testing is not feasible.

14 My concern and suggestion was that
15 another kind of empirical validity testing be
16 done that is feasible, which is to do some
17 testing on the validity of the outcome; in this
18 case, ED visits or admissions to the hospital
19 seven days after colonoscopy.

20 So my validity question is simply, out
21 the additions that are being counted, how many of
22 them are plausibly related to the colonoscopy?

1 And that's a simple, element-level validity
2 question that I proposed in my initial review
3 that could be done.

4 So the developers came back with the
5 response that, in fact, they had done work
6 related to that, which is, on the one hand,
7 great, but also undercuts the rationale for not
8 doing an empirical validity testing when, in
9 fact, it had been at least partially already
10 completed.

11 The evidence that was presented was
12 twofold, one is a reference to research that had
13 been done in a single site where 68 percent of
14 the ED visits after colonoscopy were plausibly
15 related to the procedure itself. That's the 68
16 percent ascertainment of what I think the measure
17 is trying to get at.

18 The issue with that is, that's just
19 one site, so I'm really curious about the
20 distribution of the proportion of admissions that
21 are related to colonoscopy.

22 The other point of evidence that was

1 offered was a paper that was published, and if
2 you go to the very end of the discussion guide,
3 there's a Table 2, copied and pasted from a paper
4 which I also looked up and reviewed. This is the
5 top 10 most frequent diagnoses accompanying an
6 unplanned hospital visit within seven days of an
7 outpatient colonoscopy.

8 So this is exactly the kind of
9 information I would have accepted as empirical
10 validity testing of the outcome. My current
11 issue is that this only represents about 30
12 percent of the unplanned hospital visits, and I
13 don't have the information on what the other 70
14 percent -- you know, what were the reasons for
15 the other 70 percent of the visits.

16 I looked through the paper and some of
17 the supplemental materials briefly, but I
18 couldn't easily put my finger on that.

19 So this issue I'm left with -- And I
20 think the reviewers may have an answer to this
21 question or may be able to get it, but I would be
22 satisfied with what's the distribution of the

1 proportion of visits that are plausibly related
2 to colonoscopy? And that's -- I guess it is
3 simple current validity testing outcome that
4 could have been provided. Therefore, I'm not
5 persuaded by the rationale that empiric testing
6 is not feasible.

7 That's one issue. The other issue
8 that was related to the validity ratings for this
9 measure had to do with the inclusion, the
10 analysis, and decisions to include SES variables
11 in the risk-adjustment model. And there were
12 some specific questions raised by the
13 subcommittee on that, and also some responses
14 from the developers. I'll leave it to my co-
15 discussant and other subcommittee members to get
16 into the details on that issue, and I'll stop
17 there.

18 MS. WILBON: Okay, thanks, Alex.
19 Sean, did you have anything to add to that before
20 we open it up to the other sub-group members?

21 MEMBER O'BRIEN: I'd say go ahead and
22 open up to the other members, and I may weigh in

1 on their responses.

2 MS. WILBON: Thanks.

3 MEMBER O'BRIEN: Very comprehensive.

4 MS. WILBON: Other Sub-group 3 members
5 have comments on this measure?

6 CHAIR NERENZ: Yes, Dave Nerenz here.
7 Just on the issue of time and to stay focused, I
8 would be perfectly happy if we just didn't get
9 into the social risk factor discussion because,
10 at least in my mind, it didn't bear on my vote on
11 either the reliability or validity. I've raised
12 concerns in that area, but it's not something
13 that we're voting on. So if it was up to me, I'd
14 leave that discussion aside and focus purely on
15 what leads to the focus on validity.

16 MS. WILBON: Thanks. Other sub-group
17 members comments? Otherwise, we'll allow the
18 developers to provide their response at this
19 point.

20 Okay. Yale CORE team, would you like
21 to respond to the concerns laid out?

22 MS. DRYE: Sure. Hi, this is

1 Elizabeth Drye from CORE. I'm one of the senior
2 presenters. I'm one of the key members on the
3 phone, who worked on the center for a long time,
4 so we appreciate the committee's careful
5 consideration, and I apologize for connection
6 issues, can you guys hear me okay? This should
7 end in a second.

8 MS. WILBON: Yes.

9 MS. DRYE: I'm working from
10 unpredictable settings. So I think the main
11 question, the residual concern I'm hearing on
12 empirical validity really has to do with the
13 validity of the outcome as reflecting the quality
14 of care. And so as the committee saw, we tried
15 to provide more detailed information.

16 We had not run those analyses on the
17 current data set, but we have them from prior --
18 you know, very similar data sets; they're just
19 earlier years of that cohort, using the same
20 hospital and ambulatory surgeries in the claims.
21 So they should be completely consistent with what
22 validities in our current application. We didn't

1 rerun them because they're actually kind of
2 burdensome to do that especially now with limited
3 access to data, given the shelter in place
4 requirements.

5 So the reason we presented this type
6 -- you know, most frequent is because to give you
7 a good picture, there's a long tail those which,
8 I think we could probably get those up and share,
9 but in the bigger picture, so if he wanted that,
10 we could try to hold those prior spreadsheets
11 out; I think we would be fine with that.

12 But in the big picture of thinking
13 about this outcome as a signal of quality. You
14 know, when we're thinking about it and its
15 validity, we looked at these agreements for
16 return, we run them by our clinical experts, in
17 this case largely gastroenterologists and even
18 physicians and others we think about, could they
19 be related or not?

20 And there's not a bright line between
21 the difference, we've talked about this many
22 times of related versus -- You can't say, Is this

1 related or not, for sure. Somebody comes back
2 with abdominal pain, you know, maybe it's one
3 thing, maybe it's not. Probably it is. If they
4 came back with symptoms, is it related to the
5 course of care, their prep for the procedure, the
6 anesthesia, the post-anesthesia care, the
7 restarting of their medications.

8 There's hammering of the post-
9 procedure period, how good the instructions were.
10 We don't know because some of them are related or
11 not related.

12 So we have not tried to -- we couldn't
13 give you exactly what percent are related or non-
14 related because it's just not knowable. And I
15 just -- I hear the concern, but I'm also just not
16 sure where to go next because I think those of us
17 who engaged with clinicians on this -- I'm a
18 pediatrician, not a gastroenterologist or adult
19 medicine doctor, but just have vetted it in
20 conversations, looking at data, looking at
21 variations of it, we're comfortable with it. I'm
22 not sure what else we can give you at this time.

1 We're really -- Supporting research show that,
2 you know, careful review of medical records,
3 those tend to be single site studies, that there
4 are presentable reasons for these that have been
5 submitted within seven days.

6 So I'm not sure what else I can give
7 you that's totally going to get you to the
8 comfort level of, yes, this is a valid outcome.
9 I'm a little bit limited. I think our group is a
10 little bit limited in what we can do in the very
11 short term, but we're willing to bring back more,
12 if it's helpful and it's feasible from out end.

13 Because we do have more occasions that
14 we haven't shared data from our prior work. And
15 I'm going to stop there for Craig Parzynski, our
16 senior analyst on this, and he knows what he can
17 access and not in the current COVID environment.
18 So, Craig, did you want to add anything that we
19 might share?

20 MR. PARZYNSKI: Yes. You know, I
21 think in just the time that we have turned
22 around, we weren't able to do a lot more besides

1 what we've done in the past. I think if we had a
2 little bit more time we can do a lot of the same
3 thing in our newer data, but we just, given time
4 constraints, weren't able to turn that around
5 quickly enough, given the recent changes in the
6 country and the world.

7 MEMBER SOX-HARRIS: This is Alex Sox-
8 Harris. So just, of course, speaking for myself,
9 I understand the issues of not being able to
10 completely determine which diagnoses are related
11 to the colonoscopy or not. But I think it's
12 possible to extract some signal, like if there
13 are leg breaks. There are certain things, a
14 proportion of things that are clearly not related
15 to colonoscopy. It might be another way to think
16 about it.

17 But I think you can do it, and I also
18 think it would be informative and helpful for the
19 interpretation of a measure to know roughly the
20 proportion of things that are being counted that
21 should be counted and how that varies from site
22 to site. I think that aspect of it is important

1 because it does bear directly on the validity of
2 comparisons.

3 MS. DRYE: So I don't think we can
4 draw -- this is Elizabeth again from Yale -- It's
5 really hard. We can share that with you for you
6 to make your own conclusions, but it's really
7 hard for us to draw a line about what's related
8 and non-related. That is why EMS has decided to
9 go with admission measures, and in this case that
10 is the 70 is a rate that includes admission. But
11 our decline is all cause on client.

12 You know, in the early years, looking
13 at readmission, you might look at engagement and
14 remember it, and there were algorithms for
15 related versus unrelated. There were people who
16 really tried to parse that out; there still are;
17 3M is really focused that way.

18 But our goal, our hypothesis and the
19 conceptual model for this is that it's not
20 particular outcomes that can be prevented or
21 unprevented, but we can lower the risk of many
22 types of outcomes with better care. So we can

1 lower the risk of urinary retention, and I mean
2 they would return to the hospital for urinary
3 retention care, which would lower the risk of
4 syncope; lower the risk abdominal pain.

5 Of course, you can lower the risk
6 because these are fairly low within the
7 procedural realm of influence of that person's
8 study, doing procedure of the hemorrhagic
9 complications in more severe complications,
10 certainly as infections.

11 So the goal is not in any one sense,
12 kind of, you know, well this is pneumonia, that
13 is urinary tract infection was, you know, must
14 have been and prevented or not, it's the overall.
15 We're charting the total and incentivizing a
16 reduction in the risk across the board.

17 So the one thing I don't want to
18 comment is that we should come back and say that
19 these are related or unrelated. We can
20 definitely share more information if we have a
21 reasonable time frame for doing that, and that's
22 helpful. But I don't think that we can -- I

1 think it would be hard to pivot and try to draw a
2 line on what's related or unrelated at this
3 juncture. It's not consistent with our
4 conceptual approach, I guess. That's how I would
5 describe it.

6 I definitely want to be -- I don't
7 want to say no. I want to get you what you need,
8 but I'm just thinking how it wouldn't be, I don't
9 think possible for our group to produce that
10 distinction for you.

11 MEMBER SOX-HARRIS: Yes. I'll just
12 say one more thing, and then hopefully some of my
13 other subgroup members can weigh in on this.

14 But I completely understand what
15 you're saying, and I'm not asking for a bright
16 line. I'm just asking for some empirical work on
17 the validity of the outcome which is what's
18 required from NQF. I think that's possible and
19 would be informative.

20 CHAIR CELLA: And there's Eric with a
21 hand up.

22 MEMBER WEINHANDL: Yes, thank you.

1 Yes, so I have a question or two for the
2 developer and his comments. I agree with you;
3 I've worked extensively with claims data, and I'm
4 generally hesitant to make the related versus
5 unrelated distinction on the basis of
6 retrospective data. So that is not something
7 that I would personally add or be compelled one
8 way or the other by.

9 I do have two concerns I have with
10 prospective trade validity, and please correct me
11 if I'm wrong. But I believe in all the materials
12 I reviewed, but the subgroup reviewed,
13 everything we did see, including in that
14 discussion guide within the context of ICD-9
15 codes, and maybe it's just because of lag of
16 data, but it would be nice to be able to see what
17 some of the principals as far as diagnoses are on
18 the hospitalizations in the ICD-10 era; provide
19 some level of comfort with what we're looking at.
20 So that's one thing.

21 And then I guess the other thing that
22 I wondered about with respect to validity was

1 just that as far as I could see, the conclusion
2 criteria did not include the possibility that
3 the patient recently did discharge from the
4 hospital, such that the seven-day period during
5 which hospitalizations are being tracked could
6 potentially be a readmission.

7 And so the colonoscopy is potentially
8 occurring in the middle of the period of
9 hospitalization and readmission. That's more of
10 a question, and it's whether the developer has
11 had any consideration to that, whether that
12 interferes with matters of certification, or if
13 it loses its interpretability.

14 MS. DRYE: Yes. Okay. On the first
15 point, yes, I think they could provide us a more
16 and longer list of reasons for return in ICD-10.
17 Craig, do you think that's doable? Again,
18 sometimes we get a one- or two-day turn around;
19 and that won't be doable because we have really
20 limited ability to have analysts running this
21 data right now because of all the restrictions in
22 Connecticut. But we are all actually doing that

1 work.

2 But, Craig, what do you think might be
3 doable between the ICD-10 code and now?

4 MR. PARZYNSKI: Yes, we can definitely
5 run that. I think, in terms of how long it would
6 take, it would probably be in the realm of two
7 weeks, just given the restrictions we have.

8 But it is something that's definitely
9 feasible, and you know, and as others have
10 mentioned, there would be a lot of speculation as
11 to what's related or not, but certainly is
12 useful. You know, something that definitely
13 appears or not. But definitely feasible and
14 probably about two weeks, I would say.

15 MS. DRYE: Okay. And then on the
16 second part about whether the colonoscopy could
17 be occurring post-admission, I feel like we might
18 have looked at that before. I'm not sure, but
19 that might be something that we can look at as
20 well, but a conceptual basis for the cohort is
21 that these are elective procedures. The patient
22 can't be in the middle of a hospitalization.

1 But could it have been in the last
2 week? I think we can probably look at that. I'm
3 not sure if it would really change anything. The
4 limit is drawn to private, you know, patients who
5 are acutely ill. For example, with
6 diverticulitis. But if it's feasible we'll get
7 that, and I can even ask Craig to confirm. I
8 think it will be doable.

9 MR. PARZYNSKI: If I may add
10 something, I think we might be restricted in that
11 one, then, just because the data comes from, you
12 know, the production contractor, and he might not
13 have some of that data necessary to complete
14 that. But that's something we can look at. I
15 think I'm about 90 percent sure we can look at
16 that.

17 MEMBER SOX-HARRIS: Okay. If it turns
18 out that two percent or three percent of the
19 patients with a denominator, but if it turns out
20 that two or three of them were hospitalized in
21 the last month before the colonoscopy, then I
22 would say well, my consideration is largely due

1 to, you know, unfortunate --

2 I think what caught my attention was
3 just the fact that of looking through the
4 technical report, I was surprised that the risk-
5 standardized rate of hospital patients were as
6 high as they were for just a seven-day follow-up
7 period. That led me to wonder, without data of
8 course, whether or not there were hospital
9 patients that were recurring before the
10 colonoscopy.

11 MS. PETER: Hi, this is Doris. Let me
12 just say that the rates are per thousand
13 colonoscopies, so maybe that point is not
14 obvious.

15 MEMBER SOX-HARRIS: Yes, and I took
16 note of that. It's closer, maybe a little bit
17 one way or the other. So that's why I asked the
18 question.

19 CHAIR CELLA: So we've got Joe with
20 his hand up, and just for time's check, we should
21 probably be wrapping up this discussion in the
22 next five minutes or so, so as to move on to

1 including these other two measures.

2 MEMBER KUNISCH: Yes. Hi, this is Joe
3 Kunisch. You know, I did support what the other
4 subgroup panel members are requesting, and I
5 applaud your effort to try to turn this around
6 and do it. But, you know, this might be more of
7 a question to ask NQF.

8 Are we being consistent? There are a
9 lot of readmission measures out there that have
10 been NQF endorsed, and I just don't want to say,
11 Let's again hold another measurer/developer on
12 specific measure to a higher standard to then
13 those other readmission measures that have
14 already been passed. That started with a note to
15 the same thing; you know, readmission is always
16 30 days readmissions. So was it actually related
17 to that event when they were discharged?

18 So, again, just trying to be
19 consistent with it in the overall scheme.

20 MS. WILBON: Sure. Hi, Joe, this is
21 Ashlie. I think -- so it's hard to say across
22 all readmission measures. I'm not as familiar

1 with the portfolio to say what type of empirical
2 validity actually has been done.

3 I think certainly our requirement
4 about empirical validity testing at maintenance
5 is consistent, and I think certainly maybe even
6 the types of validity testing that have come up
7 as recommendations from the panel, I think
8 certainly could be considered by the developer.

9 I don't personally have a sense of
10 whether or not those requests are more or less
11 than other recommendations that have been put
12 forward, so I don't have a great response to that
13 at this point without diving deeper. But
14 hopefully, the requirement for empirical testing
15 is standard, and I think ultimately the decision
16 for the subgroup is to determine whether or not,
17 based on this discussion, it would have been
18 submitted by the developer based on what's
19 feasible; that the rationale is acceptable or
20 not.

21 CHAIR CELLA: This is Alex. Just to
22 be clear, I'm not insisting that that particular

1 kind of validity testing be done. It's just that
2 that's one example, and therefore it's possible
3 to do something in that realm, and that standard
4 should be applied consistently across measures.

5 MS. DRYE: Hi, it's Elizabeth Drye.
6 I wanted to raise a question along those lines,
7 and I'm thinking about it in real time. I'm not
8 sure that I have a conclusion, but we've moved,
9 and I think it's okay to thinking about the
10 outcome, and while we're thinking about the
11 outcome about the indicator of quality, and we
12 talked about true analyses, redoing the signature
13 return analogy ICD-10 codes.

14 And to the second one, it's giving me
15 a little bit of a -- we could go back and look at
16 where patients recently in the hospital, I think
17 we want to say, before we do that analysis, why
18 would that invalidate the outcome in our view?

19 When I think about it, and if I'm
20 doing my feet so I may not be thinking right.
21 These are outpatient colonoscopies we've tried to
22 exclude with a lot of experience, the ones that

1 probably reflect really -- We tried to pull out
2 admissions and not count if they are about
3 solitaire for example, a colonoscopy to the
4 extent colon cancer stays and then return them to
5 the hospital.

6 So those are out, and I think if we
7 saw -- if we're going to run analysis, I want to
8 know how we would interpret it, that if two
9 percent of patients were in the hospital in the
10 last 30 days, I think we need to think, does that
11 invalidate the outcome as a valid indicator of
12 quality; either patients selected for same-day
13 outpatient procedures who really I don't think
14 would be expected to return to the hospital for
15 unplanned events. But I think that we would be
16 implying that those unplanned events were
17 somewhat not related to Colonoscopy, they were
18 related to prior admissions.

19 I just want to make sure that we're
20 not going down a tangential path that maybe if we
21 think about -- we just really need to know why it
22 would unravel the validity of five percent, 10

1 percent. I really don't think it's true. But if
2 it were, why would it unravel the validity that
3 takes gastroenterologists and surgeons saying you
4 need patients in a center, then they get admitted
5 for unplanned reasons, and the next seven days
6 there's not likely a single cause, there's no
7 admission rate -- the use of hospital spikes
8 within a few days after operation, then it drops
9 off again.

10 But with all of our senses not likely
11 being related, in many cases the procedure
12 unravels if they've been admitted 25 days ago.
13 I'm not sure that's true, and I think we should
14 go into analysis knowing a clear sense of how
15 they reflect, conceptually, what we're trying to
16 measure.

17 MS. WILBON: Are there other subgroup
18 or other members of the panel who have other
19 thoughts for the developer, or is there a sense
20 that we could bring this to a vote?

21 Okay. Hearing no comments, I think
22 that means we will bring it to a vote then. So

1 we will be having our Subgroup 3 members voting
2 again, and Hannah is willing to make sure that
3 that is up for you.

4 Again, we're only voting on validity
5 for this measure, 2539. I do just want to do a
6 quick check for our denominator to make sure
7 everyone came back after the break. I heard
8 Alex; I heard David; I heard Eric; I heard Joe.
9 Lacy, are you there?

10 MEMBER FABIAN: Yes, I'm here.

11 MS. WILBON: Okay. Marybeth?

12 MEMBER FARQUHAR: Yes, I'm here.

13 MS. WILBON: Okay. Sam?

14 MEMBER SIMON: Yes, I'm here.

15 MS. WILBON: Okay. And Sean?

16 MEMBER O'BRIEN: Here.

17 MS. WILBON: Okay. We'll have eight
18 people voting again. Looking to please revisit
19 that link for voting. The issue is up here for
20 you to vote for validity on two 2539.

21 MS. INGBER: Okay. We have our votes.
22 We'll just be adjudicating the results. Okay,

1 thank you for your patience. I'll share my
2 screen now to share the results.

3 Okay. So 2539, overall rating is that
4 for validity we have one vote for high, four
5 votes for moderate, one vote for low, and two
6 votes for insufficient, the measure passing on
7 validity.

8 MS. WILBON: Thanks, Hannah, and
9 thanks to the Yale CORE team for joining us. We
10 will keep moving on to the next measure.

11 CHAIR CELLA: This is Dave Cella. So
12 we go back to Subgroup 1, which seemed to be the
13 most disagreeable group. That's maybe because I'm
14 being a member, 0715.

15 MS. WILBON: Yes. We're going back to
16 the measure that we --

17 CHAIR CELLA: The Boston Children's
18 Hospital. Are they on? It should be 0715.
19 There you go; that's it.

20 MS. WILBON: I think Lisa, are you
21 there? If you cannot speak at *1, you should let
22 your operator know that you're there to speak.

1 MS. BERGERSEN: Hello?

2 MS. WILBON: Lisa, go ahead.

3 MS. BERGERSEN: Okay.

4 CHAIR CELLA: Yes, we can hear you.

5 Hi, Lisa. On behalf of the committee, let me

6 apologize again for deferring you until now.

7 Thank you for coming back today for this

8 discussion.

9 We have limited time, so we're going
10 to move as quickly as we can to the lead
11 discussions. Or, I guess first you're going to
12 set up, ask me and then Patrick and Matt, we have
13 a discussion.

14 MS. BERGERSEN: Yes, thanks, Dave.
15 I'll do just a really brief overview and then
16 hand it over Patrick and Matt to take it from
17 there.

18 This is a maintenance measure. The
19 last endorsement was in 2015. It is a ratio of
20 observed to be expected major adverse events
21 among patients undergoing congenital cardiac
22 cath, risk-adjusted using the Catheterization for

1 Congenital Heart Disease Risk Model. The risk
2 methods are at CHARM II.

3 It uses electronic health data, health
4 records and registry data measured at the
5 facility level it is risk adjusted. There were
6 concerns for both about the reliability and
7 validity, so we will be voting on both. The
8 measure developer did submit a response

9 And I will hand it over to Patrick and
10 Matt to give us a more detailed view of the
11 subgroup.

12 MR. ROMANO: Thank you very much.
13 This is Patrick Romano; can you hear me?

14 MS. WILBON: Yes, we can.

15 MR. ROMANO: Okay, great. So this is
16 Measure 0715, Standardized adverse event ratio
17 for congenital cardiac catheterization. This is
18 a risk-standardized outcome measure that
19 basically represents an observed over expected
20 ratio for a set of adverse events that can occur
21 after catheterization for congenital heart
22 disease.

1 Matt and I have conferred, so let me
2 kind of quickly run through. So the measure was
3 initially sourced for both reliability and
4 validity not passed in CNR respectively.

5 I think that -- Or we think really
6 that the correct assessment on both reliability
7 and validity would have been insufficient, based
8 on the original submission. But a lot of
9 additional materials were acquired by the
10 developers, and those materials are in the packet
11 staring at page 49.

12 So in summary, the reliability issue
13 was really unclear because the investigators were
14 reporting only on the reliability of the outcome
15 assessment, and they've corrected that with
16 additional information that is in their
17 submission. So it's now clear that what they do
18 is both denominator reliability assessment by
19 matching chief volumes from their registry of
20 institutional records. They report 97 to 99
21 percent agreement on this denominator case
22 ascertainment.

1 Further, they did a random audit of
2 650 cases, 50 from each of the 13 participating
3 centers, and they now report the agreement for
4 the outcome measure, which was very high in the
5 seven percent, as well as for the procedure type,
6 which was 100 percent, and key risk adjuster,
7 hemodynamic indicator, which was also 97 percent
8 agreement.

9 So I think we're prepared to say that
10 the reliability issues have been addressed, which
11 is supplemental information. And we'll be
12 recommending -- of course, it doesn't qualify for
13 a high score because there's no information on
14 score level reliability; they're only reporting
15 on data element reliability which means it
16 qualifies for a moderate rating now on four
17 levels -- (unintelligible).

18 So I'll turn it over to Matt or any
19 other members of the subgroup if they have a
20 different view or have any specific questions.

21 CHAIR CELLA: Anything to add to add
22 to that?

1 MEMBER AUSTIN: No, I don't. Patrick
2 and I sort of chatted yesterday in an email, and
3 that was where we mentioned.

4 CHAIR CELLA: Okay. You didn't
5 comment on validity. Are you saying that the
6 validity vote would flow from the improved
7 measure report or reliability?

8 MR. ROMANO: No. That's a separate
9 issue, right? Are we voting on reliability
10 first?

11 CHAIR CELLA: I think we're talking
12 about all of it, and then we'll vote on both
13 after the discussion. So if you can talk about
14 the validity?

15 MR. ROMANO: Okay, fine. I'll go
16 forward and talk about validity. Now, validity
17 is a little bit more difficult because the menu
18 developers say on that checklist or form, they
19 say that they're recording performance at score-
20 level validity. However, they are not doing so.

21 MEMBER AUSTIN: Yeah, and this is Matt. The only
22 thing I would add to that is, you know, the

1 measure developer did, in their documentation,
2 provide back an explanation that they felt like
3 there was no natural gold standard for them to
4 compare against.

5 And I feel like in some ways it
6 overlaps maybe with the prior measure's
7 conversation about when there is this sort of
8 lack of a natural measure to compare against, how
9 do we evaluate that?

10 But given the guidelines that NQF has
11 set out that's for maintenance measures, that
12 there is the expectation of empirical score level
13 validity testing. There seems to be insufficient
14 information where we live at.

15 MEMBER ROMANO: Right, another way to
16 address that obviously, besides having some kind
17 of external gold standard, would be to have some
18 process measures at the facility level to
19 demonstrate that in this case, they were out of
20 13 testing facilities.

21 Two had better than expected or low
22 SAERs, and one had a significantly high SAER, and

1 so you know, were there processes of care
2 differences across those facilities? Was there
3 any explanation for those differences that would
4 provide some validation of the performance score?
5 That would be another way to go, but the
6 developers were not able to do that.

7 Obviously with 13 units in the
8 reliability and validity studies, their ability
9 to look at unit characteristics and so forth is
10 very limited.

11 CHAIR CELLA: Thanks, Patrick and
12 Matt. Would anyone else on the subgroup like to
13 add anything particularly to the validity
14 discussion? I don't see any hands up. Larry's
15 got his hand up now. Go ahead, Larry.

16 MEMBER GLANCE: Yeah, hi. So I
17 appreciate the discussion with Patrick and Matt
18 as well. I think I'd like to address the
19 validity issue.

20 So there are many different ways to
21 assess validity, and certainly one of the main
22 emphases in the NQF approach has been to view

1 empiric validity testing by using construct
2 validity to compare a supposed measure to
3 existing measures.

4 This is something that we talk about
5 quite a bit, and the limitation of this approach
6 is that other credible measures are not gold
7 standards, and so comparing a new measure to
8 supposed credible measures, I think and others
9 may agree, sometimes has really some good
10 validity, no pun intended.

11 The emphasis in our validity
12 evaluation has typically been on the risk
13 adjustment model itself, on whether or not it's
14 valid. Does it show good discrimination? Does
15 it show good calibration?

16 And the reason for that is that in a
17 perfect world, if you had a perfect risk
18 assessment model, then you would know exactly
19 what the expected outcomes would be at the
20 provider level or whatever group level you're
21 evaluating. So if you knew what their expected
22 outcomes were, then you could compare the

1 observed to the expected and use that ultimately
2 as a measure of quality.

3 And so I think that what we tried to
4 argue, and this is not trying to change NQF
5 policy in any way, but what we tried to argue in
6 the whitepaper that we wrote evaluating
7 scientific accessibility of a specific outcome
8 measure, that this is probably the most important
9 way to evaluate the validity of a risk adjusted
10 outcome measure is to focus on the risk
11 adjustment model itself.

12 So I would argue that the fact that
13 these developers did not provide evidence on what
14 NQF refers to as empiric validity testing,
15 meaning looking at construct validity, should not
16 be a reason to rate this as insufficient. I
17 would strongly suggest that this should be
18 moderate, not low and not insufficient. Thanks.

19 CHAIR CELLA: Thanks, Larry.

20 MEMBER ROMANO: This is Patrick. I
21 guess that maybe Ashlie can address this, but I
22 think that we are forced to implement current NQF

1 policy as described in algorithm three of the
2 measure evaluation criteria effective September
3 2019, and that's on page 25 of the measure
4 evaluation criteria document.

5 And so I mean I understand that in
6 some cases, knowing that the model performs well
7 in itself may be sufficient. It begs the
8 question of whether there is anything that
9 providers can do to reduce the outcome rate,
10 whether there is any preventability or
11 actionability in the measure.

12 So I think that is the alternative
13 type of evidence that we would be looking for,
14 that there is something that high performing
15 entities are doing differently than what low
16 performing entities are doing.

17 And you know, if the C-statistic of
18 the model was 0.95, then that may leave
19 essentially no room for quality, but a C-
20 statistic of 0.75 in a model with three risk
21 adjusters -- in this case, age, procedure
22 classification, and a scoring of hemodynamic

1 status -- certainly leaves a lot of room for
2 either quality factors or unobserved confounders,
3 and we don't know which.

4 CHAIR CELLA: So this is Dave C.
5 Ashlie, Patrick is asking if maybe you could
6 provide some guidance. I guess if you could do
7 that under the context of helping us sort out the
8 role of this committee in looking at validity as
9 it relates to actionability versus the sort of
10 more basic idea that the risk model itself is
11 accurate and is well validated, that that could,
12 for this committee, be sufficient for a
13 determination of moderate validity as an example.

14 MS. WILBON: Sure, hi, this is Ashlie.
15 Yeah, actually according to our criteria, it is
16 actually consistent with what Patrick said in
17 that risk adjustment is but one sub criteria of
18 the validity criteria, and so we do --

19 We are, you know, asking for, as you
20 guys know, validity testing of the measure's
21 score which would tell us something about the
22 accuracy of the measure and being able to, you

1 know, accurately reflect the performance of
2 providers and compare providers with the measure.
3 And so with that, I would agree that testing of
4 the risk model alone does not meet our current
5 criteria.

6 CHAIR CELLA: Okay, I see no other
7 hands up. Thank you, Ashlie. I think it's time
8 for us to allow the developers a chance to weigh
9 in.

10 MS. BERGERSEN: Hi, thank you very
11 much for this rich discussion over the past
12 couple of days and all of the time. I'd first
13 like to just start by addressing this measure as
14 we endorsed it. We had discussions early on when
15 signing this initial letter --- this was actually
16 (unintelligible) given the significant updates.
17 It looks similar to Chart 1.

18 The significant updates used in the
19 model, specifically the strategic risk group and
20 a new committee, and as well as a change in the
21 outcomes, I think clinically relevant adverse
22 events to major -- to limiting them to major life

1 threatening adverse events.

2 However, I think I can, I'll try to
3 address some of the concerns, but it is very
4 similar, but I'll try to address some of the
5 concerns related to validity at the score level.

6 We did respond as stated that there is
7 no similar constructs by which to compare it to,
8 and some in our field and other fields
9 (unintelligible) proposed volume, and you can see
10 with the supplemental data that we provided
11 across the SAERs, (unintelligible) the highest
12 variability in the volume from the highest
13 performers to the low performers, we could not
14 follow these metrics as a surrogate for quality,
15 which is, you know, why we pursued this measure.

16 We do have some experience with Chart
17 1, and we've been actively running this registry
18 as a quality improvement initiative for the past
19 decade.

20 When the measure was first endorsed,
21 I wouldn't be able to say with confidence, you
22 know, whether it was differentiating between

1 confounders versus quality. Obviously there is
2 still some (unintelligible).

3 However, I can provide expert data to
4 show validity. Someone mentioned some evidential
5 terms and process measures. We have looked into
6 outliers (unintelligible), and specifically in
7 the data provided to you, there was one outlier
8 institution.

9 And we were able over the past year to
10 do a root cause analysis into the major adverse
11 events, and through that look, we were able to
12 identify some differences in their practices
13 around financial management in the
14 (unintelligible) lab which was actionable for the
15 center.

16 Moving forward, this is, you know,
17 that sort of root cause analysis is just that in
18 the past year when that site reached out with
19 questions about there being an outlier. I don't
20 know if that addresses the concerns of this
21 potentially, but I wanted to share that. And --

22 CHAIR CELLA: Okay, thank you. Are

1 there any other comments from either the
2 committee or the developer? This is Dave Cella
3 again.

4 I think the layout and reliability,
5 more of a stay forward recommendation of
6 validity. You have a dichotomous choice here as
7 to which perspective you take in your votes. I
8 think we can go to a vote if there is no other
9 discussion.

10 MS. WILBON: Thanks, Dave. This is
11 Ashlie. I just want to point out we will push
12 forward the vote for subgroup one. I do just
13 want to do a quick check for who is on the line
14 so we make sure we have the right denominator.

15 The vote on reliability will go first,
16 and then the vote on validity should be focused
17 on whether or not you accept the developer's
18 rationale for not including empirical validity
19 testing for much of what we did for the prior
20 measure.

21 So I think with that, let me just do
22 a quick check of who is on the line, and if you

1 could also be locating the link or pulling up the
2 voting tool, that would be great. Daniel
3 Deutscher, are you there?

4 MEMBER DEUTSCHER: Yes, I'm here.

5 MS. WILBON: All right, Dave Cella is
6 there. Matt is there. John Bott?

7 MEMBER BOTT: Yep, here.

8 MS. WILBON: Joe Hyder? Okay,
9 Patrick, I know you're there. Sherrie had to
10 step away. Terri, are you there?

11 MEMBER WARHOLAK: I am.

12 MS. WILBON: Okay, Mike Stoto?

13 MEMBER STOTO: Yes, I'm here.

14 MS. WILBON: Okay, and Larry, you're
15 there. Okay, we've got one, two, three, four,
16 five, six, seven, eight. Okay, Hannah, we'll
17 have eight people voting, and please go ahead and
18 find your voting link and submit your votes.

19 MS. INGBER: Thanks, Ashlie. Voting
20 is now open on measure 0715. Your options for
21 reliability, sorry, your options are high,
22 moderate, low, or insufficient.

1 CHAIR CELLA: Just be sure to note
2 that this is the reliability vote.

3 MS. INGBER: Thank you, yes.

4 CHAIR CELLA: I know you said that.
5 I'm just repeating it, so --

6 MS. INGBER: Yeah.

7 CHAIR CELLA: -- it's clear.

8 MS. INGBER: Okay, I'm going to go
9 ahead and show the results. Just bear with me
10 one moment. Okay, so as you can see, voting is
11 closed for measure 0715.

12 We have zero -- for the rating for
13 reliability, we have zero votes for high, eight
14 votes for moderate, zero votes for low, and zero
15 votes for insufficient. Therefore, the measure
16 passes. Thanks, everyone.

17 MS. WILBON: So next we'll do a vote
18 for validity.

19 CHAIR CELLA: Some people are really
20 thinking about this one.

21 MS. WILBON: I think we have all our
22 votes in. Hannah is working on getting it on the

1 screen.

2 MS. INGBER: Yeah, I was more thinking
3 about the tech. Okay, I'm ready now.

4 CHAIR CELLA: Okay.

5 MS. INGBER: Okay, ready, so you can
6 see here that the overall rating for, sorry, for
7 validity for 0715, we have zero votes for high,
8 three votes for moderate, one vote for low, and
9 four votes for insufficient. Therefore, the
10 measure does not pass on validity.

11 CHAIR CELLA: Okay. Thank you.

12 MS. BERGERSEN: Thank you.

13 CHAIR CELLA: Let's move -- thank you
14 very much for calling back in today again. Let's
15 move on now to 3576 if we can get that on the
16 screen.

17 This is pediatric asthma emergency
18 department use. It did not pass reliability or
19 validity, and Ashlie, do you want to set it up or
20 do we first check and see if the developer is
21 around?

22 MS. WILBON: Yes, let's do a quick

1 check. I think they were checking in as well to
2 make sure they were getting on the line in time.
3 Is the developer up there?

4 DR. BARDACH: Yeah, Naomi Bardach is
5 online.

6 MS. WILBON: Hi, Naomi. Thanks for
7 joining us.

8 DR. BARDACH: No problem. Thanks.

9 MS. WILBON: Okay, so we will get
10 started with 3576. I will do a brief overview
11 and we'll hand it over to John and Daniel to do
12 some more in-depth review. One second here.

13 Okay, there we are, 3576, pediatric
14 asthma emergency department use is a new measure.
15 The measure estimates the rate of emergency
16 department visits for children ages three to 21
17 who are being managed for identifiable asthma
18 using very specified definitions. The measure is
19 reported in visits per 100 child-years.

20 It is based on claims and measured at
21 the health plan level. It is risk adjusted and
22 includes some social factors. The measure did

1 not pass reliability or validity, and the
2 developer did submit additional materials for
3 consideration based on the panel's preliminary
4 analysis.

5 So with that, I will hand it over to
6 John and Daniel to review some of the panel's
7 concerns.

8 (Simultaneous speaking.)

9 CHAIR NERENZ: Yeah, I think Terri is
10 listed as --

11 MS. WILBON: Yeah.

12 CHAIR NERENZ: -- the first to
13 discuss, no? Okay, Terri, do you want to go
14 first?

15 MS. WILBON: Apologies, Terri and
16 Daniel, sorry about that.

17 MEMBER BOTT: Yeah, I didn't think I
18 was on this one, okay.

19 MEMBER WARHOLAK: Yeah, okay. So good
20 morning and afternoon, everybody. I wanted to
21 just give an overview of what the subgroups
22 thought.

1 For reliability, there were some
2 concerns that the ICCs were extremely low. There
3 were also some concerns about the complexity of
4 the specifications in calculating age in child
5 years.

6 In addition, there were some concerns
7 noted with the approach and the results for
8 testing reliability and plan variation, in that
9 the ICC was not performed on a randomly selected
10 split sample. And they go onto validity, and
11 then we'll talk a little bit about the
12 developer's response.

13 For validity, the committee subgroups
14 had concerns concerning the empirical validity
15 testing that was done at the score level using a
16 difference-in-difference model and a negative
17 binomial regression. They thought that the
18 approach didn't adequately demonstrate the
19 validity of the measure, but rather the QI
20 intervention.

21 There were some concerns that the
22 measure was specified at the health plan level

1 and that testing was done at the facility level,
2 and then also finally, that the R-squared value
3 for the risk model was very low.

4 So I want to move on now to just give
5 a little overview, and I really have to commend
6 the developer. You did an enormous amount of
7 work in your response. Daniel and I did a little
8 sidebar here offline, and it seems to address a
9 lot of concerns.

10 I think there might still be some
11 left, but it seems to me, and Daniel mentioned
12 this as well -- and NQF, if you could weigh in on
13 this -- it looks, because it's so
14 methodologically and conceptually different than
15 the original submission, should this now be
16 considered in the next cycle as the new
17 submission?

18 Because it seems like a lot of
19 information to digest and evaluate in such a
20 brief period of time. So if NQF could jump in,
21 and then Daniel, if you want to jump in as well?

22 (Simultaneous speaking.)

1 MS. WILBON: Go ahead, Daniel, sorry.

2 MEMBER DEUTSCHER: Yeah, okay, sorry.

3 So I just wanted to maybe note a couple of
4 things, one for reliability and one for validity.

5 So if I understand correctly, the
6 method used originally to assess reliability used
7 a mixed model that accounted for variables
8 included in the risk adjustment model, and
9 clustering within providers.

10 To my understanding, this is more of
11 an appropriate first step in determining the
12 proportion of the total variance, the performance
13 outcome that is accounted by clustering within
14 providers. However, this might not demonstrate
15 the provider-specific reliability estimates from
16 which overall provider level reliability estimate
17 and be count related.

18 I think the initial approach, and I'll
19 mention the additional analysis that was
20 submitted in a minute, but this approach I think
21 allows an overall estimation of whether there is
22 a significant amount of variance in performance

1 that is explained by the provider level, and if
2 it is significant enough, then maybe developers
3 can then go to the next step which is to
4 calculate the provider specific reliability
5 estimate.

6 This next step, to my understanding,
7 initially was not conducted, and the results
8 reported mentioned by Terri suggested there is
9 not enough or maybe almost no between-provider
10 variance to enable detecting differences between
11 provider performance or not in a reliable way.

12 Now, and I also commend the developers
13 for the large amount of additional materials that
14 were submitted, and within those materials, the
15 developers have included a totally new set of
16 analysis for reliability, and this time it was
17 first based on the health plan level, so that's
18 one big fix that was done.

19 The method used, again if I understood
20 correctly, was a split sample reliability testing
21 basically comparing two sets of provider scores
22 from those split samples, and then an ICC was

1 calculated with the result being 0.7, I think,
2 for one set of health plans, and a little bit
3 under 0.9 for the larger set.

4 I wanted to note that this ICC is
5 conceptually different than the signal-to-noise
6 approach or ICC type, and maybe the developers
7 could explain why the ICC, which some could also
8 argue being relatively low, but in the fact that
9 they assess the accuracy or stability of the
10 provider level score, where does that provide
11 evidence that the measure is effective at
12 detecting reliability differences between
13 providers' performance? So that's maybe one
14 question the developers could address.

15 The second comment I wanted to add for
16 risk adjustment, the Chair mentioned the initial
17 results were very low, almost nonexistent R-
18 squared, and then the additional analysis which
19 was totally on a different level, again moved to
20 the health plan level.

21 R-squares were higher, but there were
22 large differences between plans. So for one

1 plan, the model has an R-square of 0.13, for
2 another it was almost 0.6 or 0.56, I noted here.
3 I wonder if this questions the model's predictive
4 or external validity.

5 So those were the two additional
6 comments I wanted to add, and I agree that the
7 amount of additional information, which I think
8 some of that information addresses the concerns
9 and maybe some do not. I think it really
10 deserves a new submission since it's really not
11 only different, it's also different content wise,
12 but also method wise.

13 So yeah, so I'll turn this back to
14 you, Ashlie. Just as Terri mentioned, I'm
15 wondering what was the NQF's policy in such a
16 case. Thanks.

17 MS. WILBON: Sure, thanks, Terri and
18 Daniel, for that. So a couple of things. I
19 think some of it may be, there may be two
20 different issues, maybe a process of how the
21 submission actually gets updated to reflect the
22 information that was submitted as a response to

1 the preliminary analyses, and then kind of what
2 is considered for voting today.

3 So with the process changes that we
4 made last cycle, we do now allow for the
5 developer to submit additional information for
6 consideration. So we would ask that the votes
7 that we submit today in reconsideration of the
8 measure do take into consideration the additional
9 materials that they submitted, and that your vote
10 should kind of weigh those additional, that
11 additional information.

12 In terms of kind of the new
13 submission, our policy right now is that we do
14 ask that developers kind of maintain the same
15 submission per se, so we have the same measure
16 number, same information in terms of the testing
17 attachment and so forth, but what we will do is
18 make sure that the information they have
19 submitted as additional information becomes a
20 part of their packet.

21 What we want to do is kind of tell a
22 story of the measure throughout the process. We

1 don't want to kind of, you know, remove
2 information that was there before so that the
3 standing committee really has a holistic view of
4 the measure as it's matriculated through the
5 process.

6 We will work with the developer after
7 the committee reviews the measure to clean up the
8 submission so that, you know, by the time it's
9 endorsed, that the packet actually represents the
10 measure that was actually recommended for
11 endorsement if that is the outcome. And so
12 hopefully that's helpful, but if not, please let
13 me know and I'll try to clarify.

14 MEMBER DEUTSCHER: Yeah, thanks for
15 that.

16 CHAIR CELLA: This is Dave C. Any
17 other comments from the committee or from the
18 developer, from Dr. Bardach?

19 DR. BARDACH: Sorry, this is Dr.
20 Bardach. Did you want me to say something?

21 CHAIR CELLA: If you would like, yeah,
22 please do, and then we have another hand raised,

1 but go ahead.

2 DR. BARDACH: Okay, I wasn't sure if
3 you would include me in the request for comments.

4 CHAIR CELLA: If you want to comment
5 on what was just discussed, please go ahead, and
6 then we can go to Matt Austin.

7 DR. BARDACH: Okay. No problem.
8 Yeah, I wanted to also preface my comments by
9 saying thank you very much for the careful review
10 and the very thoughtful method feedback.

11 I think it's probably helpful to give
12 a little bit of explanation and context to what
13 the testing was and what the new submission of
14 testing is because I think this issue of should
15 we submit a new application or not, it's probably
16 helpful to clarify what we did submit for the
17 whole committee to understand.

18 The original submission technical
19 specifications as a measure are still the same.
20 The technical specifications haven't changed at
21 all. The new data that we gave when you guys
22 requested additional (unintelligible), and you

1 gave us all the comments and you gave us an
2 opportunity to respond.

3 We changed our testing for reliability
4 and validity in response to the comments from
5 reviewers, and there was actually -- we used the
6 methodology that was suggested by the reviewers
7 in the comments, and so that's what we gave to
8 you guys to review again.

9 It is quite different, and let me
10 explain why it's so different, and it was
11 actually extremely helpful to get those comments
12 for us to be able to understand more about our
13 measure and how to do the testing.

14 The basic issue, and this is super
15 deep in the weeds, but I think it's really
16 important to explain, the way the data set comes
17 out of our measure specification is that it is a
18 patient-month level data set.

19 That means what we're trying to look
20 at in that data set is each line is: how many ED
21 visits did you have in that month for that one
22 patient? That number is going to be actually

1 very hard to predict and very unreliable if you
2 just are looking at the month number line.

3 So our original reliability constant
4 actually was looking at that, and we were amazed
5 that our ICC was still very low, and we submitted
6 because we couldn't quite figure out what was the
7 right way to do it.

8 And so the comments back from the
9 methods panel were actually very helpful in us
10 being able to think about the fact that actually
11 the reliability we're looking at is, you know,
12 the conceptual and important reliability is to
13 think about the plan level variation across the
14 measure, which is 100 child-years.

15 So the reliability testing that we did
16 and presented in our second submission, and that
17 you guys are talking about now, is the
18 reliability of looking at the plan level
19 reliability rather than the method level
20 reliability.

21 So that's what that split sample
22 testing was able to allow us to accomplish, and

1 for the rest of the committee I'll say out loud,
2 it is a plan level measure. It is not a provider
3 level measure. So we're looking at just trying
4 to do plan level reliability and validity.

5 So let me just look at my notes again.
6 I think those were probably the biggest responses
7 to give. Oh, sorry, the one other thing, the
8 validity, to just clarify, there's two types of
9 validity that you guys have already sort of
10 mentioned during the course of my listening into
11 the last hour-and-a-half or so, but there's
12 validity of the model itself, the risk model and
13 then there's construct validity. The first set
14 of results that we gave was actually more focused
15 on construct validity or face validity.

16 We basically took a plotting from the
17 collaborative with a lot of focus in the quality
18 group collaborative on cost of patient care, and
19 then we said for those people who participate in
20 the quality collaborative, the clinics that
21 participated versus the clinics that did not
22 participate, is there a difference in this

1 outcome measure of asthma ED utilization in order
2 to basically say: is this actionable for a health
3 plan that wants to actually improve care?

4 Can they go to their clinics and say,
5 "Hey, we need you to focus on asthma," and their
6 asthma care processes, and will that actually be
7 related to this measure? And so that was what we
8 were trying to present in that type of validity
9 analysis. That was what we did looking at those
10 differences.

11 The response that we sent you was to
12 actually -- the request from reviewers was for
13 the validity of the model, and so we repeated all
14 of our analyses and then the new data set would
15 show you just Massachusetts data, and the new
16 analysis was in California data to show, you
17 know, what are the results in the two different
18 states and how do they compare? So that's just
19 to clarify why the analyses look so different.

20 CHAIR CELLA: Thank you. Matt, would
21 you like to comment now, Matt Austin?

22 MEMBER AUSTIN: Yes, thank you so

1 much. So my concern around validity was -- and
2 I've sort of been trained to sort of weed through
3 all of this and sort through all of this somewhat
4 on the fly too.

5 My recollection is that the validity
6 testing was not done at a health plan level, and
7 it was done at some sort of lower level of
8 analysis. Did you all provide any validity
9 testing that was done at the health plan?
10 Because my understanding of NQF's requirements is
11 that the testing has to be done at the level of
12 the measure's specification.

13 DR. BARDACH: We, in our resubmission,
14 we did it at the health plan level. Yeah, we
15 looked at the health plan. We gave a whole new
16 set of analyses that looked at the R-squared and
17 the variation in the -- I'm sorry, hold on.

18 I'm trying to find where it is in our
19 document -- the variation in performance at the
20 health plan level, both in California and in
21 Massachusetts. So it looks like most of that
22 data is all in (unintelligible) number 20 in the

1 document.

2 MEMBER AUSTIN: Okay, yes, thank you
3 for directing me to that. I'll take a further
4 look at that. Thank you.

5 DR. BARDACH: No problem. Yeah, I
6 know it was a lot.

7 CHAIR CELLA: Yes, on the one hand,
8 it's good to get the opportunity to hear from
9 this panelist as to the concerns, but then by the
10 time we get there, then if they're long
11 responses, it's hard to find the time to really,
12 really sink it in, and I think that's where the
13 question of, you know, should this be --

14 There's so much in the response.
15 Should this be a new submission? But I think we
16 are going to -- I'm not saying we're closing to
17 vote now, but I think there will be a vote coming
18 soon. And if I misheard, Ashlie, is that
19 correct? We will be voting on this as a
20 submission with the developer's response?

21 MS. WILBON: Yes, we should be --

22 CHAIR CELLA: Okay.

1 MS. WILBON: -- now considering what
2 they submitted, yes.

3 CHAIR CELLA: Okay, so as we're all
4 sort of, you know, looking through the response
5 to shore up the original concerns, I'll just ask
6 if there are any other comments from the subgroup
7 or anyone on the panel, anyone in the overall
8 committee, or any last words from the developer?

9 Okay. Well then I guess, Ashlie, you
10 can walk us through the voting.

11 MS. WILBON: Sure, so then subgroup
12 one is up again. So I won't redo roll call. I'm
13 hoping everyone is still on. We'll be working
14 with a denominator of --

15 CHAIR CELLA: Well, one second,
16 Ashlie. Mike Stoto left, I think, unless --

17 MS. WILBON: Oh, no, you're right.
18 You're right. Thank you for verifying that. So
19 Mike --

20 CHAIR CELLA: And Larry is still here,
21 but we're going to lose Larry in 10 minutes or
22 so, so you know, we're fine, but I think we're at

1 seven.

2 MS. WILBON: Yeah, so one other note
3 to make is that Patrick is recused from this
4 matter, so our denominator goes down as well, so
5 I think we'll be having six.

6 CHAIR CELLA: Okay.

7 MS. WILBON: Let me just double check
8 my notes, six voting. We'll have, yeah, six
9 voting on this measure for the subgroup, and
10 Hannah -- and we'll be voting on both reliability
11 and validity.

12 And again, votes should be taking into
13 consideration the additional material submitted
14 by the developer, and please locate the voting
15 link, and Hannah will put forth the voting for
16 reliability first. We'll post the results and
17 then vote on validity.

18 MEMBER AUSTIN: Ashlie, this is Matt.
19 Is six enough for a quorum?

20 MS. WILBON: It is. It is. We did
21 make quorum because Patrick's recusal kind of
22 takes the denominator down, so we're still within

1 quorum. Thank you for bringing that up.

2 MS. INGBER: Okay. We're just waiting
3 on one more vote.

4 MS. WILBON: Okay. Hannah is going to
5 show us the results.

6 MS. INGBER: Sorry, I was just having
7 a little trouble getting unmuted. Okay, I will
8 share my screen now.

9 Okay. As you can see, the responses
10 for 3576 overall rating of reliability, we have
11 zero votes for high, three votes for moderate,
12 two votes for low, and one vote for insufficient.
13 Therefore, a consensus is not reached on this
14 measure for reliability.

15 MS. WILBON: Thanks, Hannah. So
16 Hannah will work on getting the validity vote up
17 for you, and then we'll go from there.

18 MS. INGBER: Okay, voting is now open
19 on validity for 3576. Okay. I'm going to go
20 ahead and share my screen again. So voting is
21 closed on -- oops, sorry -- 3576 for an overall
22 rating of validity.

1 We have two votes for moderate, three
2 votes for low, and one vote for insufficient.
3 Therefore, the measure fails on validity. I'm
4 sorry, it does not pass on validity. My bad.

5 CHAIR CELLA: Okay. Thank you, and
6 thank you to UCSF and Dr. Bardach for joining us.
7 I think it's time for public comment, Ashlie.
8 We're back on schedule.

9 MS. WILBON: We are. Kudos to the
10 panel. Thanks for getting us back on schedule.
11 Yes, we will open it up for public comment at
12 this time, and we'll do a very brief wrap up, and
13 we will look to close on time.

14 If you would like to make a public
15 comment, please press *1 to let the operator know
16 you'd like to speak, or you can enter a comment
17 in the chat box.

18 OPERATOR: We have no comments over
19 the phone lines.

20 MS. WILBON: Thank you. I also don't
21 see any comments in the chat box, so we'll keep
22 moving. If there are comments, please feel free

1 to add them in the chat box until we close.

2 For a brief follow up, we did have an
3 opportunity -- we did have a placeholder here for
4 some process improvement feedback. Given where
5 we are right now with the timing, I am not going
6 to spend time on that. We will have some time
7 allocated at our next meeting to do a brief
8 debrief, and we'll do so with the co-chairs as
9 well.

10 I did also just want to keep on
11 everyone's radar about some of the papers we
12 discussed, and Jack will be reaching out with an
13 email reminder for folks to respond with their
14 interest in participating on one of the writing
15 groups for the paper.

16 I think we at least identified at
17 least three papers on reliability, risk
18 adjustment, and our social risk adjustment, and
19 discussing validity of cost measures, or just
20 kind of general issues in evaluating cost
21 measures, so we'll be in touch about that.

22 Also a couple of next steps for this

1 cycle, the measure submission deadline for
2 measures that we just reviewed in terms of them
3 submitting their full submission for the
4 committees to consider, which would be the
5 important feasibility --- use and feasibility
6 sections, will be coming up or is in process now
7 for the next couple of weeks, and we will be
8 summarizing the discussions of the methods panel
9 for these measures and providing those results to
10 the various standing committees.

11 The standing committees will be
12 meeting to do recommendations for endorsement
13 early summer, the May, June time frame, and we
14 expect to see that decision for endorsement for
15 this set of measures around October.

16 And our next cycle begins for measure
17 review in the fall. Our intent to submit
18 deadline is August 3, so just a few dates to keep
19 in mind, and also we just wanted to list here for
20 you the next webinar date, or the remaining
21 webinar and in-person meeting dates we have
22 scheduled.

1 Certainly depending on where we are
2 with this crisis, hopefully we'll all be able to
3 meet in person again by October, but those dates
4 are scheduled through the end of the year, so
5 hopefully you have them on your calendar, and I
6 think that's it.

7 I did just want to give a big thanks
8 to our co-chairs, Dave Cella and Dave Nerenz, for
9 keeping us on task today and for facilitating
10 such thoughtful and engaging discussions over the
11 last couple of days, and for all of our other
12 methods panel members for bearing through a very
13 long but fruitful meeting over the last couple of
14 days via webinar, which isn't ideal, but I think
15 everyone did a great job and we appreciate
16 everyone staying engaged. Dave and Dave, any
17 final words for the group?

18 (Simultaneous speaking.)

19 CHAIR CELLA: Go ahead, Dave.

20 CHAIR NERENZ: It's hard to go
21 alphabetical. Just to echo the thanks back a
22 couple other ways, the staff did a great job of

1 putting back on the (unintelligible) supporting
2 this whole enterprise.

3 This thing could have totally blown up
4 given how we had to adjust on short notice doing
5 a virtual meeting, and it went amazingly well, so
6 thanks to Ashlie and Hannah, and the whole team
7 for the way this was put together, and for the
8 whole panel.

9 This is hard, especially in these
10 times. We're pulled in different directions. We
11 have lots of other things on our minds, other
12 competing priorities. It's hard to do this
13 without the face-to-face engagement, and again, I
14 think this went amazingly well under the
15 circumstances. So thanks, you all, so much for
16 your thought, dedication, and seriousness of
17 effort, really good.

18 CHAIR CELLA: Well this is Dave C. I
19 have nothing to add. I think you said it all,
20 Dave, and I think it's pretty impressive that
21 we're able to give you six minutes back. Thanks
22 again to NQF for really a great setup of all of

1 this and helping get the technology to work and
2 everything. Thank you.

3 MS. WILBON: Thanks, everyone, and I
4 appreciate your time. And I hope you all stay
5 healthy and well, and we will meet again. Take
6 care, everyone.

7 CHAIR CELLA: Bye-bye.

8 CHAIR NERENZ: Yes. Thank you.

9 (Whereupon, the above-entitled matter
10 went off the record at 12:54 p.m.)

A			
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