

NATIONAL QUALITY FORUM

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SCIENTIFIC METHODS PANEL

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MONDAY

OCTOBER 28, 2019

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The Scientific Methods Panel met at
the National Quality Forum, 5th Floor Conference
Room, 1099 14th Street, N.W., Washington, D.C.,
at 9:00 a.m., Dave Cella and David Nerenz, Co-
Chairs, presiding.

PRESENT:

DAVID CELLA, PhD, Northwestern University;
Co-Chair

DAVID NERENZ, PhD, Center for Health Policy and
Health Services Research, Henry Ford
Health System; Co-Chair

J. MATT AUSTIN, PhD, Armstrong Institute for
Patient Safety and Quality at Johns
Hopkins Medicine

BIJAN BORAH, MSc, PhD, Mayo Clinic

JOHN BOTT, MBA, MSSW, Healthcare Ratings,
Consumer Reports

DANIEL DEUTSCHER, PT, PhD, Maccabi Healthcare
Services

LACY FABIAN, PhD, The MITRE Corporation

MARYBETH FARQUHAR, PhD, MSN, RN, American
Urological Association

JEFFREY GEPPERT, EdM, JD, Battelle Memorial
Institute

LAURENT GLANCE, MD, University of Rochester
School of Medicine and Dentistry

JOSEPH HYDER, MD, Mayo Clinic

SHERRIE KAPLAN, PhD, MPH, UC Irvine School of
Medicine

JOSEPH KUNISCH, PhD, RN-BC, CPHQ, Memorial
Hermann Health System

ZHENQIU LIN, PhD, Yale-New Haven Hospital

JACK NEEDLEMAN, PhD, UCLA

EUGENE NUCCIO, PhD, University of Colorado,
Anschutz Medical Campus

SEAN O'BRIEN, PhD, Duke University Medical
Center

PATRICK ROMANO, MD, MPH, UC Davis

SAM SIMON, PhD, Mathematica Policy Research

ALEX SOX-HARRIS, PhD, MS, Stanford University

CHRISTIE TEIGLAND, PhD, Avalere Health

RONALD WALTERS, MD, MBA, MHA, MS, University of
Texas MD Anderson Cancer Center

TERRI WARHOLAK, PhD, RPh, CPHQ, FAPhA,
University of Arizona, College of Pharmacy

ERIC WEINHANDL, PhD, MS, Fresenius Medical Care
North America*

NQF STAFF:

MICHAEL ABRAMS, Senior Director
SHANTANU AGRAWAL, MD, MPhil, President and CEO
KAREN JOHNSON, Senior Director
ANDREW LYZENGA, Senior Director
ELISA MUNTHALI, Senior Vice President
YETUNDE OGUNGBEMI, Project Manager
SAM STOLPE, Senior Director
ASHLIE WILBON, Senior Director

ALSO PRESENT:

MARK ANTMAN, STS*
MARY BARTON, NCQA
ANNA CHRISTENSEN, Mathematica*
CINDY CULLEN, Mathematica*
BOB REHM, NCQA
DAN ROMAN, NCQA
DAVE SHAHIAN, STS*

* present by teleconference

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

9:06 a.m.

MS. JOHNSON: Welcome to our Fall 2019 cycle Scientific Methods Panel meeting. This is pretty exciting for us. We've been able to gather people together in the past for some methods discussions.

Today we will be doing measure reviews. So we've done these over the phone before, I think we'll probably -- It will probably be more fun, more interesting, more interactive being able to do it in person.

It's always good to be able to see body language, get to know your fellow panelists. So thank you for coming. I am Karen Johnson. I am one of the senior directors here at NQF and I have the pleasure of getting to work with the methods panel.

So you guys take up a lot of my time and thank you so much --

(Laughter.)

MS. JOHNSON: So I hope you guys enjoy

1 this interaction. We are going to be doing --
2 We are going to start off with our usual, if we
3 could just go to the next slide, we'll do our
4 welcome introductions and disclosures of
5 interest. We do have to do those today.

6 Then we will spend a little time going
7 over process and just a few reminders about our
8 criteria and then we will get into our measure
9 evaluations.

10 And I'll give you -- Where should I be
11 pointing? Is it --

12 MS. WILBON: Nowhere. Just anywhere.

13 MS. JOHNSON: Anywhere.

14 (Laughter.)

15 MS. JOHNSON: Anywhere isn't working.

16 There we go, okay, anywhere works, okay. So
17 content leads, we're going to just do a real
18 quick introduction in a couple of minutes here of
19 our staff, but before we do that we will have
20 Dave and Dave say hello, our esteemed co-chairs,
21 and then we'll go around and introduce our staff,
22 including Shantanu, who, sorry, we didn't put you

1 on our slide.

2 MR. AGRAWAL: Don't worry.

3 MS. JOHNSON: But Shantanu, our
4 fearless leader. Dave and Dave, would you like
5 to welcome folks to the meeting.

6 CO-CHAIR NERENZ: Sure. Welcome and
7 we're looking forward to a good couple of days.
8 I guess the first thing we should do, we tried a
9 couple of years ago to establish a Dave and David
10 distinction and we couldn't hold it. I couldn't
11 even hold it myself.

12 (Laughter.)

13 CO-CHAIR NERENZ: So I think we are
14 Dave N. and Dave C., at least that is a reliable
15 distinction. Otherwise, we can't remember which
16 is which.

17 It's great to have you here. I've
18 always enjoyed the face-to-face meetings. It's
19 great to see people and have the discussion. I
20 always learn a lot from these and I think this is
21 going to be unique.

22 As everybody knows it's the first time

1 we've done this particular approach to discussion
2 on measures that did not retrieve consensus in
3 the subgroup.

4 So I've lost a little sleep over this
5 because I am thinking that it's probably as easy
6 to get a disagreement among 25 people as it is
7 among six people and then I'm not sure where we
8 go.

9 But it will be interesting learning
10 along the way, so I am glad you are here and glad
11 you took time to do this and I'm looking forward
12 to a good couple days.

13 CO-CHAIR CELLA: Hi, everyone. I am
14 Dave Cella, just add my welcome and thank you for
15 all the time and attention that you are paying to
16 these important reviews.

17 Do you want to say something about the
18 consistency now or later?

19 (Simultaneous speaking.)

20 MEMBER ROMANO: We're having trouble
21 hearing at this end.

22 (Simultaneous speaking.)

1 CO-CHAIR CELLA: Okay. Hi. I'm Dave
2 Cella and I'll just talk a little bit louder and
3 add my welcome to Dave N.'s welcome.

4 MEMBER ROMANO: Are your microphones
5 in the ceiling or --

6 MS. WILBON: Yes, the green discs.
7 The green discs.

8 MEMBER ROMANO: Oh, the green discs,
9 okay.

10 MS. JOHNSON: Yes, so what we may do
11 is you may still have to use your outside voices
12 in here. So we will let you know if we can't
13 hear you on this end and you guys just let us
14 know if on that end you can't hear us.

15 MS. WILBON: And it's being recorded?

16 MS. JOHNSON: It is being recorded.

17 MS. WILBON: So you can hear
18 everything we are saying?

19 MS. JOHNSON: Yes. These will go --
20 When we go on breaks you'll notice that they will
21 turn red. That means they are muted. If they
22 are green we are not muted.

1 MEMBER ROMANO: Is there a way to turn
2 up the amplification or is that not an option?

3 MS. MUNTHALI: So we do have some
4 mics. There are about four mics, we'll pass
5 those around. We did this last week with the
6 CSAC.

7 We apologize, we just moved in and so
8 this is part of being in a new home, but we did
9 have our IT colleagues working on the sound, so
10 they are going to come to make sure that
11 everything is okay for us.

12 MEMBER KUNISCH: It's a beautiful
13 space.

14 MS. MUNTHALI: Thank you.

15 MEMBER KUNISCH: It's visually very
16 nice.

17 MS. MUNTHALI: But I think the folks
18 on the phone can hear us perfectly, which is very
19 ironic.

20 (Laughter.)

21 MS. JOHNSON: All right. Let's go
22 around this way and we'll get staff and then

1 we'll get staff on this side and then we'll get
2 Elisa to go over the DOIs.

3 MS. MUNTHALI: Okay. So hello,
4 everyone. My name is Elisa Munthali. I am the
5 Senior Vice President for Quality Measurement and
6 I wanted to thank you so much for all of the time
7 you put into the Scientific Methods Panel and for
8 being here in person and for those on the phone
9 thank you for joining us virtually.

10 I know a couple couldn't make it, but
11 you are all so committed and to give you a lot of
12 work and we so appreciate the volunteer hours
13 that you put into this, so thank you. Shantanu?

14 MR. AGRAWAL: Yes. Yes, I was working
15 on the sound. So I am Shantanu Agrawal, the CEO
16 of NQF. Thank you all for being here. I really
17 appreciate all the time that you take to work on
18 this extremely critical and important committee.

19 I do think it would be highly remiss
20 of us, there is a lot of intellectual brainpower
21 in the room, lots of statistical and
22 methodological power.

1 I do want the over/under on a Game 7
2 of the World Series. It's going to be really
3 important for the entire committee and for the
4 entire city as it turns out. So, again, thank
5 you for being here.

6 MR. LYZENGA: Hi. Andrew Lyzenga,
7 Senior Director here at NQF. I am looking
8 forward to getting started for the day.

9 MR. ABRAMS: Yes, good morning,
10 everybody. I am Michael Abrams, also a Senior
11 Director here at NQF, and excited to be working
12 on this effort with you all.

13 MS. WILBON: Good morning, everyone.
14 My name is Ashlie Wilbon. I think it got a
15 chance to say good morning to everyone, but there
16 may be a few that I missed, so, welcome.

17 We are excited to have you guys here
18 today and, yeah, I hope everyone has fun today.

19 MR. STOLPE: Good morning, everyone.
20 Sam Stolpe, also a Senior Director here at NQF,
21 and I just wanted to add a welcome. I didn't get
22 to say hello to everyone, but I especially wanted

1 to welcome the newcomers to the panel. Thanks
2 for making the trip out.

3 MS. OGUNGBEMI: Hi. I am Yetunde
4 Ogungbemi. Good morning, everyone. I will
5 reiterate Karen's comments, you take up a lot of
6 my time, but it's a pleasure. Welcome, thank
7 you.

8 MS. JOHNSON: Okay. And with that I
9 think we'll just move straight into -- Well, in
10 just a second, before that I want to make sure
11 that we congratulate our friend Dave Cella on his
12 election to the National Academy of Medicine.

13 (Applause.)

14 CO-CHAIR CELLA: Thank you.

15 MS. JOHNSON: Speech?

16 (Laughter.)

17 CO-CHAIR CELLA: I, you know, it's
18 just one of things where, you know, you sort of
19 generally say why me. I mean it's really quite
20 an honor and I was pretty surprised, so thank
21 you.

22 MS. JOHNSON: Congratulations.

1 CO-CHAIR CELLA: Thank you.

2 MS. JOHNSON: Yes. All right, Elisa,
3 do you want to walk us through DOIs?

4 MS. MUNTHALI: Yes. So welcome and
5 hello, everyone, again. So when you were first
6 selected to be a part of this committee we sent
7 you a pretty lengthy disclosure of interest form
8 and information and what we are asking you today
9 is to orally disclose what you gave us in written
10 form.

11 We do not want you to recite your very
12 impressive resumes, but there are a couple of
13 things in particular that we are looking for. We
14 are interested in any grants or research or
15 consulting that is related to the work of the
16 Scientific Methods Panel.

17 And before we go around the room, so
18 what we will do is go around the room clockwise
19 to my left and then to I think Jen who is on the
20 phone and Eric who is also on the phone.

21 And so what I would like you to
22 remember is that you sit on this group as an

1 individual. You do not represent anyone who may
2 have nominated you for this committee or your
3 employer.

4 We are interested in both paid and
5 unpaid activities but only as they are related to
6 the work in front of you. And I think this is
7 the most important reminder, just because you
8 disclose does not mean you have a conflict of
9 interest.

10 We do this in the interest of
11 transparency and openness. So I think we'll
12 start with Christie, yes.

13 MEMBER TEIGLAND: And I have nothing
14 to disclose.

15 MS. MUNTHALI: Perfect. Thank you.
16 And if you can just introduce yourself and let us
17 know who you are with.

18 MEMBER TEIGLAND: Oh, sure, yes. Hi.
19 Christie Teigland. I am a Principal of Health
20 Economics Advanced Analytics at Avalere Health.
21 They were acquired by Inovalon about three, four
22 years ago now almost, and I was previously with

1 Inovalon, so I do a lot of big data research.

2 MEMBER NUCCIO: Gene Nuccio,
3 University of Colorado Anschutz Medical Campus.
4 My background is primarily in home health, post-
5 acute care, and so I've worked on the Whole
6 Health Measures, the value-based purchasing, and
7 some MedPAC work, but I have no conflict with any
8 measure today.

9 MEMBER BOTT: John Bott. I am an
10 independent contractor. Currently I am doing
11 some work helping Thomas Jefferson University
12 Employer Health Care Alliance Cooperative in
13 Wisconsin, the Leapfrog group, a couple attempts,
14 I don't know if it's salient or not, selected for
15 the AHRQ ESIs, which essentially -- manages that
16 contract, and also I am a CMS Hospital Star
17 Ratings -- that's all.

18 MEMBER WARHOLAK: Good morning. I am
19 Terri Warholak and I am a professor at the
20 University of Arizona College of Pharmacy.

21 I have been working on psychometrics
22 for many years and teach that and I have also

1 been working with the Pharmacy Quality Alliance
2 as a volunteer for many years as well.

3 I have no conflicts with any of the
4 measures today.

5 MEMBER FARQUHAR: Good morning. My
6 name is Marybeth Farquhar. I am the Executive
7 Vice President for the American Neurological
8 Association.

9 I am six months new into that job. I
10 am in charge of guidelines, measure development,
11 and research as well as the data registry that we
12 are hosting, and I have no conflict of interest.

13 MEMBER DEUTSCHER: Hello, good
14 morning. My name is Daniel Deutscher. I work
15 out of Israel. Maccabi Healthcare Systems is a
16 public health plan in Israel where I serve as the
17 National Director of Research.

18 I have been involved in measure
19 development, patient-reported outcome measures
20 for many years and also involved very much in
21 creating large databases, big data analysis using
22 patient-reported outcome, lots of treatment data,

1 patient data.

2 I am a -- I also serve as a consultant
3 for FOTO, Focus on Therapeutic Outcomes, they are
4 submitting to this committee measures on a
5 regular basis, so this is the disclosure I have.

6 MEMBER HYDER: Hi. My name is Joe
7 Hyder. I am anesthesiologist IC physician and
8 epidemiologist at Mayo Clinic in Rochester,
9 Minnesota.

10 I have worked for and have some work
11 with pro bono the American Society of
12 Anesthesiologists, their committee on performance
13 and outcome measures and core measures -- but I
14 have no conflict.

15 MEMBER SOX-HARRIS: I am Alex Sox-
16 Harris. I am a health services researcher at the
17 Department of Veteran Affairs in Palo Alto and at
18 Stanford University Department of Surgery.

19 I have federally funded research
20 looking at the measurement properties of various
21 quality measures. I think there is one measure
22 today, it's bereavement that is put forward by

1 the VA and I know some of those people, so that
2 is a potential conflict.

3 I have worked with some professional
4 societies helping develop quality measures, but
5 nothing that is in front of the group today.

6 MEMBER BORAH: Hi, everyone. I am
7 Bijan Borah. I am a professor of health services
8 research at Mayo Clinic and I have nothing to
9 disclose with regard to these measures.

10 MEMBER LIN: Hi. My name is Zhenqiu
11 Lin. I am a Senior Research Scientist from Yale
12 School of Medicine and Senior Director of Data
13 Management and Analytic at Yale CORE.

14 So I have been working on measure
15 development for, oh, over a decade, and we will
16 have some measures before this panel.

17 MEMBER O'BRIEN: Hi. I am Sean
18 O'Brien. I am a biostatistician at Duke
19 University. I have been working on measure
20 development for probably about that long or a
21 little longer.

22 I previously served on a handful of

1 NQF panels and task forces, including the measure
2 testing task force and the panel for risk
3 adjustment and socioeconomic status and I
4 was a statistical consultant to NQF a couple
5 times.

6 I work with national sample registries
7 from the Society of Thoracic Surgeons and
8 American College of Cardiology, so I do have
9 conflicts with a handful of the measures, or a
10 couple of the measures that we are doing this
11 weekend.

12 MEMBER AUSTIN: Yes, good morning. I
13 am Matt Austin. I am on the faculty at the Johns
14 Hopkins Armstrong Institute for Patient Safety
15 and Quality.

16 Probably my most significant contract
17 is to provide guidance around measurement
18 equities and there is no conflicts.

19 MEMBER GEPPERT: Jeffrey Geppert,
20 Battelle Memorial Institute. My only disclosure,
21 brief work on contracts with the Centers for
22 Medicare and Medicaid Services to manage their

1 portfolio measures for accountability programs,
2 including NQF endorsement.

3 MEMBER ROMANO: I am Patrick Romano.
4 I am a general internist and general
5 pediatrician. I am employed by the University of
6 California Davis Health, UC Davis Health, in
7 Sacramento, California.

8 I have worked on measure development
9 and testing for 25 years, or more. Currently my
10 group has contracts with AHRQ related to the
11 hospital quality indicators and CMS related to
12 patient safety indicators.

13 We also work with UCSF on a contract
14 to develop a new quality measure around a CT
15 dose, radiation dose, which is funded by CMS. So
16 through these relationships I work with Impact
17 International on what is called the CMS Patient
18 Safety Measures contract and our team has one
19 measure that is before this committee now, which
20 is 3533(b), I think.

21 MEMBER SIMON: All right. Sam Simon.
22 I am a Director of Quality of Measures at

1 Mathematica. We are a CMS measure developer. We
2 are a contractor for the Centers for Medicare &
3 Medicaid Services and one of the measures that I
4 advised is up for committees the measure --

5 MEMBER KUNISCH: Good morning. Joe
6 Kunisch. I am with Memorial Hermann Health
7 System in Houston. Go 'stros.

8 (Laughter.)

9 MEMBER KUNISCH: We'll talk about
10 that.

11 (Laughter.)

12 MEMBER KUNISCH: But I oversee all
13 their regulatory reporting programs and our
14 organization also participates in multiple
15 electronic clinical quality measures as seen with
16 the CMS contractors and I do not believe any of
17 them are up for review. That's all.

18 MEMBER NEEDLEMAN: I am Jack
19 Needleman. I am a Professor and Chair of the
20 Department of Health Policy and Management at the
21 UCLA Fielding School of Public Health.

22 I am a health economist by training.

1 I have previously served and continue to serve,
2 previously served NQF as a member of the
3 Technical Expert Panel on the hospital-related
4 nursing quality performance measures.

5 I currently serve, and have served
6 since the beginning, on the Cost and Resource Use
7 Committee. I have provided some unpaid
8 consulting to the American Nurses Association as
9 they have tried to move the nurse staffing
10 measures through the NQF endorsement process and
11 have no current conflicts of interest with any of
12 the measures today and as far as I know no
13 conflicts with any of the other members of the
14 committee.

15 (Laughter.)

16 MEMBER KAPLAN: I am Sherrie Kaplan
17 and I psychometrician by training. I am a
18 Professor of Medicine and Assistant Vice
19 Chancellor for the Healthcare Measurement and
20 Evaluation at UC Irvine.

21 I think the UC's are represented in
22 this room. But, anyway, so I am on the NQF

1 Patient Experience and Function Committee and I
2 have, currently my husband and I are unpaid
3 consultants to the Danish Government for a
4 planning initiative on diabetes quality for their
5 country.

6 I don't think that puts me in conflict
7 with the measures because I don't really have a
8 vested measure developer role in that. I have
9 grants under review and consideration from AHRQ
10 for the child health rating inventories. It's a
11 measure of animated measure of children's self-
12 reported health ages 4 to 12.

13 MEMBER WALTERS: My name is Ron
14 Walters. I am a medical oncologist at MD
15 Anderson in Houston. I have nothing to disclose
16 and I'm, same thing, the only conflict I had with
17 the prostate measure was I suggested we needed
18 one. I didn't have anything to do with
19 development.

20 By the way, for those of you that
21 watched the game, there are only two times, 1906,
22 1996, they showed this on a little graphic, that

1 the home team has not won a game during Game 5.

2 They didn't say what the statistics
3 were for the sixth game, but you can rest with
4 some hope that if that holds true you're in good
5 shape.

6 (Simultaneous speaking.)

7 MEMBER GLANCE: Good morning,
8 everybody. Hi, my name is Larry Glance. I am
9 from the University of Rochester. I am a cardiac
10 anesthesiologist and a health outcomes
11 researcher. I am professor and vice chair for
12 research in my department.

13 I don't believe I have any conflicts
14 of interest. My disclosure is that I also serve
15 on the American Society of Anesthesiologists
16 Committee for Performance and Outcomes
17 Measurement and we do develop quality metrics for
18 anesthesiologists, none of which I believe are in
19 front of this committee.

20 MEMBER FABIAN: Good morning. My name
21 is Lacey Fabian. I am a research psychologist by
22 training currently at the MITRE Corporation. My

1 background is always focused on quality measures,
2 particularly from the development side and then
3 from the best practices side.

4 My work is also now shifting to focus
5 more on clinical decision support as well.

6 CO-CHAIR CELLA: I am Dave Cella from
7 Northwestern University. I chair the department
8 called Medical Social Sciences. I have worked as
9 a consultant and a PEP member for Yale, RAND, and
10 RTI. Yale and RAND current, RTI in the past, but
11 none of those, there are no measures in front of
12 the committee for this meeting that are related
13 to anything I have advised on.

14 CO-CHAIR NERENZ: Dave Nerenz. I am
15 Director Emeritus now of the Center for Health
16 Policy, Health Services Research at Henry Ford
17 Health System in Detroit.

18 I have worked at the intersection of
19 quality measurement and racial and ethnic
20 disparities of care for over 25 years. I was co-
21 chair of the NQF panel on socioeconomic risk
22 adjustment.

1 I have published a few things about
2 quality measures and their effect on providers
3 who care for vulnerable populations. So I guess
4 I have some opinions out there, but I don't have
5 conflicts of interest.

6 I am not a measure developer. I don't
7 have a connection to anything in front of us
8 these two days.

9 MS. MUNTHALI: Thank you, everyone.
10 Oh, sorry.

11 CO-CHAIR CELLA: May I just ask,
12 because there are some new people here and it's a
13 long table I just want to call your attention to
14 the role models of Sherrie Kaplan and Eugene
15 Nuccio.

16 If you could tip your -- Thank you.
17 Tip your name cards in 30 degrees so we can see
18 them from here that would be very much
19 appreciated. Thank you.

20 MS. MUNTHALI: Thank you for that
21 reminder. And so we'll go to the phone, Jennifer
22 Perloff. Jen, are you with us perhaps on mute?

1 (No audible response.)

2 MS. MUNTHALI: Okay. Eric Weinhandl?

3 MEMBER WEINHANDL: Yes, good morning.

4 MS. MUNTHALI: Good morning.

5 MEMBER WEINHANDL: This is Eric.

6 Sorry I am unable to join you this time, a
7 conflict with one of my children's schedules.

8 So I am an epidemiologist
9 biostatistician. I am currently employed by
10 Fresenius Medical Care North America. It's
11 (telephonic interference) health services
12 provider as well a manufacturer (telephonic
13 interference) products.

14 I am an epidemiologist biostatistician
15 myself. I have worked in chronic kidney disease
16 and dialysis specifically since I graduated from
17 college, all things really.

18 So any time that there is a metric
19 that comes up that is related to that in some
20 way, shape, or form I probably have some kind of
21 convoluted conflict of interest.

22 In the case of today's measures before

1 the committee I believe the (telephonic
2 interference) issue is the one that would be more
3 directly pertinent to my conflicts. I
4 (telephonic interference) topic is the specific
5 case of this metric I have focused on a pro bono
6 basis to the Care Quality Alliance, which is the
7 measure -- it's good to be here.

8 MS. MUNTHALI: Thank you so much,
9 Eric, and thank you for being with us virtually.
10 Before I turn the meeting over to Ashlie and
11 Karen I just want to remind you that if at any
12 time you remember that you have a conflict we
13 would like you to speak up.

14 You can do so in real time or you can
15 come to any one of us on the NQF staff.
16 Likewise, if you believe that one of your
17 colleagues was acting in a biased manner we want
18 you to speak up.

19 So thank you very much and I will turn
20 it over to Karen.

21 MS. JOHNSON: So thank you, everybody,
22 and in terms of recusals we will talk about that

1 a little bit later in the morning, but we have --
2 I am also going to go through our meeting
3 materials that when we get to that part you'll
4 notice that we have noted who is recused on
5 certain measures.

6 I am going to ask you guys to help us
7 be honest on this. If we missed somebody please
8 make sure that you let us know that we missed and
9 that you should be recused from a measure, but
10 we'll get into that as we go.

11 So we wanted to do a little bit of a,
12 just a reminder, perhaps a little bit of a
13 reminder for some of you and maybe a little bit
14 of a reminder for people who are a little bit new
15 to the process.

16 So first of all our Scientific Methods
17 Panel was formed in 2017, so you guys are two
18 years old now. You are one of our newest groups
19 here at NQF and the formation of the Scientific
20 Methods Panel was actually a direct outcome of
21 the Kaizen Event that we did here in the Spring
22 of 2017 really to try to help us not only become

1 more agile in our endorsement process, but also
2 hopefully to become more consistent in the
3 process and to take some burden off of our
4 already empaneled standing committees.

5 So you have a two-fold charge. One
6 that you had intimate experience with in the last
7 several weeks, and that's conducting the
8 evaluation of conflicts measures for reliability
9 of validity, and then also you serve as our
10 advisors on methods, on our criteria, on, you
11 know, what's new in the measurement science
12 world, so we look to you for that advice.

13 So the evaluation process, this may be
14 a little bit new to you, maybe not to everybody,
15 but what happens is developers, or stewards,
16 submit specifications and the testing attachment
17 to us at certain times in the year, and that's
18 called our intent to submit deadline.

19 And we take that information when it
20 comes in the door and we determine which measures
21 are sent to the methods panel. So we don't send
22 you every measure that comes in for potential

1 endorsement, we send you the ones that we call
2 complex measures.

3 The complex measures are outcome
4 measures, intermediate health outcomes for
5 patient-reported outcomes, any cost measures that
6 come in the door or resources measures, any
7 composite measures, and any instrument-based
8 measures, okay.

9 So those are the complex ones. Those
10 are usually the hard ones, right, that you guys
11 get. So we figure out which ones those are and
12 send them to you.

13 And while we are doing that we, even
14 before we send them to you we do try to take a
15 first look and just make sure that some of our
16 minimum requirements are met before we send them
17 out to you.

18 So we want to make sure that testing
19 is done at the levels of analysis and that sort
20 of thing that they have been specified for. And
21 as you know different measure types we have
22 different requirements for levels of testing that

1 we require.

2 In the summer, this summer actually --
3 Actually, no, not this summer, this year, so
4 calendar year 2019 we said it is time that we
5 really start expecting to see testing done with
6 ICD-10 data as opposed to ICD-9. So we've had a
7 several year grace period, but we are really
8 trying to invoke the ICD-10 testing.

9 We also want to make sure that things
10 that need to be answered in our submission forms
11 actually have a response and we also allow, well
12 we don't allow, we expect by the time a measure
13 comes back around for maintenance we expect
14 empirical testing for validity.

15 Now that is not always going to be
16 possible for every measure developer. So if they
17 are still relying on face validity even at the
18 maintenance evaluation we ask for a justification
19 of why they weren't able to do empirical testing,
20 so we make sure that at least that is included in
21 there.

22 All right. Then we ship it out to

1 you. No, before we do that, let's see. There is
2 a lot of steps in here that I am sure you guys
3 are aware of.

4 We ask you guys to submit your
5 measure-specific disclosures of interest. So
6 this is kind of the overall kind of public one,
7 but we ask for the measure-specific ones and
8 that's what tells us who needs to be recused from
9 the discussion.

10 We then assign measures to subgroups.
11 So the number of subgroups depends on the number
12 of measures that have come in the door that are
13 going to you guys and who gets which measures
14 depends on your expertise, need for recusal,
15 previous experience, I'll explain that in a
16 minute, and then, obviously, the number of
17 measures, so the more measures we have the more
18 that you probably will be assigned.

19 In terms of previous experience, we do
20 note, you know, sometimes measures have come in
21 and they haven't made it past the methods panel,
22 so we try, if that's the case, we try to make

1 sure that at least one or two people who have
2 reviewed a measure before has a chance to review
3 it again.

4 It can't be, just the way it works
5 out, it can't be exactly the same people, but we
6 do try to have some overlap there. We give you
7 four weeks to complete those initial evaluations
8 and as you know you fill out that form that we
9 have, we call that the preliminary analysis for,
10 or here at NQF we will call it the PA, because we
11 love using acronyms, so the PA form.

12 And then finally when you submit those
13 to us we collate those evaluations and ratings,
14 we figure out did a measure pass, did it not
15 pass, did it fall kind of in between pass and no
16 pass, and we call that consensus not reached, or
17 CNR, okay.

18 So that, and you can see that in your
19 discussion guide kind of where things landed on
20 the ratings, okay.

21 Now this fall we actually have some
22 new process and you're seeing part of that today

1 because you are here in D.C. with us in a big
2 room as opposed to doing all of this over the
3 phone over like eight different calls in a 2-week
4 period.

5 So we are allowing, let's see -- Do I
6 have this in the right order? I hope I do. We
7 have given you guys opportunity to pull measures
8 for discussion.

9 So once you see where those ratings
10 are you can say, hey, this measure passed, but
11 I'd still like to talk about it, so we gave you
12 that option to do that. If you did that then
13 that is on our agenda for today and tomorrow.

14 We have developed a discussion guide
15 and figured out the agenda, so our ordering, and
16 that is based on those initial ratings and EPAs.
17 It's based on whether or not developers have
18 provided additional information and whether any
19 of the measures were pulled, and we also as staff
20 have the opportunity to pull measures for
21 discussion.

22 I missed one really important change

1 to our process. I don't know how I missed it,
2 but we were able, because we were able to have
3 this in-person meeting and we pushed this meeting
4 a little further in a timeline than we were able
5 to push those phone calls that we had before,
6 that allowed us a small amount of time, not a
7 huge amount, but some time to actually let
8 developers respond to your initial evaluations,
9 okay.

10 So we took those evaluations, we
11 combined those, we sent them out to developers,
12 and developers could choose, they didn't have to,
13 but they could choose to make responses in
14 written form to you guys.

15 Most of them actually did take us up
16 on that and provided some written responses and
17 hopefully we are able to speak to the main
18 concerns or even all of the concerns that you
19 raised in your evaluations.

20 All of those things we at NQF are
21 making available to the public. That's also a
22 change from what we did before. So before we had

1 these discussion guides and those were pretty
2 much we gave those to the developers, we gave
3 them to you, but nobody else saw them.

4 Now everybody has these. So these are
5 posted. If they are not posted, they will be. I
6 think they are already up on our website, so
7 members of the public who are following along you
8 should be able to see those.

9 Obviously, we have our in-person
10 meeting and we will vote today and first thing
11 tomorrow on some of these measures and then,
12 finally, we will provide summaries of your
13 discussion and votes to our standing committees.

14 So that's changed a little bit from
15 what we have done before. Before we did not do
16 that if the measure did not pass the methods
17 panel.

18 Now even if the methods panel does not
19 pass a particular measure we will still provide
20 that detailed summary to the standing committees
21 and the standing committees will have an
22 opportunity to discuss those measures should they

1 desire to do that.

2 Let me stop there and see if anybody
3 has any questions about our new process. And,
4 Sherrie, thank you for doing that. I have -- I
5 meant to give you a few housekeeping -- Sherrie
6 has been here before.

7 Just a couple of reminders before we
8 go in, this meeting is open to the public as we
9 talked about, so people can be listening on the
10 phone.

11 It is being recorded and the fellow
12 down at the very end with the headphones on is
13 our court reporter, so he is making sure that we
14 have a really good transcript of the meeting
15 today and tomorrow.

16 For those of you on the phone you are
17 already doing a great job, but we would ask that
18 you would mute your lines when you are not
19 speaking and if you do want to speak be sure to
20 tell us your name so that we know who you are,
21 and, SMP members, methods panel members who are
22 on the phone you can certainly use our chat

1 function in our web platform and let us know if
2 you want to talk, but you should also just feel
3 free to jump in.

4 You are at a little bit of a
5 disadvantage, so just, you know, if you need to
6 talk just talk. And, finally, well two more
7 things, your tent cards, if you guys in the room
8 want to talk we ask that you put your tent cards
9 up like this and that signals us that you want to
10 say something.

11 And then, finally, when the time comes
12 we will have developers and/or stewards in the
13 room to help answer questions. If they aren't in
14 the room we will actually allow them and ask them
15 to sit at our table, so that's why we have a
16 couple of chairs over here set aside for our
17 developer colleagues. So now, Sherrie.

18 MEMBER KAPLAN: I just wanted to
19 remark on and ask about the communication between
20 the standing committees and this panel, because
21 there is, as having sat on one of them there is
22 some confusion about, you know, well you guys

1 didn't disagree.

2 Well, you guys, but the idea that, you
3 know, their communication, our communications
4 with them is right now I don't think optimized
5 and I think, you know, a better understanding by
6 the committees might help, especially for one
7 struggling as the patient experience committee is
8 with this patient level error time we were
9 talking about averaging across patients, within
10 patient across items and then across patient and
11 in between providers.

12 There is a lot more of that that goes
13 on in that committee. So our communication with
14 them I don't think right now is as clear as it
15 could be.

16 MS. JOHNSON: It's a good question and
17 so far we haven't figured out how to make that,
18 so let's put that on our parking lot for tomorrow
19 and let's talk about how, you know, ideas that we
20 might have to do that.

21 Some of you guys, as you mentioned,
22 are on these panels so you can be kind of the

1 liaison, if you will, to those standing
2 committees, but that's not true across the board
3 and what we have done is we have expected staff
4 to take on that kind of liaison role and that may
5 or may not have worked out as well as we had
6 hoped.

7 We were really -- There is a lot of
8 meetings of our standing committees and it didn't
9 feel fair to ask you guys to do more so we
10 haven't asked you guys to actually go to our
11 meetings, but maybe that's something we want to
12 at least talk about.

13 We just kind of decided that we
14 wouldn't do that to you.

15 MEMBER KAPLAN: Yes. Well I was just
16 going for a little more clarity on the role of
17 this committee to help us understand exactly what
18 we are doing for you.

19 MS. JOHNSON: Okay. Let's --

20 MEMBER KAPLAN: And you don't have to
21 do that now.

22 MS. JOHNSON: Yes, let's think about

1 that tomorrow for sure because we as staff
2 actually write those descriptions of what
3 happened.

4 Maybe we need to have you guys look at
5 those and make sure we're getting it right. That
6 might help. We think we are, of course, we don't
7 write out stuff that we think is wrong, right,
8 but we might not be clear enough so maybe that's
9 something we can do as well. Thank you. Jack?

10 MEMBER NEEDLEMAN: Jack Needleman. So
11 this is less of -- This is not a question, it is
12 a comment and really directed to some of the new
13 members, so, of course, they are going to be
14 coming into some conversations that have been
15 underway, so you have not talked about some of
16 things that the switch to this committee has
17 produced in terms of the review process.

18 I have seen two things that I think
19 are particularly relevant and the developers are
20 still adjusting to it and we're still trying to
21 sort out our standards.

22 One is because there has been a lot

1 more methodological expertise looking at the
2 measures the standards I believe for reliability
3 and validity have been ratcheted up.

4 Now others on the committee may not
5 agree about that, but my sense is we're applying
6 higher standards than have historically been
7 applied and the developers are adjusting to that.

8 The second thing is as we saw in many
9 of the submissions the developers are using the
10 standards that are sort of out in the literature
11 for what's a strong relationship and an
12 acceptable level of conformance, whatever the
13 measure is.

14 And as we have looked at some of the
15 data related to what that means in terms of
16 ranking and stability of ranking there has been a
17 lot of discussion on the committee about whether
18 those standards are frankly rigorous enough.

19 We have not resolved what our new
20 standards are, but that keeps coming up in
21 conversation among us and I expect will come up
22 again today.

1 MS. JOHNSON: Thanks, Jack. Patrick,
2 go ahead.

3 MEMBER ROMANO: Yes. Patrick Romano.
4 Could you clarify when you say that the SMP meets
5 in person to discuss and vote?

6 So is the entire SMP voting on every
7 measure or are people only voting on the
8 subcommittee that they served on?

9 MS. JOHNSON: The answer is yes to
10 both. So I will actually get into that in a few
11 minutes and I'll explain how we're going to have
12 you guys vote.

13 MS. WILBON: Karen, should we tell
14 people where bathrooms are and stuff like that?

15 MS. JOHNSON: Oh, yes.

16 MS. WILBON: I actually don't know
17 where the bathroom is.

18 MS. JOHNSON: Ashlie suggested we let
19 you know where the men's room and ladies' rooms
20 are, and that's actually a good question, where
21 are they? They are --

22 (Laughter.)

1 (Simultaneous speaking.)

2 MS. MUNTHALI: They are just the
3 reception desk and then to your immediate left is
4 the women's restroom and the men's restroom is
5 just down the hall. I guess Andrew has confirmed
6 that.

7 MR. LYZENGA: On the other side.

8 MS. MUNTHALI: Yes, on the other side.

9 MS. JOHNSON: Okay. Is that clear as
10 mud?

11 MS. MUNTHALI: On the other side of
12 the kitchen.

13 MS. JOHNSON: Yes, so go past the
14 kitchen, go --

15 MS. WILBON: Oh, down this hallway?

16 MS. JOHNSON: Yes, so past the
17 receptionist --

18 (Simultaneous speaking.)

19 MS. WILBON: Okay. Thank you.

20 CO-CHAIR CELLA: Just a quick
21 question, do the SMP members on the phone have a
22 hand raise function?

1 MS. JOHNSON: They do.

2 CO-CHAIR CELLA: All right.

3 (Simultaneous speaking.)

4 CO-CHAIR CELLA: Okay, all right.

5 MS. JOHNSON: She has taken care of
6 that. Okay. Oh, yes, Patrick?

7 MEMBER ROMANO: One other question.

8 MS. JOHNSON: Uh-huh?

9 MEMBER ROMANO: At some point it might
10 be helpful since we're going to be discussing
11 materials that were distributed to other
12 subgroups I'm not sure if there is a structure to
13 the Sharepoint site, help find all of those
14 materials?

15 MS. JOHNSON: Oh, yes.

16 MEMBER ROMANO: That might be helpful
17 to give a bit of orientation to where to find the
18 materials for other sectors.

19 MS. JOHNSON: Okay. Yes, very bluntly
20 they are all under the Fall 2019 little tab, a
21 plus mark that you see, and I don't even think
22 they are in alphabetical order --

1 (Simultaneous speaking.)

2 MS. WILBON: -- numerical order by
3 measure number.

4 MS. JOHNSON: It's numerical?

5 MS. WILBON: Mm-hmm.

6 MS. JOHNSON: I usually just do the
7 "find" on the page and it will take me to that.

8 MS. WILBON: Yes.

9 MS. OGUNGBEMI: We can show you guys
10 real quick.

11 MS. JOHNSON: Yes, we can bring that
12 up.

13 (Off microphone comment.)

14 MS. JOHNSON: Yes, it's way down at
15 the bottom. So all the measure documents are
16 all at the bottom, yes, and then we are looking
17 at Project, Fall 2019, and remember Sharepoint it
18 has those little plus signs.

19 You have to remember that those plus
20 signs will explode things for you. There you
21 are. And then there are the measures. And
22 Ashlie tells me they are in numeric order, they

1 are.

2 MS. WILBON: They are in numeric
3 order.

4 MS. JOHNSON: Okay, all right. And
5 like I say you can always do a "find" and just
6 type in, usually I type in the measure number and
7 it will take me to it.

8 So they are not split out into
9 subgroups and things like that on the Sharepoint
10 page.

11 (Off microphone comments.)

12 MS. JOHNSON: I was going to say I
13 don't think they are in chronological order.
14 Sharepoint is --

15 (Off microphone comments.)

16 MS. JOHNSON: No.

17 (Off microphone comments.)

18 MS. JOHNSON: No.

19 (Off microphone comments.)

20 MS. JOHNSON: Yes, I -- It surprised
21 me when she said she thought they were because I
22 didn't think they were.

1 MS. WILBON: Not in the order of the
2 agenda, but they are in numerical order.

3 MS. JOHNSON: Are they actually in
4 numerical order?

5 MS. WILBON: They are in numerical
6 order.

7 MS. JOHNSON: Oh, they are, okay.

8 MS. WILBON: Yes.

9 MS. JOHNSON: Okay. So they are not
10 in the same order that we will be discussing
11 them, but they are in numerical order.

12 MS. WILBON: Yes.

13 MS. JOHNSON: All right, color me
14 surprised.

15 MEMBER SIMON: Karen, can you just
16 drill down into one of the measures because I am
17 not sure I can get into -- I have a listing of
18 the measures, but I don't seem to be able to
19 access the actual material.

20 MS. JOHNSON: All right, okay. You
21 should click on the blue link, so on the title,
22 and then click. Again those plus signs --

1 MEMBER SIMON: Oh, okay.

2 MS. JOHNSON: -- will fool you every
3 time. And the MIF, in case you guys, we have
4 this odd -- We don't have a completely
5 standardized naming structure.

6 MIF at NQF stands for Measure
7 Information Form. That's where your
8 specifications are going to live, and then we
9 have the testing attachment, so usually the
10 testing attachment is named testing attachment in
11 some way or another, but developers will often
12 re-name and put their own naming structure on
13 that and we don't change it back.

14 The other things that are in these
15 folders might be if they were say an appendix
16 that the developer provided for you that might be
17 in there as well.

18 I think we have the PA forms that all
19 of you guys filled out, those are in there.

20 MS. OGUNGBEMI: Just the combined one.

21 MS. JOHNSON: Just the combined one,
22 okay. So there is a combined PA form. You

1 probably named it something fairly similar.

2 MS. OGUNGBEMI: Right here.

3 MS. JOHNSON: Yes, I can't read that
4 from here.

5 MS. OGUNGBEMI: It's named SMP
6 combined SA/PA form and then the measure number.

7 MS. JOHNSON: Okay. So just so you
8 know what the combined PA form is, all of you in
9 the subgroups who did a PA we used the word
10 combine function and combined all the information
11 from the individual PAs that came through.

12 All of your comments are in there.
13 They are in there and it will be noted by
14 Panelist 1, Panelist 2, Panelist 3. So people
15 will know who was on the subgroup but they won't
16 know who made individual comments.

17 There may be a couple other types of
18 things in there. If it's an e-measure then there
19 is probably some HTML code and maybe some value
20 sets, things like that in there.

21 It's pretty much what we were provided
22 in terms of materials for you to look at plus the

1 PA form. Oh, and the other really important
2 thing, the developer responses, so if the
3 developers took advantage of their opportunity to
4 give you additional information that is also in
5 there as well.

6 Okay. Just so you know what's going
7 on in this cycle, so we had a total of 55
8 measures submitted this cycle. That is really
9 low for us this cycle.

10 So we're not exactly sure why we had
11 relatively few measures, but it probably worked
12 out, especially for your newbies, you didn't have
13 quite so many measures to have to deal with this
14 cycle.

15 So you guys looked at 22 of those 55,
16 of those ten were new, the remainder were
17 maintenance measures being considered for
18 continued endorsements.

19 Okay. In terms of the types of
20 measures, ten health outcomes, three composites,
21 six intermediate clinical outcomes, and three
22 PRO-PMs.

1 And then our initial results, which is
2 always interesting to look at, and it will be
3 interesting to see where we land after today and
4 after tomorrow, 13 passed both reliability and
5 validity.

6 Three of them did not pass either
7 reliability or validity. So remember that in
8 order to be endorsed measures have to pass both
9 reliability and validity.

10 So three of them there was a no pass
11 and then six there was some consensus not reached
12 on one or the other, reliability or validity. So
13 today we will be looking at 15 of those 22
14 measures.

15 So the ones that we are automatically
16 looking at are the CNRs, the ones where consensus
17 was not reached, automatically looking at those.
18 We said that we would look at the ones that did
19 not pass if the developers provided additional
20 information and the developers for all three of
21 the measures that there was a not pass on there
22 they did provide additional information, so those

1 are on there as well.

2 And then, finally, measures where one
3 of our panelists and/or staff pulled for
4 discussion that also made our agenda. So, again,
5 15 of the 22 we'll be talking about today and
6 tomorrow morning. Sherrie?

7 MEMBER KAPLAN: Can you define for all
8 of us the definition of consensus not reached
9 just one more time?

10 MS. JOHNSON: Yes.

11 MEMBER KAPLAN: Because some of it
12 looked like it was a little bit difficult to
13 understand.

14 MS. JOHNSON: It is a little difficult
15 to understand. So you have for both reliability
16 and validity you have the options of voting high,
17 moderate, low, or insufficient.

18 So a high and a moderate rating
19 together are passed, so in order to pass that
20 criterion we have to have more, and I am looking
21 at Ashlie and you tend to keep me honest, we have
22 to have more than 60 percent with a high or

1 moderate gives us a pass.

2 MS. WILBON: I want to make sure that
3 I have that right, too, because I get --

4 MS. JOHNSON: Okay. So more than --
5 (Simultaneous speaking.)

6 MS. WILBON: There it is.

7 MS. JOHNSON: Yes, that's a quorum.
8 Yes, there, oh, great. You got it on here, all
9 right. If it's between 40 and 60 percent that is
10 CNR and that is inclusive, all right.

11 So if luck of the draw has it at 60
12 percent then it's CNR, it's not a pass, all
13 right. The 60.111 would be pass. The less than
14 is less than the 40 percent of the, in that
15 bottom of either a high or a moderate.

16 We also have quorum. That means that
17 we have to have enough people putting in a vote
18 and that changes depending on the number of
19 people in the subgroups who actually did what we
20 would call the deep dive on the evaluation, okay.

21 MEMBER KAPLAN: One more clarifying
22 question.

1 MS. JOHNSON: Uh-huh.

2 MEMBER KAPLAN: So in a six person
3 issue three is half --

4 MS. JOHNSON: Yes.

5 MEMBER KAPLAN: -- but four puts -- So
6 one person can change the definition of --

7 MS. JOHNSON: One person, yes.

8 MEMBER KAPLAN: Okay.

9 MS. JOHNSON: Yes. And it's a little
10 tricky and that's actually -- We'll talk about
11 that a little bit when we talk about how we're
12 voting and stuff, right.

13 It's a little tricky, but that's where
14 we are right now in our process. Patrick?

15 MEMBER ROMANO: Sorry to ask newbie
16 questions, but --

17 MS. JOHNSON: That's fine.

18 MEMBER ROMANO: -- so the 33 measures
19 that were submitted that didn't come here is that
20 because they were process measures or for other
21 reasons weren't considered complex measures?

22 MS. JOHNSON: Yes.

1 MEMBER ROMANO: And then linked to
2 that, do we ever re-assess how the developers
3 have classified their measure? For example, one
4 of the measures that I think was submitted here
5 that passed is a transfusion ratio measure that I
6 would have considered to be a process measure but
7 it was classified as an outcome measure by the
8 developer.

9 MS. JOHNSON: Yes. That one is, the
10 renal ones especially, what we do is we look at
11 them as staff and sometimes we will actually have
12 the developers change, sometimes we have a long
13 discussion back and forth about whether we think
14 they should change or not.

15 Those particular measures I think when
16 they first came through I think we decided that
17 they would okay as intermediate clinical
18 outcomes, that's kind of where we thought they
19 landed, and maybe they did land on an outcome
20 outcome.

21 Some of things are really tricky and
22 sometimes it doesn't matter in terms of our

1 criteria. If it doesn't matter then we will let
2 the developer kind of pick which ones they
3 prefer.

4 So there is some that are very
5 obviously outcomes and very obviously process.
6 Some of them are kind of straddling that line and
7 we try to compromise and figure out the best way
8 forward for those.

9 Okay. Can we go back to slide -- Any
10 other questions? Then let's go to slide -- Oh,
11 yes, John?

12 MEMBER BOTT: Yes, it was noted
13 earlier that developers were given an opportunity
14 to provide additional information and I see in
15 the discussion guide at some points they did, but
16 for some measures they did not.

17 Does that mean -- Well, the question
18 is do they have the opportunity to come here
19 today? If they did not present additional
20 information up until now did they have the
21 opportunity to come here today for the first time
22 and present additional information?

1 MS. JOHNSON: We have said that the
2 answer to that one is no because we wanted to --
3 I mean they could provide something a little
4 different, maybe if you had a new question today
5 that, you know, you didn't have before they could
6 certainly do that if they are in the room or on
7 the phone. They could do that.

8 Pretty much the only folks who do not
9 provide extra stuff were a few that passed on
10 both reliability and validity, so they didn't see
11 the need to add additional stuff.

12 And, as a matter of fact, if those
13 measures passed and were not pulled by us or by
14 you guys then they are not the agenda so we're
15 not even going to talk about them in these two
16 days.

17 So we want to be able to allow them to
18 give us more information, but we also want to
19 have you guys to have at least a little time to
20 think about and look at that information, so, no.

21 MEMBER BOTT: Okay. Great, thanks.

22 MS. JOHNSON: Any other questions?

1 (No audible response.)

2 MS. JOHNSON: Okay. So what's our
3 process for today? It is a little bit different
4 than what we have done on the phone, but not
5 completely differently.

6 First of all, we will have staff
7 introduce the measure. So we'll try not to be
8 very long-winded with this, describe what the
9 measure is and then we'll hand it over to the
10 lead discussant to summarize key concerns, okay.

11 So there may be a lot of concerns on
12 measures that there is usually a few that are the
13 key ones, so that's the one that we'd like you to
14 focus on and then we will ask other members of
15 the subgroup to comment if you have other things
16 that you want to add, so if you feel like there
17 was something that you thought was really a key
18 that your fellow subgroup member did not address.

19 Then we want to actually let the
20 developers have two to three minutes to give you
21 kind of synopsis of their response, so an initial
22 response.

1 Then we want to open up the discussion
2 to everybody on the full panel. So this is even
3 if you were not a subgroup member for a
4 particular measure you can still ask questions,
5 you can still give your opinion about a
6 methodology or whatever, whatever you want to do,
7 the discussion is open.

8 A couple of notes here, a few people
9 are recused. So that should be on your, we have
10 an annotated agenda that should be listing all
11 the people who are recused.

12 That means that not only can you not
13 vote on a measure we also ask you not to discuss
14 that measure. So you pretty much have to just
15 kind of be a spectator on those if you are
16 recused for a particular measure.

17 Now the developers, again, some of
18 them may be in the room, some on the phone, they
19 can certainly respond to any questions for
20 panelists in this discussion.

21 So you would just say, you know, and,
22 you know, developer, answer this question, and

1 let them know what you are curious about. And
2 then we will have voting. Now this is -- I hope
3 it's not completely confusing, we're going to try
4 this.

5 We are going to ask the subgroup
6 members, and these are the people who did the
7 deep dive on these measures, to cast the final
8 vote, okay.

9 Now that will be the vote in this room
10 and, Yetunde, just make sure we are not going to
11 not show the final count until everything is
12 done, okay.

13 Those of you who did not, who were not
14 part of the subgroup we're also going to ask you
15 to vote, okay, but it's a shadow vote, all right.
16 And I think I have -- I'll get to that in a
17 minute. I have a slide that talks about that in
18 a little more detail of what I am looking for,
19 okay.

20 So we have some meeting materials for
21 you. You should see on your, placed in front of
22 you the annotated agenda and that tells you, we

1 don't necessarily expect you guys to remember
2 what subgroup you were and all that kind of
3 stuff, right, so it tells you which groups, who
4 was in which subgroups, who the lead discussants
5 are, and those of you who are recused, all right.

6 So that is all on the annotated
7 agenda. It is printed out for you and we emailed
8 that you I think on Thursday, I think. We also
9 have the discussion guide.

10 So the discussion guide includes what
11 we think is the pertinent information from the
12 submissions. It's certainly not everything,
13 right, because it's a two or three page summary,
14 but the goal is to hopefully minimize the need
15 for back and forth with the actual materials that
16 were submitted.

17 Now that said, we can pull up the
18 measure submission information for any measure,
19 so if we need to do that we will. The measures
20 are included in the same order as the agenda, so
21 on the discussion guide everything is in the same
22 order that's the way we will be going through

1 today.

2 We split it up first by subgroup, so
3 Subgroup 1 we'll have your measures first, and
4 then we'll go to Subgroup 2, and then within the
5 Subgroup 1 measures we did it by rating.

6 So first we are going to discuss the
7 ones that were CNR, or consensus not reached, and
8 then we'll discuss the ones that did not pass and
9 then we'll discuss the ones that were passed but
10 not pulled, passed but pulled, and then I have
11 passed but not pulled.

12 We're not going to discuss those, but
13 those are actually on your discussion guide
14 anyway. We wanted you to have the full
15 information, okay.

16 Now Appendix B in the discussion guide
17 actually includes all the additional information
18 that was provided by the developers. So it's
19 there in the appendix and it should also be
20 linked to the appendix.

21 If you are looking at it
22 electronically you should be able to just click

1 and go to the like section in appendix to look at
2 the additional information that was provided.

3 MS. WILBON: There is also a bookmark
4 in the PDF. If you open the bookmark tab you'll
5 be able to see the outline so you can kind of
6 click around and see that as well.

7 MS. JOHNSON: Okay, so the voting
8 process. So we talked about this I think in one
9 of our discussions as a group, and it might have
10 been, it think it was probably before the new
11 folks came aboard.

12 We talked about who should be voting.
13 We're going to have everybody in the room. Do we
14 allow everybody to vote even if everybody didn't
15 do the deep dives or should we keep the votes
16 just to the people who did the deep dives?

17 And there is pros and cons of doing
18 each, right. So it would be great and it would
19 be I think a stronger vote if we could allow
20 everybody to hear, view, think, discuss, and then
21 vote, and then we would have and end of 28 or
22 something along those lines voting.

1 But we also know that people may feel
2 that that's really unfair and that if you didn't
3 spend quite a bit of time looking at the details
4 of the measure it might not be fair for you to be
5 able to cast a vote, okay.

6 So we tried to split it down the
7 middle, okay. So we will have the official votes
8 be like they were in the last two cycles, they
9 are the subgroup votes.

10 So if there were six of you in a
11 subgroup then our denominator for the voting will
12 be six, okay. And it's also only the members of
13 the subgroup who provided a PA who are eligible
14 to vote.

15 So in a couple subgroups there were a
16 couple of people who either couldn't do all of
17 them measures or something like that, so the ones
18 that you did the deep dive on and submitted the
19 PA for you are eligible to vote in your subgroup.

20 And, again, those are the results that
21 will be the official vote of the SMP. Now that
22 said, we also want to know how -- We might not be

1 able to figure out how fair it is, but we wanted
2 to get some information about a shadow, how
3 others would have voted even if you didn't do
4 that deep dive, okay, that's what I am looking
5 for.

6 So we are asking you to vote via
7 SurveyMonkey and we sent out --

8 MS. WILBON: I will send it right now.

9 MS. JOHNSON: Okay. She is sending
10 out that link right now. So your email should
11 get you that link to the SurveyMonkey and I'll
12 tell you what the questions are on there in just
13 a minute.

14 So if you did not provide a
15 preliminary analysis for a measure then we would
16 ask you to vote via SurveyMonkey, okay, and don't
17 worry about it, you can look at the annotated
18 agenda and you should be able to see which one
19 you should or shouldn't be voting for, okay, or
20 on.

21 Now the results from that shadow vote
22 is going to help us determine if we should change

1 our voting structure in the future, okay. So
2 some of the questions that we have on here, I'll
3 just read them out, we want to know your name.

4 You have to pick which measure we are
5 on, okay, you pick that out, and then we ask you
6 this question, were you able to look at any of
7 the materials for this measure.

8 So your choices are I did a thorough
9 review of all measure materials, the discussion
10 guide, the forms, the specs, all that kind of
11 stuff, and anything additional, I did a thorough
12 review of it.

13 And, again, we didn't expect you
14 necessarily to do that, that would have been only
15 if you wanted to do that beyond your subgroup.
16 Your next option is I reviewed the information in
17 the discussion guide only.

18 Your third option is I did a cursory
19 review of some or all of the materials and then
20 your fourth option is, no, I did not review this
21 measure at all, okay.

22 And then once you tell us that we ask

1 you what your vote for reliability would be and
2 your options are high, moderate, low, or
3 insufficient, or N/A, this criteria was not
4 reconsidered during the meeting, or I am not
5 comfortable submitting a vote at this time.

6 Okay, so what we are trying to
7 understand from you is how much extra work you
8 guys did on these measures and given that amount
9 of extra work how comfortable do you feel that
10 you could make a fair rating after you have seen
11 or read or heard whatever you seen or read or
12 heard. That's the idea, okay.

13 So we'll see how this works. I have
14 no idea, it will be really interesting to find
15 out if overall the votes kind of track with what
16 the subgroups end up doing or if they are very
17 different, okay.

18 And Sherrie and Ron are looking at me
19 and kind of smiling. I don't know if that means
20 you don't want to know or it will be really
21 interesting to find out or --

22 MEMBER KAPLAN: No, I was just

1 thinking that it would be better to have
2 everybody vote and then understand what color
3 their vote is, like -- something like that.

4 Because if you don't make people vote
5 the probabilities that they will vote are
6 probably limited and you're going to get sample
7 sizes all over the place.

8 MS. JOHNSON: Yes.

9 MEMBER KAPLAN: Because if it was me
10 I would consider --

11 MS. JOHNSON: You would have all --
12 (Simultaneous speaking.)

13 MEMBER KAPLAN: -- do at the NIH, you
14 know, and then see what happens with that vote
15 and see how much it would have moved somebody
16 around depending on their level of comfort votes.

17 MS. JOHNSON: We did think about that
18 a little bit. We actually have a comment box for
19 you to add to in your SurveyMonkey so you can
20 tell us maybe a little bit more you like doing
21 that and -- Oh, I'm sorry, Terri, yes?

22 MEMBER WARHOLAK: I have a new person

1 question.

2 MS. JOHNSON: Mm-hmm.

3 MEMBER WARHOLAK: So there are two
4 different voting platforms that I need to log
5 into?

6 MS. JOHNSON: Yes.

7 MEMBER WARHOLAK: There is poll
8 everywhere and that's if I am on the panel and
9 then there is the SurveyMonkey if I am not, is
10 that correct?

11 MS. JOHNSON: Yes. So you will be
12 using both of them in the next day and a half.

13 MEMBER WARHOLAK: Okay.

14 MS. JOHNSON: Yes, and you'll be using
15 mostly SurveyMonkey, right, as most of the
16 measures you didn't do a deep dive on, unless you
17 did a lot more homework than we assigned you.

18 MEMBER WARHOLAK: Okay. Thank you

19 MS. JOHNSON: Yes. Yes, and, Sherrie,
20 we'll see how it works. It may turn out that we
21 change it up next cycle, that we knew that --
22 Yes?

1 MEMBER WALTERS: I was just thinking
2 that if it's me I'm lazy and I wouldn't like --
3 and it's easier for them to vote, I would do that
4 rather than commit myself to making a vote and
5 then trying to explain my --

6 MS. JOHNSON: Yes. Yes. We'll see
7 how it works this time and we may actually do
8 something very different next time. Yes?

9 MEMBER BOTT: I was just commenting
10 you might want to study the reliability and
11 validity of that process --

12 (Laughter.)

13 MEMBER BOTT: -- because I have my
14 guesses as to what those are.

15 MS. JOHNSON: Yes. Yes. Yes. No, it
16 will be interesting, we actually didn't know -- I
17 will tell you what my gut feeling is, my gut
18 feeling is that when hearing and looking at the
19 discussion guide and hearing the discussion I
20 feel like probably most of you will feel like you
21 have enough information that it will be okay and
22 fair and not unfair to cast that vote, but we

1 didn't want to make that decision for you.

2 We wanted to see if that was really
3 true and then given that we wanted to see if
4 there is any like systematic variation between
5 those who did do the deep dive and those who
6 didn't do it.

7 MEMBER BOTT: Yes. Apologies if
8 somebody just said this, but I think you'd get
9 more of an honest response for those of us who
10 don't have to vote, or we weren't reviewing that
11 measure if we did not have to type in our name,
12 because I'm embarrassed of how few measures I
13 reviewed --

14 (Laughter.)

15 MEMBER BOTT: But why ask for our
16 name, what's it matter? You know, if 20-x of us
17 did not review the measure who cares what person
18 --

19 (Simultaneous speaking.)

20 FEMALE VOICE: That's true.

21 MS. JOHNSON: It's just -- We wouldn't
22 have done anything -- Is that a have to --

1 (Simultaneous speaking.)

2 MS. WILBON: You don't have to --
3 Actually none of the fields are required. I mean
4 we would like you to --

5 MS. JOHNSON: Yes.

6 (Simultaneous speaking.)

7 MS. WILBON: -- skip the name.

8 MEMBER BOTT: Santa Claus.

9 MS. JOHNSON: Skip it and do what Mitt
10 Romney did and --

11 (Laughter.)

12 MEMBER BOTT: I just wanted you to get
13 the best information --

14 (Simultaneous speaking.)

15 MS. JOHNSON: Yes. We don't need to
16 know your name. We don't -- Yes, that's just
17 kind of a typical thing we put in our surveys,
18 so, yes we don't need to know your name. Just
19 don't even do that, unless you don't care and you
20 want to tell us that's fine, too.

21 (Off microphone comment.)

22 MS. JOHNSON: Is there anybody online,

1 on the phone who wanted to say something?

2 (No audible response.)

3 CO-CHAIR NERENZ: Maybe just one
4 other, kind of in response to John, I haven't
5 been on an NIH study section for awhile, but it
6 was certainly understood at that time that not
7 everybody on the study section read every grant,
8 every page, every paper in full detail but we
9 still voted and there was no shame in voting
10 without having knowledge of the materials.

11 I might extend that to here, but we've
12 been given a discussion guide, but also behind
13 the discussion guide all kinds of materials. I
14 would just declare, at least coming from me, I
15 attach no shame to anybody who did not read all
16 of the full detail materials for all of the
17 measures in front of us.

18 That's part of the function of having
19 a subgroup. So I am thinking that when it comes
20 time for us to vote about things for which we are
21 not part of the subgroup if all we saw was the
22 discussion guide or if we just skimmed it or

1 maybe just right now we're looking through some
2 of the materials, don't worry about anybody
3 thinking you haven't done your job because there
4 are a lot of materials here and that's why we
5 have the subgroups.

6 MS. JOHNSON: I would want to be very
7 careful of not to make you feel like we expected
8 you to do the deep dives on all of them, because
9 we do not, okay. We do not. If you want to
10 that's great, but you don't have to and we don't
11 expect you to.

12 And somebody on the line if you
13 wouldn't mind muting your phone, we can hear some
14 background noise. Thank you.

15 Any questions about that? I think it
16 might be a little bit confusing at first, but I
17 really think we were just a little nervous going
18 straight to having everybody vote and using that
19 one without having this kind of interim process
20 to see how we think it's going to work.

21 MS. WILBON: And before we vote each
22 time we'll queue you, we'll queue the group of

1 people who will be voting on which tool so you'll
2 know, yes.

3 And even if you vote in the wrong
4 place we'll figure it out and we'll work through
5 it, so no worries. We'll guide you through the
6 process.

7 MS. JOHNSON: We're also trying to be
8 really careful and usually what we do when we do
9 voting is you can kind of see the numbers kind
10 of, as votes come in you can kind of see how the
11 numbers are stacking up.

12 We have asked you today to hide that
13 so that the people in the room are not going to
14 influence the people who are doing the shadow
15 voting, at least we hope that that's the case,
16 right. So we think we can make that happen.
17 Sherrie?

18 MEMBER KAPLAN: I just -- I won't
19 interrupt you again --

20 MS. JOHNSON: That's okay.

21 MEMBER KAPLAN: -- but I just have one
22 more question about the voting, the basis for

1 voting, because when we had these discussions
2 before we sometimes raise issues that NQF has not
3 yet presented to measures developers in terms of
4 advancing measurement science and so on.

5 And so I want to make sure that in
6 fairness to all the measurement developers that
7 we are basing it on the criteria they responded
8 to from NQF --

9 MS. JOHNSON: Yes.

10 MEMBER KAPLAN: -- and not what we are
11 kind of starting to raise about maybe elevating
12 the --

13 (Simultaneous speaking.)

14 MS. JOHNSON: Yes. So we will try.
15 There is a couple things, one is I have a few
16 slides just to remind people of some of the basic
17 things, and then as we go through we will
18 endeavor to make sure that we make it very clear.

19 So, for example, we've had discussions
20 and I think many of you would love to see score
21 level reliability testing across the board for
22 all measures, right.

1 That is not a requirement at this
2 point so we can't ding people for not having it
3 unless their measure type says they have to have
4 it.

5 And I'll get to another slide, but
6 another one is showing a distribution of signal
7 to noise reliability estimates, that is guidance,
8 so it's guidance that you guys provided very,
9 very recently.

10 It's too early to have expected
11 developers to be able to bring that and so we
12 can't hold them to that. So we will be very, we
13 will be paying attention, all of us, on the
14 inference and trying to make sure that we don't
15 let any of that go through.

16 If you have a question please answer
17 because we do want to be very fair. We don't
18 want to hold people to something that is not one
19 of our requirements. And, Jack?

20 MEMBER NEEDLEMAN: Yes. I had a
21 slightly different perspective than Sherrie on
22 this.

1 I agree with you, you can't hold
2 people for documentation that was not required,
3 but the standards have been evolving and the
4 standards that might have led to approval in the
5 past are not necessarily the standards that will
6 lead to approval right now.

7 And absence of convincing
8 documentation that something has been met has
9 led, at least some of us, to describe measures as
10 less than reliable or less than valid and that
11 discussion I suspect is going to continue during
12 the day.

13 MS. JOHNSON: I agree. And I will
14 also say that, you know, you guys know things to
15 look for and it may be in the past others didn't
16 know to look for, all right.

17 So just by definition of having this
18 panel we are going to be looking a little more
19 rigorously. All right, there we go. Just a
20 reminder about our ratings, if you want to give a
21 measure a high rating remember that score level
22 testing is required, okay.

1 Otherwise, and it would be a moderate
2 rating would be the highest, a measure may be
3 eligible for a high but the sampling method, the
4 results, something like that may make you choose
5 a moderate.

6 So we do have those algorithms that
7 the algorithms tell you the highest possible
8 rating. It doesn't mean that if it falls its way
9 through on a certain place in the algorithm then
10 it has to have that rating, okay.

11 So for a moderate it's the highest
12 rating, it's the highest rating eligible. If
13 only data element is tested, is provided, or if
14 face validity testing is conducted.

15 So if all you have in front of you is
16 face validity then you should never be giving a
17 high rating, okay. And the same thing, it could
18 be eligible for moderate but because the sampling
19 or the methodology or the actual results you may
20 choose low instead. You don't have to choose
21 moderate.

22 Low is used primarily if the testing

1 results are not satisfactory. So if we assumed
2 that the methodology is correct and that the data
3 and the testing sample is reasonable but the
4 numbers just don't satisfy you so that would be
5 low.

6 And that's different for insufficient.
7 So you would use insufficient when you really
8 just don't feel like you have enough information
9 to assign one or the other leads, just something
10 is just not clear enough that you feel
11 comfortable assigning a lead.

12 Okay. Just a reminder, none of this
13 is new to you guys. Testing requirements do vary
14 by type of measure. So for health outcomes,
15 intermediate clinical outcomes, cost and resource
16 use structure process all of them are, we have
17 different requirements.

18 For both reliability and validity NQF
19 requires either data element testing or score
20 level testing, okay. So that's, there is final
21 outcomes, intermediate outcomes, cost resource
22 use structure process, so it could be either or.

1 We would prefer both but we don't
2 require both, okay. So you can't take them down
3 if they don't have both. It impacts the ratings,
4 as we have already described, and the exception
5 is the face validity for new measures we do
6 accept it.

7 So on your discussion guide we tell
8 you right under the name of the measure we tell
9 you if it's a new measure or a maintenance
10 measure.

11 If it's a new measure and they are
12 providing face validity that's okay, okay, unless
13 it is one of these other kinds of measures. So
14 this is where it gets a little tricky.

15 The next one is probably something
16 that you guys don't like very much and maybe
17 something that we might want to change at some
18 point.

19 If data element validity testing is
20 provided we do not at this point require
21 additional reliability testing, okay. So then
22 what do you do?

1 Well you figure out what you would
2 have did as the rating for validity, the validity
3 testing, you look at that and apply that to
4 reliability.

5 Now we still do see this, it happens
6 on occasion. It's not nearly as common as it
7 used to be, okay, so it's self-correcting a
8 little bit, but that's just something that we've
9 had for a long time.

10 Again, it might be something that in
11 the future we will change, but right now that's
12 one of our kind of rules.

13 CO-CHAIR NERENZ: What does the word
14 additional mean? Does that mean, for example,
15 you don't need measure score of reliability?

16 MS. JOHNSON: Right.

17 CO-CHAIR NERENZ: Does it mean you
18 don't need any reliability?

19 MS. JOHNSON: You don't need any. So
20 if you have shown the validity of the data
21 elements then we don't make you do anything else
22 as long as it's one of these kinds of measures.

1 Larry?

2 MEMBER GLANCE: Just a quick comment.

3 So I think all of us understand the structure
4 that you are presenting. I think that some of
5 this probably a lot of us are uncomfortable with
6 saying that a measure is scientifically
7 acceptable if the only thing people have looked
8 at is data quality, meaning data reliability and
9 data validity.

10 Luckily, I think most measure
11 developers provide us with information on score
12 level validity and score level reliability, but I
13 think in the rare instances where the only thing
14 we hear about is data quality, you know, even
15 though it's sort of like we're changing things on
16 the fly a little bit I think it would be very
17 difficult for me to say, yes, you know, you've
18 told us about data reliability, you've told us
19 about data validity, this is the only thing that
20 NQF asked you for and we're okay saying that this
21 is scientifically acceptable.

22 And I also know that having spent

1 several years on the standing committee for re-
2 admission measures I think people sort of
3 understood this structure, but at the end of the
4 day if it was a risk-adjusted outcome measure and
5 the risk adjustment model was no good, so there
6 was a problem with score level validity, we just
7 voted it down regardless of what this algorithm
8 said.

9 I think it's important to think about
10 that when we are looking at the measures today
11 because honestly I think in this day and age if
12 the only thing we have on a measure is data
13 quality information I don't think we can really
14 pass it as being scientifically acceptable
15 regardless of what this algorithm says.

16 That's my opinion and I think
17 practically speaking I think that may be what a
18 lot of us employed when we were looking at these
19 measures.

20 MS. JOHNSON: I think what -- So a
21 couple things on that. First of all, we would
22 like you to apply the criteria and just vote

1 whether you think it meets our requirements.

2 So I know that it's going to make some
3 of you uncomfortable in certain situations, but
4 don't hold them higher than our requirements,
5 okay.

6 Now that said, most of the time,
7 almost every time, the measures that come to you
8 guys, the conflicts measures, almost always have
9 these other things so you're not going to get
10 into this kind of uncomfortable situation really
11 often.

12 That's not necessarily true for the
13 process measures and/or structure measures that
14 you guys aren't seeing, okay. Now we can and I
15 expect that we will be putting forward in March
16 to our CSAC, who oversees our criteria, we will
17 probably be putting forward some of your
18 suggestions, such as this, should we raise the
19 bar of what we're asking and at that time we will
20 kind of talk about the pros and cons, the ins and
21 outs, and see what the CSAC allows us to do.

22 So, yes, I think you might be in a bit

1 of an uncomfortable situation on a few of your
2 measures and, again, we really need consistency
3 to the extent that we can get it, so please try
4 to use our criteria as the basis of your votes.

5 CO-CHAIR NERENZ: And just again as we
6 get into this now, because I know it's about
7 time, as each measure comes up why don't you just
8 remind us, staff or somebody, what are our
9 requirements for this measure and what must it
10 have and then we can just keep that in mind as we
11 go through.

12 MS. JOHNSON: Yes, we can do that.
13 All right, there we go. Composite measures, we
14 have a couple different kinds of composites, kind
15 of the traditional ones where you have data
16 aggregated at the measure entity and then --
17 Sorry, I didn't say that right. Data that are,
18 the components are aggregated at the measure
19 entity and then aggregated again as a composite.

20 We also have all or none measures. So
21 those are what we mean by composite measures and
22 those actually have an additional criterion that

1 we'd have to look at and that also is must pass.

2 But that does not, we do not count the
3 measures that are based on multi-item scales. So
4 even though the word composite is used in that
5 scenario that's not how we are using it at NQF,
6 okay, so we will do what Dave has reminded us and
7 remind you again of our composite definition.

8 Slow level validity testing is not
9 required for composite measures until they become
10 a maintenance measure in which case we do expect
11 it, okay, and I already talked about the
12 additional --

13 And instrument-based measures, which
14 we don't have as many this cycle as we did last
15 cycle. Last cycle we had tons of them. This
16 time we don't, but this is one where we actually
17 are expecting both levels of analysis and we've
18 had this discussion many times what do we mean by
19 data element, we just really want to know that
20 the relevant items in the instrument are reliable
21 and valid.

22 And I know, Sherrie, we haven't

1 probably quite got that perfectly yet, but that's
2 the idea, but then we also want to go beyond just
3 how good is the instrument, we want to know how
4 good in terms of reliability and validity the
5 actual performance measure is.

6 And then another reminder, and this
7 sometimes can throw people off, we allow people
8 to put multiple performance measures under the
9 same NQF number, okay.

10 So what that means is we might be
11 discussing Measure 1234 but if it is an
12 instrument-based measure there may be ten
13 individual PRO-PMs or other kinds of PMs
14 underneath that number.

15 All of those you have to think about
16 those separately. You could end up, if you need
17 to you could provide separate scores or separate
18 ratings for those if you feel like we need to,
19 and some of them could actually pass and others
20 not pass, okay.

21 So it's more of a convenience that we
22 have allowed people to put them under the same

1 number, but we do consider them separate
2 measures.

3 All right, eQMs, eMeasures, testing
4 for a more and more EHR system is required. This
5 is I think the only definite that we have in
6 terms of testing.

7 Testing is reliability testing that is
8 not required if based on data from structured
9 data fields, but if based on unstructured data
10 fields then we would require both reliability and
11 validity testing.

12 And as of the summer of this year we
13 actually now require data element validation for
14 eQMs, and that is new.

15 Okay, a few more reminders. We are
16 almost done. Testing must align with
17 specifications. So this is not something new but
18 it is something that we have been more rigorous
19 in upholding and we are particularly interested
20 in level of analysis and minimum sample sizes.

21 So what we are saying here is if a
22 measure developer says that this is specified for

1 two levels of analysis we expect separate testing
2 for both of those levels of analysis, okay.

3 And similar for the minimum sample
4 sizes, if there is no minimum like threshold each
5 provider has to have at least say 25 patients or
6 something like that, if that's not specified then
7 we expect the testing not to have limited to just
8 25 or more, something along those lines. We want
9 those to align.

10 I have already talked about the
11 performance measures and how there could be more
12 than one under one NQF number. It's very obvious
13 when you are talking about PRO-PMs all based on
14 one instrument, but it can happen with other
15 kinds of measures as well.

16 Okay. For risk-adjusted measures just
17 remember that inclusion or not of certain risk
18 factors cannot be a reason for rejecting a
19 measure, so you should certainly talk about any
20 concerns that you have, but, you know, whether or
21 not one particular factor or set of factors is or
22 isn't included can't beat out why you would take

1 a measure completely down.

2 That said, the information about
3 discrimination calibration or overall methodology
4 of risk adjustment can be grounds for taking a
5 measure down or not passing a measure.

6 For all measures we want to make sure
7 that we understand the specifications. And,
8 finally, empirical testing is required at the, or
9 is expected at the time of maintenance
10 evaluation.

11 And, again, I've already mentioned
12 this, this is the face validity thing. If face
13 validity is still being used then there should be
14 a justification for that.

15 And, Patrick, do you have a question?

16 MEMBER ROMANO: Yes. On the last
17 slide, could you just go back? I just wanted to
18 clarify this last bullet.

19 So, of course, there are many examples
20 of this last point that I just wanted to make
21 sure I have the right understanding, which is
22 that NQF is focusing on measures that are used or

1 usable for both quality improvement and
2 accountability applications and, therefore, it's
3 often the case that, for example, a composite
4 might have a set of component measures and those
5 components might be used internally.

6 They might be reported as part of a
7 dashboard from a registry sponsor for example,
8 but if there is one measure that is the composite
9 that is actually going forward as the
10 accountability measure that's what we are voting
11 on, is that right?

12 MS. JOHNSON: Yes.

13 (Simultaneous speaking.)

14 MEMBER ROMANO: So we are not passing
15 each of the component measures separately?

16 MS. JOHNSON: No. Not in the
17 composite measures, no. Now occasionally --

18 MEMBER ROMANO: But even in cases
19 where there might be -- I think we had a case
20 here where there is a bunch of measures that are
21 being proposed essentially for internal purposes
22 as different ways of looking at the same problem

1 but there is one measure that is the
2 accountability measure. So shouldn't we focus on
3 that measure?

4 MS. JOHNSON: Yes. So the developers
5 will be telling you occasionally there will be a
6 composite measure or something along those lines
7 and they may say we're only putting forward the
8 composite for a potential endorsement, so that's
9 what you should be paying attention to with our
10 criteria.

11 Now sometimes when you are evaluating
12 composite you do have to think about the
13 individual components and pieces of those, right,
14 but maybe you are not, especially for reliability
15 you might not be as interested in the components.

16 Sometimes even with composites they
17 will say I'm actually interested in having
18 individual things looked at for endorsement and
19 the composite, so they should be telling you and
20 they should be very clear are we looking at three
21 performance measures, are we looking at one, are
22 we looking at ten, are we looking at one.

1 MEMBER ROMANO: And would staff then
2 force them to split those into separate number or
3 not necessarily?

4 MS. JOHNSON: Not necessarily.

5 CO-CHAIR NERENZ: Actually one thing
6 that might help clarify, you know, a composite is
7 one thing. You basically take a set of measures
8 and you mathematically combine them and you get a
9 composite measure and then that is up for
10 endorsement.

11 The CAHPS survey is an example in any
12 of the setting it's used. It is one survey and
13 it gives one number at NQF but from it are
14 derived several measures.

15 They are not composites in the
16 definition we are using here. They are separate
17 measures. I don't think we have any in front of
18 us today, but in the prior cycle those of us in
19 the subgroup who might have a hospital CAHPS
20 survey that generates six measures and we have to
21 evaluate all six of them but they have one
22 number, but that's not a composite.

1 CO-CHAIR CELLA: Matt and then
2 Sherrie.

3 MEMBER AUSTIN: Yes, I mean it's sort
4 on this note of having multiple measures under
5 one number. There has been a couple of measures
6 through the rounds where it feels like I am being
7 asked to evaluate different measures under the
8 same form.

9 Can I just maybe get some
10 clarification on why NQF chooses not to split
11 those out into separate measures? It just feels
12 slightly confusing trying to assess sort of
13 multiple measures that are under one number.

14 MS. JOHNSON: Yes. Yes, and in that
15 case I think it is a little bit unfair that the
16 onus is a little bit on you that if you feel like
17 certain pieces need a certain rating you have to
18 tell us that, you know, because we don't give you
19 that, kind of we don't split out and give you a
20 special form.

21 It really comes down to us trying to
22 be, I don't know what the right word is, us

1 trying to kind of meet the developers in the
2 middle who don't want to fill out ten forms for
3 each of their, for example, hospital CAHPS
4 measures, actually 11, because so many of the
5 things, not just -- Reliability and validity, the
6 methodology and the sampling, the testing dataset
7 would usually be the same.

8 The numbers, the results will be
9 different, but other things like evidence, the
10 usability, the feasibility, all those kinds of
11 things are the same and they really don't like
12 copying and pasting so we have allowed them to
13 put things on one form.

14 So it's not optimal. It makes our
15 counting off, too, right, because we'll count and
16 we'll say, you know, we have one hospital CAHPS,
17 but we really don't, we have 11 measures that
18 were based on the hospital CAHPS.

19 CO-CHAIR CELLA: Sherrie?

20 MEMBER KAPLAN: I just wanted to
21 clarify because this terminology confusion it
22 still confuses me. An instrument the way it's

1 being considered is a data collection method,
2 right?

3 MS. JOHNSON: Yes.

4 MEMBER KAPLAN: So that it's a survey,
5 for example, in the case of HCAHPS. HCAHPS is if
6 you are measuring the whole construct of overall
7 quality of care it is the whole score.

8 But if you are measuring
9 doctor/patient communication it's meant to be
10 used at the provider level out of that then that
11 is a measure of a construct, doctor/patient
12 communication, in that case it has three items
13 and the precision gets really at issue then.

14 So, you know, if for example it wasn't
15 HCAHPS and it's only the sort of overall concepts
16 of being measured with that data collection
17 instrument, like lumbar pain and other kinds of
18 things that are related, but the whole instrument
19 has multiple different measures on it that aren't
20 necessarily part of an overall construct then it
21 gets confusing.

22 You know, you would not in that case

1 evaluate the instrument. You would not evaluate
2 the whole thing because it's got multiple
3 different and independent parts.

4 MS. JOHNSON: Yes. You just --

5 MEMBER KAPLAN: So NQF will never ask
6 us to evaluate an instrument with things that are
7 unrelated measures that are unrelated on it.

8 MS. JOHNSON: Right. We would only
9 ask you to be thinking about the things that go
10 into that particular measure.

11 So they might have, and as a matter of
12 fact we have an example of that today where it's
13 a measure that has several different domains in
14 there but they are only putting forward one of
15 those domains for endorsement.

16 So we're not asking for all the
17 information about all that other stuff. We're
18 only interested in that one.

19 CO-CHAIR NERENZ: Okay, we got to keep
20 going.

21 MS. JOHNSON: All right. I think that
22 might have been it.

1 (Multiple nos.)

2 (Simultaneous speaking.)

3 MEMBER NEEDLEMAN: If we move to the
4 next slides as Patrick brought us back, I want to
5 talk about, I need some clarification on the risk
6 adjustment statement because we've had a lot of
7 discussion in this committee that the risk
8 adjusters, whether they are doing what we think
9 they are doing and whether they are doing it
10 appropriately.

11 So the statement about inclusion or
12 not inclusion of certain things seems to run
13 counter to the discussion we've had about
14 socioeconomics, say certainly there is a lot of
15 presentation in there.

16 When we have looked at it as
17 individuals collectively we've been wondering
18 whether the variance explained by the risk
19 adjuster is about the right level it would expect
20 given the variance in the thing being studied and
21 the precision of the risk adjuster.

22 We have asked how much the rankings or

1 the scores change as a result of the inclusion of
2 risk adjustment. All those I assume fall into
3 the calibration issue.

4 But there is also an issue of over
5 adjusting and that implicitly, if not explicitly,
6 deals with the issue of there is some things in
7 this risk adjuster that shouldn't be in there and
8 that seems to directly conflict with the guidance
9 you are giving us on don't comment on individual
10 elements of the risk adjustment, so I would like
11 some clarification.

12 MS. JOHNSON: Yes. We want you to be
13 very comfortable commenting on any of that stuff,
14 so please do if you have any concerns about any
15 of that definitely comment.

16 We are just saying we don't want you
17 to rate as low because of that only, okay. So
18 don't take it down because of that, and the
19 reason is that we actually on these things, some
20 of these things are very much clinically, there
21 is content and clinical judgement that is needed
22 for that and while many of you have that we don't

1 necessarily, we're not asking you necessarily to
2 put on your clinical hat for that.

3 We actually want that decision to be
4 a standing committee decision.

5 MEMBER NEEDLEMAN: And since I don't
6 have a clinical hat, although as an economist I
7 practice many professions without a license.

8 (Laughter.)

9 MEMBER NEEDLEMAN: I have in my
10 comments said the standing committees take more
11 of a look at this.

12 MS. JOHNSON: Yes.

13 MEMBER NEEDLEMAN: That's the sort of
14 guidance you want from us?

15 MS. JOHNSON: That's what we want,
16 yes. So we don't want you to not talk about it,
17 we just don't want you to fail. We want them to
18 have the opportunity to hear your concerns and
19 then take it from there.

20 Okay. There is only one more slide
21 and I think I have already gotten to that one.

22 CO-CHAIR NERENZ: All right.

1 MS. JOHNSON: And then, Zhenqiu, I
2 will get you in just a second. We do have a
3 little bit of additional guidelines in terms of
4 asking for more detail about methodology
5 reporting only and one overall statistic for
6 signal to noise reliability, giving a whole lot
7 more information about the construct validation
8 methodology and what you are trying to do.

9 This is all new guidance, we've talked
10 about this. Don't hold our developers in this
11 cycle to these things now, this is still
12 relatively new.

13 It's not that you don't want it, it's
14 just that we don't want to take them down for
15 these at this point, okay.

16 CO-CHAIR NERENZ: Zhenqiu?

17 MEMBER LIN: So to follow on Jack's
18 question, so for example this measure about
19 mortality, and then you view it through in
20 hospital complication as research has been
21 variable and then we wouldn't agree that's a
22 right thing to do, right?

1 If that happened to me that should be
2 grounds for a rejection.

3 MS. WILBON: I'm sorry, Zhenqiu, can
4 you speak up just a little bit --

5 MS. JOHNSON: Yes, I --

6 MS. WILBON: -- I couldn't hear you.

7 MEMBER LIN: So if the measure is a
8 mortality measure and then you include the
9 hospital complication as risk adjustment variable
10 which is a direct result of quality of care, all
11 this is going to be predictable, right.

12 But in that case to me like -- this
13 you include that as risk variable that should be
14 ground for rejection I would imagine.

15 MS. JOHNSON: You know, I see what you
16 are saying and I think technically it should be.
17 I think we would probably ask you not to take it
18 down if that's the only thing, but be very clear
19 that that is a huge concern and just say, you
20 know, that's not part of risk adjustment, you're
21 not supposed to do it that way, and that sort of
22 thing.

1 CO-CHAIR CELLA: So I'll just add, I
2 thought of examples like that also, Zhenqiu, and
3 I kind of took comfort in the sub-bullet that
4 says concerns with discrimination calibration and
5 overall method of adjustment are still grounds
6 for rejecting.

7 So just because -- The way I took it
8 is just because you might think and maybe even
9 feel strongly that a certain variable should be
10 included you have to have a reason that relates
11 to the overall adjustment as a result of it.

12 So I think there is a clause for
13 making the case you just made. Does that make
14 sense?

15 MEMBER LIN: I mean I would defer it
16 to clinician in this room, right, you've got in
17 quality of care and then complication happen
18 during part of a hospital stay, right, do you
19 think that should be included?

20 MS. JOHNSON: Why don't we hold off
21 and if that --

22 CO-CHAIR CELLA: Let's see if it comes

1 up, yes.

2 MS. JOHNSON: -- specifically comes up
3 then we'll just talk about it as part of the
4 discussion of that measure.

5 CO-CHAIR CELLA: And as we try to --
6 And we're all sort of, hopefully Dave and Dave
7 are getting aware that we are moving past our
8 time and we always think there is plenty of time
9 to go through the overview and then we get a late
10 start.

11 So I just want to say, you know, how
12 when you are in a group and you are new to a game
13 and somebody explains the rules and you don't
14 think you really understand the game and they say
15 well just start playing, it will become clear as
16 we go along.

17 I think we need to just start playing
18 the game. The NQF staff is really good at
19 reminding us if we're going off the guidelines.
20 And, also, Ashlie just sent around, because it
21 looks like most of you are on email, just sent
22 around the slides that have a lot of these

1 principles in there.

2 So the slides are available to you to
3 refer to during the discussions and let's start
4 playing.

5 MS. JOHNSON: Let's start.

6 CO-CHAIR CELLA: All right.

7 MS. JOHNSON: All right. Yetunde, you
8 might want to take us, this -- Okay, a voting
9 test. Do you want to walk us through our test?

10 MS. OGUNGBEMI: Yes. Now I do have a
11 question, do you want them to see the voting at
12 all?

13 MS. JOHNSON: We need to see the final
14 score once everybody is done. We have to --

15 MS. OGUNGBEMI: Okay. Where would you
16 like it projected?

17 MS. JOHNSON: What's our choices?

18 MS. OGUNGBEMI: There or there.

19 MS. JOHNSON: There.

20 MS. OGUNGBEMI: Okay. Okay, so during
21 the test vote you can -- Oh, first of all, did
22 everyone receive the email with the voting

1 instructions?

2 MALE VOICE: Well there is two emails
3 with voting instructions, which one?

4 CO-CHAIR NERENZ: Which one?

5 MALE VOICE: 7:50 a.m. or 9:07 a.m.?

6 MS. WILBON: The 7:50 one.

7 MS. OGUNGBEMI: Yes. So the link is
8 wholeev.com/nationalqual661 and we'll go to that
9 voting link. The voting will become active only
10 when I press the activate button.

11 So it will show like a blue or gray
12 screen currently if you aren't logged into that
13 poll. All you have to do is type in your name
14 and the survey will come up.

15 MS. JOHNSON: Okay, and everybody is
16 doing this test, right. This is just to make
17 sure you know how the in-room voting goes.

18 MS. OGUNGBEMI: So the voting is
19 active now. During each vote I will read the
20 question and the options. There will be four
21 options for all of our votes today and they will
22 rank high, moderate, low, or insufficient.

1 Of course for this test it's not
2 required for that. And so this poll here will
3 show responses, as soon as I click this it stops
4 the responses from being shown.

5 So you can see them now and then once
6 we say the vote will close I can show the
7 responses in the room if that's what we would
8 prefer to do.

9 MEMBER NEEDLEMAN: And does only our
10 first vote count our only our last vote?

11 MS. OGUNGBEMI: The last vote.

12 (Pause.)

13 MS. JOHNSON: All right, everybody.
14 okay with this measure?

15 PARTICIPANT: This is the subgroup,
16 right?

17 MS. JOHNSON: This is what you'll be
18 doing if you're part of the sub-groups, okay. If
19 you're not part of the sub-groups, you'll be
20 doing the SurveyMonkey that we're not going to do
21 a test run.

22 All right, Andrew, I think you might

1 be up. So we are going to move to Measure 2456,
2 Medication and Reconciliation, Number of
3 Unintended Medication Discrepancies per Patient.

4 And Andrew is going to lead us
5 through. Again, just a reminder, Andrew will do
6 his thing. We'll hand it off to Jen, on the
7 phone. And then we'll let the subgroup add any
8 concerns they maybe Jen may bring up. And then
9 we'll ask the developer to respond. And then
10 we'll open it up to anybody.

11 MS. WILBON: Can we just announce to
12 you that the subgroup, we're starting Subgroup 1
13 measures. That includes Dave Cella, Sherrie
14 Kaplan, Zhenqiu, Jack Needleman, Jen Perloff,
15 Christie Teigland, Terri Warholak, and Susan, oh,
16 excuse me, Susan is not here. I'm sorry, and
17 Terri Warholak. So just, you guys are on deck.

18 MR. LYZENGA: Okay. I was trying to
19 get this mic to work. I'm a hopelessly quiet
20 talker so I'll try to project.

21 So this is a measure of the quality of
22 the medication reconciliation, an interesting

1 measure unlike many of the med rec measures we
2 often see here. This is not accessing any
3 particular process or documentation or
4 attestation that some processes occurred but,
5 instead, it is looking at the actual number of
6 unintentional discrepancies on the medication
7 list per patient.

8 The measure requires a trained
9 pharmacist to do a review of the medication, a
10 patient's medication list on admission and then
11 at discharge. And then that is compared to what
12 was actually taken during the patient's care and
13 the number of, some additional analysis and
14 reviews done to see whether those discrepancies
15 were intentional or unintentional. The number of
16 unintentional discrepancies per patient is then
17 the basis of the measure.

18 So this is sort of like an
19 intermediate outcome of sorts. It's not sort of
20 a pure process measure. It's not exactly an
21 outcome either. The measure, the developer
22 recommends sampling 25 patients per month or

1 approximately one patient per weekday.

2 In terms of the testing, we had a data
3 element assessment done. There was an inter-
4 rater reliability assessment done where two study
5 pharmacists independently collected the
6 medication histories for 19 randomly selected
7 patients and calculated the percentage of
8 agreement.

9 That was one part of the reliability
10 testing. The sort of raw rate of agreement,
11 there was 77 percent. And that was looking at
12 where there was complete agreement in medication
13 dose, route, and frequency across the two
14 assessments.

15 The developer also assessed the
16 reliability of the discrepancies for its system,
17 so whether, you know, there were, the independent
18 reviewer got the same number of discrepancies as
19 the original review.

20 In that case, they got 91 percent
21 agreement and did calculate a kappa, both for
22 admission discrepancies and discharge

1 discrepancies. The kappa there was 0.64,
2 indicating in the interpretation of the
3 developer's substantial agreement.

4 For validity there was also, well, to
5 put that in straight validity, and in some sense
6 this is sort of a base validity assessment, the
7 developer did note that the literature shows that
8 pharmacists made more accurate medication
9 histories than either nurses or physicians and
10 essentially suggests that the pre-admission and
11 discharge medication history taken by trained
12 pharmacists is itself, in some sense, the gold
13 standard.

14 And they sort of claim that they don't
15 have any real gold standard to which to compare
16 this to and, you know, assert that that is, in
17 some sense, a face validity in itself that this
18 is the gold standard process.

19 They did, in addition, provide a bit,
20 well, they also provide some materials to show
21 how these expert pharmacists are trained and to
22 show that the process is transparent and

1 systematic.

2 They also provided some data showing
3 that, in their study sites, 9 of 17 study sites
4 had significant improvement in their discrepancy
5 rates in the last six months compared to the
6 first six months, and that those that did improve
7 their rates had a greater increase in the number
8 of patients receiving recommended patient level
9 interventions such as this face to face
10 collection of the medication history.

11 So I think that's intended to be a
12 sort of score level validity. It's not what we
13 typically see but showing that there is some
14 correlation between best practices and
15 improvement in the rate of discrepancies that
16 occurred here.

17 We did get a passing rating for
18 reliability, consensus not reached on validity.
19 Oh, I should add that this measure is not a
20 composite or instrument-based, so we don't have
21 any additional requirements. Data element
22 validity, and reliability testing is acceptable

1 for this measure.

2 The face validity is something that we
3 actually expect in careful validity testing at
4 the time of maintenance. This is a maintenance
5 measure. But we do accept face validity with a
6 rationale from the developer. I think that
7 rationale is, again, basically that they didn't
8 really have something to compare it to. Because
9 they are using the gold standard itself as a
10 basis for the measure.

11 A few of the questions that came up as
12 part of the subgroup reviews were whether there
13 ought to be a minimum number of patients required
14 to calculate this measure.

15 Some, you know, suggestion that the
16 standing committee of content experts should
17 review the training and instruction materials to
18 make sure that those are indeed adequate, that it
19 is, in fact, a gold standard medication history
20 being collected.

21 Some concerns about the reliability
22 testing, the result of 77 percent agreement is

1 not terribly high, necessarily. And then the
2 testing of the discrepancies, some suggested that
3 they should be based on more cases. I think
4 there were only four cases that actually were the
5 subject of that analysis.

6 In terms of validity ---

7 MS. MUNTHALI: Andrew?

8 MR. LYZENGA: Yes.

9 MS. MUNTHALI: I think we can let the
10 lead discussant, maybe go through some of those
11 items.

12 MR. LYZENGA: Okay, sure. Maybe I'll
13 just stop there.

14 MS. MUNTHALI: Yes, that would ---

15 MR. LYZENGA: So I think that's Jen on
16 the phone. Are you there?

17 CO-CHAIR CELLA: Dr. Perloff? On mute
18 maybe? We'll continue on. She's not listening,
19 I guess, right now. I thought she was signed in
20 earlier.

21 MR. LYZENGA: All right, so in terms
22 of validity, some of the concerns were that

1 excluding, there's an exclusion for patients who
2 are unavailable to be seen by a pharmacist or who
3 decline to talk to the pharmacist.

4 There was some concern that that did
5 produce bias and, you know, to see if that could
6 be, or it could be used as an excuse for not
7 getting data on difficult patients, and wondered
8 if, to address this, there should be a time limit
9 set such as those discharged in six hours or less
10 should be excluded from the ---

11 With regard to the validity testing,
12 reviewers noted that while the measure does
13 appear to have face validity from a common sense
14 perspective, there was no systematic assessment
15 done and potentially a lack of data provided to
16 support the assertion that this measure can
17 reliably and validly identify discrepancies, even
18 if it does use what is considered as the gold
19 standard for gathering medication histories.

20 So sort of the questions here are
21 whether the developer's rationale for case
22 validity of the measure is adequate, and his use

1 of what is considered the gold standard practice
2 for collecting medication histories, is
3 sufficient as a demonstration of validity.

4 And then, you know, considering this
5 additional data, suggesting improvement in
6 measure performance being associated with
7 consistent implementation of best practices, this
8 does provide additional support for the measure's
9 validity.

10 Since this past unreliability, are we
11 really just focusing on the validity discussion
12 here?

13 CO-CHAIR CELLA: Yes.

14 MR. LYZENGA: I guess we can open it
15 up for discussion at this point, again focusing,
16 if we can, on validity.

17 MS. WILBON: We'll open it up to the
18 subgroup at this time.

19 MR. LYZENGA: The subgroup.

20 MS. WILBON: Yes.

21 MEMBER KAPLAN: Okay. So I was a
22 little confused about enumerating. Because if

1 the number of patients, and I need some help
2 here, I can get it from the developers. The
3 enumerator statement, the number for each sample
4 patient in the denominator group, the total
5 number of unintentional medication discrepancies,
6 it struck me that the more medication you're on,
7 the more opportunities you have for
8 discrepancies.

9 So I wasn't clear from the adjustment
10 strategy that that was somehow managed. Because
11 what if some facilities have a whole bunch of CHF
12 patients, for example?

13 MR. LYZENGA: I do believe they
14 accounted for that. We can ask the developers if
15 they're on the line. I think the, it's actually
16 discrepancies per medication to account for that
17 question.

18 MEMBER KAPLAN: But then the
19 enumerator is not the number of medications.

20 MR. LYZENGA: I think the enumerator
21 is the number of discrepancies.

22 CO-CHAIR CELLA: The denominator is

1 the number.

2 MR. LYZENGA: That denominator is the
3 number of ---

4 MEMBER KAPLAN: It's the number of
5 medications or the number of ---

6 MR. LYZENGA: Is the developer on the
7 line? Maybe they could provide us some
8 clarification on that.

9 MEASURE DEVELOPER: Yes, this is Dr.
10 Schnipper. I'm the measure developer. How are
11 you?

12 MR. LYZENGA: Good. We can hear you.

13 MEASURE DEVELOPER: Good, you can hear
14 me okay?

15 MR. LYZENGA: Yes.

16 MEASURE DEVELOPER: Yes. So the
17 measure is the number of discrepancies per
18 medication. Because the more medications you're
19 on, the more opportunities there are for error.
20 And so we look at discrepancies in admission
21 orders and discharge orders. So basically the
22 the maximum number of discrepancies per med is

1 two. But the meds can be wrong on the admission
2 order and can be wrong on the discharge order.
3 And so that basically adjusts for the number of
4 medications that the patient is on.

5 We see no other need to adjust for
6 anything else in our studies. And now we've done
7 two studies at teaching hospitals. But I'm happy
8 to answer any more questions about that
9 particular piece. Thank you.

10 MEMBER KAPLAN: So I have a follow-up
11 question on that. Because if a facility has a
12 small number of patients on a huge number of
13 medications, and the precision of the estimates
14 then is, so that's just a small number of
15 patients.

16 So smaller facilities might have fewer
17 opportunities to have discrepancies, because they
18 have smaller numbers of patients? Help me
19 understand what the relationship of facility size
20 is to this.

21 MEASURE DEVELOPER: That's a great
22 question. And I think the question came up a few

1 minutes ago. I did sort of a minimum number of
2 cases to provide validity. You know, in our
3 studies, we did 22 patients per month. And that
4 was enough patients, I think, to get a fair
5 representation of what's going on in your
6 hospital.

7 We try currently doing 20 per quarter.
8 I think it's questionable if that is enough. So
9 I think that's, you know, something that we
10 should definitely talk about offline. But a
11 hospital has to be big enough to provide enough
12 of a sample of its patients that the measure is
13 an adequate representation of, you know, of their
14 quality of care.

15 If a hospital is too small to provide
16 that number, whatever that number is that we
17 agreed to, then it would be too small to be able
18 to carry out this measure. So, you know, I would
19 pick a hospital with, you know, 20 beds or
20 something like that, it might not be.

21 And I don't know if you ever exempt
22 hospitals of a certain size, certain measures,

1 but there would be a concern, under those
2 circumstances, that you wouldn't have enough of a
3 sample size.

4 MEMBER KAPLAN: Got it. So just two
5 more quick questions. One is your follow-up data
6 from the MARQUEE study, MARQUEE II study, shows a
7 significant improvement in half of the samples --
8 of the site studies, but no change or an increase
9 in medication discrepancies in the remaining
10 sites. And that's what you're citing as
11 validity.

12 My concern is that this measure's been
13 around since 2012, it looks like. And so in the
14 meantime, we've accrued a lot more opportunities
15 for construct validity. So what would you assume
16 that people who have a large number of medication
17 discrepancies would have? For example, more
18 likely to return to the hospital for readmission
19 within 30 days or so on.

20 Have you considered, first of all,
21 with respect to only half of the studies
22 responded, or it looks like they're improving and

1 the rest either didn't change or they got worse,
2 is that good evidence of validity?

3 And then the second question is why
4 would you not then think about some other
5 construct validity type variables to test this
6 against?

7 MEASURE DEVELOPER: Right. And those
8 are all good questions. So across the 18
9 hospitals, the reduction in discrepancies, on
10 average, is very strong and consistent. It's
11 almost a straight line down from about three
12 discrepancies per patient to about one
13 discrepancy per patient.

14 Again, there's constant improvement
15 over the time of the study. Comparing the third
16 time period to the first time period is an
17 insensitive way to measure. But it was an easy
18 one to do, you know, for this particular measure.
19 But overall, the effects of the MARQUEE II study
20 were very strong.

21 We're about to submit that work
22 publication in JAMA this month. So there's that

1 piece. We are in the midst now, in terms of
2 concept validity, if we're comparing improvements
3 in discrepancy rates with reductions in hospital
4 length of stay and in readmission rates.

5 And that's fine, it's just that those,
6 you know, announcements aren't completed yet.
7 But, you know, it's a large study with a lot of
8 people. And, you know, the problem with re-
9 admissions and length of stay is that neither
10 were planned analyses but were added on.

11 And they don't always do risk
12 adjustments the same way. Not all of them
13 prescribed have been observed over expected
14 lengths of stay. Some hospitals that had more
15 selection of who got the intervention versus who
16 didn't so they could be bounded by indication,
17 given who got the interventions versus who
18 didn't, when you want to compare those who did
19 and didn't.

20 So it's more complicated than just
21 that. So we are trying to do concept validity
22 with both in-hospital length of stay and

1 readmission, we just don't have the data for you.
2 I apologize.

3 CO-CHAIR CELLA: Larry and then Jack.

4 MEMBER GLANCE: So I just wanted to
5 follow-up with a comment on what, Chair, what you
6 just made. So if you have, there's no risk
7 adjustment for this measure, correct?

8 PARTICIPANT: Right.

9 MEMBER GLANCE: It seems like there's
10 a big ---

11 MEASURE DEVELOPER: Yes. We, okay, go
12 ahead. Sorry.

13 MEMBER GLANCE: It seems like there
14 would be a big difference where, if you have the
15 patient who's on 25 different medications, it's
16 much harder to achieve successful reconciliation
17 for that patient versus a patient who has two
18 different medications.

19 And the way the measure's currently
20 structured, you could have the same outcome for
21 25 patients who are each on one medication versus
22 one patient who is on 25 different medications.

1 So in terms of score level validity
2 risk adjustment, I think there ought to be risk
3 adjustment in this measure. I think it's very
4 difficult on the face of it to say it's okay to
5 put this measure out in the wild without any risk
6 adjustment whatsoever.

7 MEASURE DEVELOPER: So a couple of
8 comments here. Those are all completely valid
9 comments. You know, I would say that we do
10 discrepancies per med, per patient. So one
11 patient with 25 is not the same as 25 patients on
12 one medication. You would still be gathering
13 data on 25 different patients. And each one of
14 them would have the number of discrepancies per
15 the number of meds that they are on. And then
16 you average that across all of your patients, so
17 just to make that clear.

18 In our studies, we do a risk
19 adjustment for a few basic things, including age,
20 and including the understanding of the patients,
21 the patients' overall understanding of their
22 medications as determined by (telephonic

1 interference) medication.

2 And certainly we have some criteria
3 such as high, medium, and low. And the question
4 was simply, you know, in terms of ease of
5 operationalization, whether that was necessary or
6 not.

7 But one point I would make is that,
8 you know, so Leapfrog is using our measure.
9 There are now thousands of hospitals that are
10 doing it. Right now, as I said, at a low level.

11 The question is really is the hospital
12 being compared to a different hospital, or is the
13 hospital being compared to itself?

14 I think there's no doubt in my mind
15 that comparing a discrepancy rate over time
16 within a hospital is a valid measure whether
17 you're improving care in that hospital.

18 I think the broader question of I've
19 got an absolute discrepancy rate of X, and you've
20 got a discrepancy rate of Y, does that mean
21 you're a better hospital than I am? And I'm
22 often not convinced that that may necessarily be

1 true.

2 I think the purpose of this measure
3 has been to drive internal quality improvements
4 to see improvements in your own hospital over
5 time. And for that, I think it's clear that it
6 does that and it really does compare. It does
7 tell you, you know, if your hospital's improving
8 your processes of care or not.

9 So, you know, I would be happy to talk
10 offline and explore ways to do more risk
11 adjustment to compare hospitals to hospitals, you
12 know, one to another, and be sure that you really
13 measured whether, you know, you're providing
14 better care than another hospital is within a
15 hospital. It definitely is measuring whether
16 improvement is taking place.

17 CO-CHAIR CELLA: Thank you. Jack, and
18 then Joe.

19 MEMBER NEEDLEMAN: Yes, to follow-up
20 a little bit on Larry Glance's comment and also
21 your statement about the use, so the intended use
22 of this measure is looking within an institution

1 over time and not doing across hospital
2 comparison.

3 MEASURE DEVELOPER: That's
4 correct.

5 MEMBER NEEDLEMAN: Okay. And then I
6 want to sure I understand the method of
7 calculation here. So I've got a patient, within
8 my 22 patients, I've got a patient on two meds.
9 And there's been a discrepancy in one. So that
10 patient gets a score on this measure of 0.5.
11 I've got a patient on ten meds, and there's a
12 discrepancy in one. And they get a score of 0.1.

13 MEASURE DEVELOPER: Correct.

14 MEMBER NEEDLEMAN: And then those
15 scores are averaged across the patients to get
16 the average score for the facility for that
17 month.

18 MEASURE DEVELOPER: Correct, that's
19 exactly right.

20 MEMBER NEEDLEMAN: So there is no
21 adjustment for the fact that it is more likely to
22 have an error the more complex the medication

1 regime of the patient is, that the patient on ten
2 meds is more likely to wind up with a discrepancy
3 because it's harder to reconcile than the patient
4 on two meds.

5 MEASURE DEVELOPER: Right. And it was
6 a linear effect, that the opportunity per med is
7 the same if there is an exponential or a, you
8 know, a quadratic, you know, then no, I don't,
9 right, so ---

10 (Simultaneous speaking.)

11 MEASURE DEVELOPER: It'd be more
12 linear. It assumed a linear relationship, you
13 know, opportunities for error.

14 MEMBER NEEDLEMAN: And as you said, as
15 long as it's within hospital measure and the case
16 mix, and therefore the medication complexity in
17 the patient stays reasonably constant over time,
18 that lack of adjustment may not produce the
19 perfect measure, but it's probably acceptable.

20 But you ought to be at least exploring
21 in your data whether or not you see more
22 discrepancies among the more medication-complex

1 patients and think about what that means for the
2 measure you're using down the road.

3 MEASURE DEVELOPER: Yes, I agree.

4 Yes, I mean, it could. Some patients' regimens
5 are more complicated than others. We've written
6 a few papers on the kinds of medication classes
7 people are on, which ones are most commonly, you
8 know, relating to discrepancies, the kind of
9 diseases people have. And, you know, there may
10 be an exponential effect, where it's
11 exponentially harder. The patient's on many
12 regimens.

13 But, you know, within a hospital, we
14 assume, over the course of a few years, case mix
15 is roughly the same within the limits of
16 sampling. And then you are measuring something
17 real.

18 You know, and the other point that I
19 would make is a point that, you know, was made at
20 the very beginning of this, which is that we
21 don't really have another measure that actually
22 measures quality.

1 Everything else is a lot of, you know,
2 did you check a box, did you do a process. And
3 we know full well that not only is that not an
4 accurate measure, but it actually can be counter
5 productive. Because hospitals will encourage
6 their providers to check a box saying I did med
7 rec, when that provider knows full well that they
8 didn't actually have the opportunity to take a
9 good medication history.

10 So instead of having transparency,
11 instead of saying I couldn't take a good
12 medication history, you're going to have to do
13 one tomorrow, you know, they checked the box that
14 said they're being measured. And so that just
15 becomes counter productive. You know, this is
16 the only measure out there that really actually
17 measures quality.

18 CO-CHAIR CELLA: Well, thank you.

19 MEASURE DEVELOPER: And it's really
20 been a powerful motivation.

21 CO-CHAIR CELLA: Thank you, thank you.

22 MEASURE DEVELOPER: Thanks again for

1 letting me speak.

2 CO-CHAIR CELLA: All right. I'm sorry
3 to break in. We're a little bit out of order,
4 and I apologize for that. We're still in the
5 period now where only the subgroup members are
6 supposed to be commenting. So Zhenqiu, you had
7 your card up, if you still want to say something,
8 and then Terri, and then Zhenqiu, then Sherrie,
9 and then Terri.

10 Remember, you have to be in the
11 subgroup at this point to speak. Everyone will
12 have a chance to say things later, but I'm also
13 going to ask If we try to be brief with what we
14 have to say. Because we've got a lot to go
15 through. And if do it at this rate, we'll be out
16 Wednesday --

17 (Laughter.)

18 CO-CHAIR CELLA: -- by 5 o'clock.

19 MEMBER LIN: So I just want to
20 clarify. I mean, this is proposed as a quality
21 improvement measure for maybe past two years,
22 right. Because otherwise, if you propose a

1 sampling scale of 25 patients, I get to Karen's
2 point, no, Sherrie's point. If you have 25
3 complicated patients, and 25 simple patients,
4 then you compare the difference across hospitals,
5 right. That would be, you know, it just may not
6 be fair.

7 And also as part of the evaluation,
8 the agreement between two trained pharmacists, 77
9 percent, so obviously pharmacy, different
10 hospitals use different pharmacies. And that's
11 going to introduce a lot of potential difference,
12 right. So how do we know? If you use this
13 measure to be better between hospital difference,
14 how can we be certain that a lot of it is not due
15 to pharmacies different?

16 CO-CHAIR CELLA: All right, Sherrie.

17 MEMBER KAPLAN: So I just follow-up on
18 Zhenqiu's and Larry's point that the precision of
19 the estimate for a patient who's on two
20 medications and one has the discrepancy is the
21 same as the score for a patient on ten
22 medications for which there are five

1 discrepancies.

2 And to me, that kind of risk
3 adjustment is really called for, and maybe a
4 recommendation. I don't know if it's true for
5 this round or not then, but maybe a
6 recommendation going forward to the standing
7 committee for what is it, a call for risk
8 adjustment?

9 Because it seems to me like that
10 really causes precision of the estimate problems
11 at patient levels. So if you're at that twice,
12 and you strike out once, you're into saying that
13 if you're at that ten times, then you strike out
14 five times. At least I get that with scores
15 analogies.

16 (Laughter.)

17 CO-CHAIR CELLA: It is the season for
18 that. Terri?

19 MEMBER WARHOLAK: Well, I had some
20 similar comments and concerns. One of the things
21 that I was worried about, I don't remember when I
22 was reviewing this that this was supposed to be a

1 within hospital measure only. And so it didn't
2 seem clear to me reading that.

3 And so I know that a lot of measures
4 are used inappropriately. So I wondered what's
5 going to be done or what is done to ensure that
6 it's used appropriately. And how is Leapfrog
7 using it? Are they using it to compare between
8 hospitals or within?

9 MR. LYZENGA: Maybe also to clarify
10 that endorsement does provide a measure suitable
11 for accountability purposes.

12 (Simultaneous speaking.)

13 CO-CHAIR CELLA: Okay, can we give the
14 developer a chance to respond if you like, and
15 then Karen.

16 MEASURE DEVELOPER: Back to you then
17 for the--

18 CO-CHAIR CELLA: Yes, if you'd like to
19 respond to the last couple of comments, please
20 do.

21 MEASURE DEVELOPER: Absolutely.
22 Leapfrog is definitely in agreement with me that

1 it is, it should be used to compare within the
2 hospital and not between hospitals. And the
3 measure developers at Leapfrog have been very
4 supportive of that piece.

5 Yes, I think the comments made about
6 precision are correct, you know. And so if the
7 feeling of this group is that further risk
8 adjustment is necessary, then we would obviously
9 work with them on that piece.

10 Was there another comment that ---

11 CO-CHAIR CELLA: I think that's good.

12 Karen?

13 MS. JOHNSON: Yes. I was just going to
14 reiterate ---

15 MEASURE DEVELOPER: Okay, thank you.

16 MEMBER KAPLAN: Yes. I was just going
17 to reiterate what Andrew said. Measures that are
18 endorsed by NQF should be suitable for both QI
19 and accountability. So it needs to be both.

20 CO-CHAIR CELLA: Jack?

21 MEMBER NEEDLEMAN: Okay. So I'm going
22 to go out for some summary comments, or I am,

1 right, as a member of the committee. I had
2 basically passed this measure when I rated it. I
3 have some concerns about subsequently what the
4 training materials are, but I'm not competent to
5 evaluate that.

6 So I'd like the standing committee to
7 look at that. Because that affects the usability
8 of the measure and, to some extent, the
9 reliability of the measure in a way that I can't
10 assess either, even if I had the materials, that
11 I can't assess.

12 So I'm still prepared to pass the
13 measure on to the standing committee. Or I'd
14 like the standing committee to look both at the,
15 think about substantively the area level of
16 agreement or disagreement among the two folks
17 that are, you know, looking at it together, and
18 whether we have a reliable enough measure in
19 practice to be usable.

20 And likewise for the training
21 materials, I'm thinking about whether or not the
22 measure, which is inherently about the training,

1 is both usable and consistent with the pace with
2 the adjustment.

3 CO-CHAIR CELLA: If I could just maybe
4 ask you, Karen, to correct me if I get this wrong
5 and then elaborate. You made a comment, Jack,
6 about whether this passes on to the standing
7 committee. Everything is going to go on to the
8 standing committee, correct?

9 MEMBER NEEDLEMAN: Right.

10 MS. JOHNSON: For potential
11 discussion, not necessarily for a re-vote.

12 CO-CHAIR CELLA: Right, right. So
13 whether this passes this committee or not, the
14 standing committee will see it. And so if you
15 could elaborate a little bit, Karen, on what
16 would be the difference in what they see if it
17 passes versus fails. Because that may affect
18 some peoples' votes.

19 MS. JOHNSON: Yes, so what we are
20 going to do is every measure that comes out of
21 the Methods Panel is going to go to the standing
22 committee. Now, the standing committee, if they

1 so choose, for measures that do not pass, the
2 standing committee can pull those for discussion.

3 That means they could have the same
4 kind of discussion that you have here, but it
5 doesn't necessarily mean that we will allow them
6 to re-vote, okay. So some measures will be
7 eligible for a re-vote. And those are measures
8 where they don't have certain things completely
9 wrong with them, right.

10 So that would be things like the
11 methodology just didn't work at all, or the
12 methodology was inappropriately applied, or they
13 didn't meet our minimum requirements for
14 endorsement, those kinds of things.

15 So what you would have to do for today
16 is just vote. Do you think that this measure,
17 we're voting only on validity, do you feel like
18 these measures or this measure actually is a
19 valid, can you, do you feel that this measure can
20 reflect the correct conclusions about quality,
21 okay? That's basically what you are trying to
22 get to with your vote on validity.

1 I don't know if that helped or not.
2 But not all measures will necessarily be up for a
3 re-vote. And that will have to be, the way we're
4 going to do it is we're going to figure out which
5 ones eligible for re-vote or not.

6 And to be honest with you, I think we
7 need to do that in consultation with our co-
8 chairs. So that's not something that we can tell
9 you today, but they will be able to pull and
10 discuss but potentially not re-vote.

11 CO-CHAIR CELLA: Is there, I guess,
12 follow-up questions, sorry for this, but is there
13 such a thing, maybe not, in this name, but such a
14 thing as a pass with caution or pass with notes?

15 MS. JOHNSON: There's always going to
16 be no votes, right. So we don't give them just
17 the pass, no pass. We give them a pretty
18 extensive discussion point of what you guys are
19 finding.

20 CO-CHAIR CELLA: So concerns will be
21 sent --

22 MS. JOHNSON: They will.

1 CO-CHAIR CELLA: -- along with --

2 MS. JOHNSON: As voted on.

3 CO-CHAIR CELLA: -- any passed.

4 MS. JOHNSON: Yes. If you pass it,
5 they will still see the concerns. If you do not
6 pass it, they will still see the concerns. We
7 will have to decide, at a future point, whether
8 it's even eligible for re-vote. And the
9 requirement that it has to be suitable for both
10 accountability and for internal QI, is probably
11 really the sticking point in terms of passing our
12 minimum requirements.

13 CO-CHAIR CELLA: Okay, any other,
14 thank you, any other subgroup comments? Let's
15 open it up then. Any comments from anyone?
16 Gene?

17 MEMBER NUCCIO: Yes, I have a couple
18 of questions. You described the issue as quote,
19 "unintentional discrepancies." Why did you
20 choose the word unintentional? A discrepancy is
21 a discrepancy. And you're not trying to
22 determine whether or not the pharmacist made the

1 problem of a wrong medication done on purpose.
2 So it's simply discrepancies, not unintentional,
3 from my perspective.

4 The second question, you cite an
5 example in Section 1B.1 of your MIF form of a
6 rate of discrepancies. And this, I think, is a
7 question that Larry and Sherrie have talked
8 about. Did you choose not to use a percentage of
9 discrepancies per patient and then average those
10 percentages which would take into account whether
11 or not at least the number of medications is
12 taken into account?

13 Complexity is a different issue. But
14 regarding complexity, were your pharmacists
15 directed to look at simply inappropriate drug
16 interactions, Drug A should not be used with Drug
17 B, or if they were also looking at dosage
18 discrepancies? And I could not find that in my
19 quick reading of the materials. So those are my
20 three questions.

21 MEASURE DEVELOPER: Can I answer?

22 MEMBER NUCCIO: Please.

1 CO-CHAIR CELLA: Yes, please.

2 MEASURE DEVELOPER: So I could, but
3 before I do that, I just wanted to get back to an
4 early point that was raised.

5 With the help of Leapfrog, we have
6 greatly improved our training materials. We feel
7 they are, you know, at this point people can
8 really achieve reliable and valid, even full
9 standard medication with which to measure
10 discrepancies.

11 And we'd be happy to share those with
12 the full committee so that, you know, folks can
13 weigh whether or not they agree with us, that the
14 training materials really are that good.

15 In terms of accountability, I hear
16 what you are saying. I don't know if it helps
17 alleviate that concern, but for example, our
18 problem is, where we have seven hospitals, what
19 we would do is say that every hospital has to
20 either achieve a certain degree of improvement or
21 achieve a certain threshold of excellence.

22 And by combining those two, I think

1 hospitals that, you know, have very different
2 case mix can still both be held accountable in an
3 absolute sense while, you know, depending on
4 improvement within their own hospital.

5 To get these two specific questions
6 though, by giving discrepancies per medication we
7 are essentially doing a percentage. In fact, if
8 you take that number and divide it by two, it
9 basically is a percentage of opportunities for
10 error, for which there is a natural error.

11 So in other words, you know, one
12 error, one discrepancy for two meds, which could
13 be considered a 0.5, is really a 0.25 percentage
14 error rate. Because there's two opportunities
15 for error for each of those two meds. Four
16 opportunities for error if you one, so you have a
17 one out of four discrepancy, you know, sort of
18 error rate as a percentage.

19 Why we use the term unintentional,
20 just to make it clear that, you know, providers
21 make changes to regimens all the time depending
22 on what people came in on. And we just wanted to

1 make it clear that, you know, adding an
2 antibiotic within that regimen is not a
3 discrepancy.

4 So if you were at the camp that a
5 discrepancy automatically incorporates the term
6 unintentional, then yes, it's redundant. But we
7 did put it there to make it clear. But yes, it's
8 an unintentional discrepancy. So if you just
9 want to call that a discrepancy, that's fine.
10 But changes are made. And we wanted to make it
11 clear that it's only the ones that were not
12 intended.

13 In terms of the types of
14 discrepancies, so dose frequency formulation, all
15 of those are considered discrepancies. You don't
16 get counted more than once per order. It's an
17 order with a discrepancy. Because an omission is
18 just as bad or worse than both the dose and/or
19 frequency discrepancy. You wouldn't want to
20 count the dose and discrepancy twice and an
21 omission only once.

22 So once an order is wrong, the order

1 is wrong. They account for the discrepancy. So
2 hope that explains that. But all the different
3 types of discrepancies are looked for as part of
4 this process. So if there are any follow-up
5 questions, I'd be happy to answer them.

6 CO-CHAIR CELLA: Thank you.

7 MEASURE DEVELOPER: Thank you again.

8 CO-CHAIR CELLA: Okay, Joe you've been
9 very patient. You're next and then Sherrie. And
10 again, let's try to be very concise.

11 MEMBER HYDER: The first question I
12 had has to do with the type of measures. I think
13 you have a definition of outcome as health state
14 of a patient or change in health state. And I'm
15 curious how this is classified as an outcome
16 measure. And then I have a second question.

17 CO-CHAIR CELLA: Okay, quick answer on
18 that one?

19 MR. LYZENGA: Just an answer that
20 typically our developers indicate whether it's an
21 outcome, or a process, or whatever when they do
22 the submission. Sometimes we talk with them and

1 do a correction. I think in this instance we
2 allowed it to come through as an outcome,
3 although that is certainly arguable. Again, it
4 doesn't quite fit in our usual categories. It
5 seems to me a little bit more like something like
6 an immediate outcome.

7 CO-CHAIR CELLA: Yes. I don't think
8 we need to worry about that here. Let's go
9 ahead, Joe, what's your next question?

10 MEMBER HYDER: The second question has
11 to do with the gold standard. So I'm thrilled
12 pharmacists are the gold standard. The way it's
13 constructed though, pharmacists aren't the gold
14 standard. It's the brief medical record review.

15 So the impression is that the medical
16 record is the holy book containing all knowledge
17 about what medication is required for the, what
18 medication was relative to the patient's
19 admission and the patient should be started on.
20 In practical terms, that's never the case.

21 So I don't know that there is a gold
22 standard in this case. And using either the

1 pharmacist or, specifically, the medical record
2 review would cause me to question the validity
3 significantly.

4 CO-CHAIR CELLA: Quick comment?

5 MEASURE DEVELOPER: Yes. So what
6 these pharmacists do is a pretty regular process,
7 interviewing the patient, getting corroborating
8 sources, talking to BCDs, calling up the
9 pharmacy, talking to family members, getting pill
10 bottles.

11 They put all of that together, then
12 they put together what they think the patient
13 should have been on and what they're actually
14 taking. So it's a pretty regulated process. It
15 is not just trusting the charts. But in the end,
16 what they come up with is as close as you can get
17 to the truth.

18 MEMBER HYDER: So that's not specified
19 in the measure as written, that has their payment
20 strategy. And then on top of that, it doesn't
21 allow for the physician directing care to say I'm
22 going to withhold the medication in anticipation

1 of something two days from now. So that maybe
2 the ascertaining strategy for that may be specify
3 in more detail.

4 CO-CHAIR CELLA: Good point. Okay,
5 Sherrie?

6 MEMBER KAPLAN: I'm just a little
7 confused about the scoring now. Because, like,
8 you said something like you're treating your role
9 like as odds ratio, like the probability of being
10 wrong and maybe because you have two outcomes.
11 You either were discrepant or you weren't. And
12 then so each opportunity has two possible
13 outcomes, yes or no. Is that right? Are you
14 doing it more like an odds ratio?

15 MEASURE DEVELOPER: It's not an odds
16 that you take the number of discrepancies per
17 medication for a patient.

18 MEMBER KAPLAN: No, but each
19 medication has an opportunity to either be
20 discrepant or not be discrepant. And that's
21 taken into account in the scoring which is more
22 like you do an odds ratio than a relative risk

1 assessment, correct?

2 MEASURE DEVELOPER: Yes. I mean, I
3 guess if you take the discrepancies per med and
4 divide it in half, you will get the number of
5 errors per opportunity for error. We still
6 present that as a numerical number and not an
7 odds ratio. It could be ---

8 MEMBER KAPLAN: It's not?

9 MEASURE DEVELOPER: -- I guess a ---
10 (Simultaneous speaking.)

11 MEASURE DEVELOPER: You know, it would
12 be another, like, X over N would be another way
13 to analyze that data. But, you know, happy to
14 talk about that more offline.

15 CO-CHAIR CELLA: Okay, thanks. Joe,
16 maybe a final point so we can vote?

17 MEMBER HYDER: Sorry.

18 CO-CHAIR CELLA: Other Joe, Joe
19 Kunisch.

20 MEMBER KUNISCH: Just real quick, the
21 way I understand it, there's no exclusions here.
22 In looking at the gold standard medication

1 history, it says shortly after admission, for
2 example, within 12 to 24 hours.

3 So if there are no exclusions and you
4 have, say, a homeless patient that comes in
5 showing symptoms of stroke, confused, can't even
6 give you their right name, there is no other
7 information on them, how would that patient be
8 treated if they're not excluded?

9 If you did everything to get that
10 medication history, which really would mean you
11 couldn't find anything, would you get a pass on
12 everything? Or would you fail on everything,
13 because you didn't get any medication history?

14 MEASURE DEVELOPER: That's a great
15 question. If it's typically impossible to
16 determine, with any sense of assurance, that you
17 can figure out what they are on, I guess you
18 would have to exclude that patient. You know,
19 under most circumstances, there is a pharmacy,
20 there's a medical record, there's something. If
21 there's nothing then, sure, the patient would be
22 excluded.

1 I think the way we say it in our
2 application is that able to take a medication
3 history, you know, after they are admitted to the
4 hospital. If it's physically impossible to take
5 any kind of history at all, then they would be
6 excluded.

7 CO-CHAIR CELLA: Okay. Thank you very
8 much. That was a good discussion. Good then,
9 let's run the vote, Poll Everywhere if you're in
10 the subgroup.

11 MS. WILBON: So Dave, sorry, so, Dave
12 I think you're not eligible to vote. But
13 everyone else in the subgroup, Sherrie, Zhenqiu,
14 Jack, Jen, Christie, and Terri should be voting
15 via the Poll Everywhere.

16 Everyone else, please pull up the
17 SurveyMonkey at the link that was emailed out
18 this morning. And we'll ask that you select
19 Measure 2456 from the dropdown. And you do not
20 have to enter your name if you don't want to.
21 And let us know what your shadow vote is.

22 CO-CHAIR CELLA: Yes, who's that?

1 Let's continue on ahead. You all got the vote
2 instructions?

3 MS. OGUNGBEMI: Yes. We're voting on
4 the validity of Measure 2456, the overall rating
5 on validity, taking into account the results and
6 scope of all testing and analysis of potential
7 threats. Voting is open. Your options are high,
8 moderate, low, and insufficient.

9 CO-CHAIR CELLA: Are we able to move
10 to 1623 while people vote, or do we need to wait?
11 Do you want to do the break now?

12 (Simultaneous speaking.)

13 CO-CHAIR CELLA: So let's try to get
14 through 1623 while you're voting. Karen, you're
15 doing the slide. And then if you do need to take
16 a bio break before the break, which is going to
17 come after this discussion, please feel free to
18 get up and do that. But let's try to get through
19 this and catch up a little.

20 Go ahead, Karen.

21 MS. JOHNSON: You want to do that
22 before ---

1 CO-CHAIR CELLA: Can we? Is it
2 possible to put that screen up. Or do we need to
3 wait for the voting to close?

4 MS. OGUNGBEMI: I can do both at the
5 same time. It's there.

6 CO-CHAIR CELLA: Oh, okay. I'll just
7 look over here. Yes.

8 (Simultaneous speaking.)

9 MEASURE DEVELOPER: I'm going to get
10 off the line then. This is Dr. Schnipper. Thank
11 you for letting me --

12 CO-CHAIR CELLA: Yes, I'm sorry.
13 Thank you, Dr. Schnipper, from everyone.

14 MS. OGUNGBEMI: Has everyone in the
15 subgroup voted that was eligible to vote? Yes,
16 okay.

17 MS. JOHNSON: Let's go ahead. Do you
18 have those results? We need to get the actual
19 results of the vote into the transcript.

20 CO-CHAIR CELLA: Oh, okay.

21 MS. JOHNSON: Yes.

22 CO-CHAIR CELLA: Well, then we do

1 wait. All right.

2 MS. JOHNSON: Yes.

3 MS. OGUNGBEMI: So we have zero votes
4 high, 50 percent moderate, 33 percent low, and 17
5 percent insufficient. So we're still at
6 consensus not reached.

7 CO-CHAIR CELLA: Not reached, okay.

8 MS. JOHNSON: Okay. All right, our
9 co-chair's wanting us to keep going, not have a
10 break. So let's do Bereaved Family Survey.

11 PARTICIPANT: Karen?

12 MS. JOHNSON: Yes?

13 PARTICIPANT: I got that measure, and
14 I'm not on the list --

15 MS. JOHNSON: Yes, you were on the
16 list, for which one, 1623 or --

17 PARTICIPANT: 1623, but I'm not listed
18 here.

19 MS. WILBON: Are you listed under
20 subgroup voting eligibility? Is that where
21 you're looking at? Okay, we only listed people
22 who have special circumstances for voting.

1 PARTICIPANT: Oh.

2 CO-CHAIR CELLA: Yes, you're okay.

3 MS. WILBON: So you're good.

4 PARTICIPANT: I'm good?

5 MS. WILBON: Yes.

6 MS. JOHNSON: Okay. So Bereaved
7 Family Survey, this is a maintenance measure.
8 And it was previously reviewed by the Methods
9 Panel and did not pass at that time. And
10 unfortunately, that made a little bit of
11 confusion for our group. And it was our fault,
12 so we will take credit for messing up on that
13 one. And I'll explain where that is.

14 So this is a measure that comes out of
15 the Bereaved Family Survey. It calculates a
16 portion of veteran decedents' family members who
17 rate overall satisfaction with the end-of-life
18 care in an in-patient setting as excellent versus
19 all the other options, very good, good, fair, or
20 poor.

21 It is based on one item in the
22 Bereaved Family Survey, Item Number 18, overall,

1 how would you rate the care that the decedent
2 received in the last month of life?

3 It is, of course, a PRO-PM. And it is
4 calculated by taking the number of respondents
5 that choose excellent versus everything else as
6 long as there are at least 12 or more valid
7 responses on all the items in the survey.

8 The level of analysis is a facility,
9 and it is risk-adjusted with five factors. Just
10 a couple of things we wanted to point out in
11 terms of the initial analyses of this.

12 There were a few commenters or SMP
13 folks, and this is probably people who are new,
14 who were pointing out that some of the things in
15 1B and 3 and 4, those items, weren't filled out
16 completely.

17 That's okay. This is not filled out
18 completely, because those are actually due a
19 little bit later in time. So really, you were
20 only supposed to be looking at the specifications
21 and the testing attachment.

22 So I can talk to you offline if that's

1 still a little confusing. But we don't have to
2 worry about them not filling out the feasibility
3 section. That's okay at this point.

4 There was also a note about waste of
5 respondent data. So I think a little bit of
6 confusion, there's this whole survey, lots of
7 different opportunities for PRO-PMs that this is
8 only being based on one item, that satisfaction
9 item.

10 That also is okay. NQF is not saying
11 that you have to use the entire survey. So
12 developers can decide which measures that they
13 develop and which ones they put forward to NQF
14 for endorsement. So the fact is, they only put
15 one PRO-PM. There could be multiple ones out of
16 the survey. That's okay.

17 And then finally, the previous
18 evaluation by the Methods Panel, we wanted to
19 give you the previous testing attachment, more
20 for your information only, so that if you were a
21 previous evaluator of this measure, you could go
22 back, and you can compare what was done before

1 versus what's done afterwards, if you were
2 curious about that.

3 Unfortunately, we did not make it as
4 clear as we should have which was the most recent
5 testing attachment. And what we think happened
6 is a few of you probably accidentally looked at the
7 previous attachment, not the most current one,
8 okay.

9 So especially the last time around,
10 there was concern about the reliability testing
11 of the one item in the instrument. The last time
12 around it was not done. This time, they did do
13 tests, re-tests, and analysis of that one item.
14 So that was done.

15 And there are a couple other things
16 throughout there that makes us think, again, that
17 maybe were looking at the wrong testing
18 attachment. So we just wanted to make sure that
19 we point that out, make sure that you understand,
20 number one, that they did provide a different and
21 more updated testing attachment. And they also,
22 in their additional responses, hit those high

1 points that were mentioned in the evaluation.

2 So all that said, I'm not going to go
3 through all the stuff on reliability, because the
4 actual ratings for reliability, it passes with a
5 high rating. So I'm not going to go through
6 that.

7 But it did not pass under validity.
8 And I think it could have been because, again,
9 and we can talk about all of this, some of the
10 main questions really was, was there any kind of
11 testing done beyond just showing the rates over
12 time, okay.

13 So let me stop there. We do want to
14 give it back to the lead discussant, but before
15 we do that, I just want to make sure, Dawn, are
16 you on the phone or anyone else from the VA, the
17 developer?

18 MEASURE DEVELOPER: Yes, myself and
19 then two other members of our team, Josh and
20 Anne.

21 MS. JOHNSON: Great, thank you, Dawn.
22 So what we're going to do is we're going to have

1 our lead discussants just point a couple of
2 things that they thought were the key issues.
3 And we'll figure out were those the issues just
4 simply because of looking at the wrong form, or
5 were there additional things that we need to talk
6 about? And then we'll go from there, okay?

7 CO-CHAIR CELLA: Christie?

8 MEASURE DEVELOPER: And do the panel
9 members, team members have our response that we
10 sent last week as well?

11 MS. JOHNSON: Yes, they do.

12 CO-CHAIR CELLA: Yes.

13 MEASURE DEVELOPER: Okay.

14 MS. JOHNSON: Yes. So our lead
15 discussant is Christie.

16 MEMBER TEIGLAND: Yes, I'll go through
17 a few things that I had noted on my review. One
18 is that they did not adjust for the type of
19 facility. And while they did note that there
20 were differences depending on the type of
21 facility, that they had risk adjusted for that.
22 So that was a confusion, a point of confusion.

1 And I'm not clear why they didn't adjust for type
2 of facility. That would seem to be important.

3 Just a small thing, they called the
4 Elixhauser score, the co-morbidity score, a
5 social risk factor. Which I think, I see some
6 heads shaking now, I would question that.

7 They also noted, regarding the missing
8 data, that there were differences. They did see
9 differences in scores after they waited for
10 response rates at the facilities. But the non-
11 responses were not really addressed. And I think
12 that could introduce some potential bias in this
13 measure.

14 They also noted that facilities that,
15 you know, that were in urban areas in the
16 northwest or the Midwest, had the biggest
17 improvements after risk adjustment and that those
18 in rural areas, the mountain areas, the west, had
19 the biggest declines in scores after risk
20 adjustment. But they didn't use regions as a
21 risk adjustment factor. So I'd like to
22 understand a little bit more about why that

1 wasn't considered as a risk adjustment factor.

2 Yes, the face validity looks pretty
3 good in terms of they did pick some facility
4 process measures that they correlated then with
5 that item. And they found good correlation that
6 facility scores were higher when they seemed to
7 do the right thing, like getting palliative care
8 in the last 90 days of life and so forth, so that
9 looked good.

10 My last comment is one that we
11 presumably can't score them down on, but I need
12 to comment on it. And there was no risk
13 adjustment for social risk factors even though,
14 again, they saw a disparities in how patients
15 responded to the overall care, end of life care,
16 based on racial, race categories.

17 So what they say is that that will let
18 facilities off the hook. And what I would point
19 out here is this is completely inconsistent with
20 all of the AHRQ past measures which I adjust for
21 race, ethnicity, income, education.

22 Because particularly, with these types

1 of surveys, cultural differences in the way that
2 you'll respond, based on not only race ethnicity
3 but income levels, people with higher incomes are
4 going to actually tend to think their care is
5 worse, right, than people in with lower incomes.
6 So I strongly question that decision, not to even
7 look at those characteristics. Yes, so those are
8 some of my concerns.

9 CO-CHAIR CELLA: Let's have a, let's
10 see, you've raised a few things that maybe we
11 should give the developer from the VA a chance to
12 respond to and then we'll have the subgroup ---

13 MS. JOHNSON: Dawn, do you want to
14 take a couple of minutes to just respond to
15 Christie's first set of concerns?

16 CO-CHAIR CELLA: Or we can move on if
17 you prefer, and you can respond to everything.

18 MEASURE DEVELOPER: Good.

19 CO-CHAIR CELLA: Go ahead.

20 MEASURE DEVELOPER: I mean, Anne and
21 Josh, would you say that the responses that we
22 gave in our response last week are, do you want

1 to add anything in addition to those?

2 MEASURE DEVELOPER: No. This is Josh,
3 not particularly. I guess in looking backwards,
4 I mean, those are really, each of those are
5 things that we considered. And we still struggle
6 with them, in particular, you know, what to
7 adjust when it comes social factors.

8 From a VA perspective, we're
9 accountable for the patients that we get, the
10 veterans that come to us. And so, again, from an
11 accountability standpoint from within the VA, we
12 don't adjust a way for having patient populations
13 that face certain challenges.

14 You know, our goal is to provide the
15 same level of care and to hold all of our
16 facilities accountable, regardless of the social
17 factors. What's different than--, why don't we
18 adjust more for medically sound patients, that's
19 a different story.

20 But that's fine. That's kind of our
21 explanation, and that comes from the VA
22 philosophy more generally. At least that was one

1 of the points that was raised. That remind me, I
2 should have written the check list, the list
3 down. Others, Dawn or Anne?

4 MEASURE DEVELOPER: Also the one item
5 was, we do our risk adjustment, we adjust for
6 facility complexities which is the high/low
7 complexity. And that was the question regarding
8 the differences in the facilities.

9 MEMBER TEIGLAND: That's not listed as
10 one of the five though. And so it's not clear
11 then in the, you're not listing it as risk
12 adjustment, checking adjustment, as far as I can
13 see. There are five. And that was not one of
14 them.

15 It was, age, number of co-morbidities,
16 Elixhauser, primary diagnosis on last admission,
17 relationship with next of kin, and the mode of
18 the survey. There was nothing about complexity
19 of the facility.

20 MEASURE DEVELOPER: Okay.

21 CO-CHAIR CELLA: So we're going to
22 continue around. And then you'll have another

1 chance to make comments. But let's go to Jack,
2 subgroup members for now.

3 MEMBER NEEDLEMAN: Okay. So this is
4 one of the measures I found in low level of
5 validity on. And I will, you know, leave it to,
6 you know -- And there were several reasons for
7 that.

8 So, one of them is the intent of the
9 measure, what it's supposed to be measuring, is
10 not clear. So, it's very hard to measure whether
11 it's valid or not.

12 The clearest statement of the intent
13 is in response to Issue 2, which is given the
14 alignment of patient family preferences with
15 treatment is the cornerstone of optimal care.

16 The purpose is to assess family's
17 perceptions of the overall quality that is
18 received. Basically, did we get what we wanted
19 for our family member or friend?

20 And that's okay. Fine. But if that's
21 the face validity, if that, the question asks
22 that, and they get an answer to that. So, on

1 face validity bases it's fine.

2 The risk adjustment model is a mess.
3 There's, you know, they include the facility
4 complexity. They don't include social risk
5 factors, which we know affect responses for
6 surveys like this.

7 They do include the disease complexity
8 when it's not clear to me that, and they have not
9 asserted that it's harder to provide care the
10 family expects for a more complex patient. And
11 therefore, we have adjusted for it.

12 Unless you believe that there's no
13 reason for the patient complexity to be in the
14 risk adjustment. But if they know that it's
15 harder to do that, then they ought to say that.
16 And they haven't.

17 I've got no problem with the face
18 validity. I've got a lot of problems with the
19 construct validity assessment. And they
20 responded to that in their comments. And I'm not
21 convinced.

22 You've got a beta coefficient of .03

1 on a measure that varies by .5 or .15. Anyway,
2 it's a very small proportion of the variance
3 that's explained. If we had an R square, or an R
4 for the correlation it would be very low.

5 And the argument that because we've
6 got a large enough sample to make a very low
7 explanation of variance be statistically
8 significant is not saying you've demonstrated to
9 me that you've actually got a correlation here,
10 which is what construct validity is supposed to
11 be looking at.

12 Given that some families want high
13 levels of intervention at the end of life, and
14 others want low levels of intervention, it's not
15 surprising to me there's a low correlation
16 between whether you prove to satisfaction whether
17 you got high or low.

18 But, and therefore, I don't believe
19 the construct validity measures are terribly
20 important here. I'd go with the face validity.
21 But I don't want the developers to believe that
22 they have demonstrated construct validity with

1 correlations and variance explained that's this
2 low.

3 CO-CHAIR CELLA: Thank you.

4 MEASURE DEVELOPER: Can I respond to
5 that as a developer? Or do I have to --

6 CO-CHAIR CELLA: Yes. No, go ahead.

7 MEASURE DEVELOPER: I would argue that
8 in fact the point of construct validity is not in
9 the effect size, which is something that it seems
10 that there's a primary concern.

11 It's in the direction of the effect,
12 and whether that direction is, we can rule out is
13 that direction driven statistically by chance
14 alone.

15 So, I think in fact we do establish
16 construct validity, in that the direction of
17 effect is, follows theoretically plausible
18 directions. And it's statistically, it rules out
19 chance as the key driver behind that.

20 Now, whether it's a huge effect or
21 not, that's a, to me a different question than
22 getting at, you know, what I think of as

1 construct validity.

2 You know, we approached it, our, the
3 nature of these linkages in directions that we
4 might expect based on theory and prior empirical.
5 And that was the goal. And not necessarily that
6 these are the, you know, we're getting R squares
7 of .8.

8 And these are defined as exploring the
9 great deal of the variability. It's more, if you
10 believe these things are appropriately related in
11 construct validity as established, you would
12 expect a positive relationship, and ruling out
13 chance as a cost.

14 CO-CHAIR CELLA: Thank you.

15 MEASURE DEVELOPER: And that was our
16 thinking behind it.

17 CO-CHAIR CELLA: Thank you. Sherrie.

18 MEMBER KAPLAN: Yes. Following up on
19 that I just, I have another concern. But what
20 constitutes a clinically meaningful difference?

21 Statistically significant differences
22 can be had for a variety of reasons. It does not

1 always need to be clinically meaningful. And so,
2 small differences between facilities by two to
3 three percent in the between facility process
4 measures, with and without failing of services,
5 for example, to me isn't a real compelling
6 argument, even though the direction is correct.

7 So, I'm a little bit push back on this
8 kind of call of, as long as it's statistically
9 significant and positive, which is good.

10 My concerns are two. One is, the
11 magnitude of the response rate varies so
12 substantially by facility, between 29 and 73
13 percent, with about an average of 48 percent
14 response rate.

15 And then, when you look at that,
16 waiting for the non-response rates changed the
17 facility score by more, well, about a quarter of
18 a standard deviation for about a third of the
19 facilities.

20 So if, that's kind of a really
21 important issue. And it brings up the issue of
22 selection bias as a potential concern, given the

1 patient characteristics between non responders
2 and responders. So, that's question number one.

3 And then, question number two. On
4 Figure 2, when you looked at the facility level
5 variation in the bereavement survey, what I would
6 have like to have seen was some standard error
7 bars on that.

8 Because that looks like, between
9 facility differences, okay. You can't really
10 look at between facility differences if you
11 looked at the standard error bars.

12 But one could argue that you could
13 look at the top and the bottom quartile, for
14 example. And those would be substantially enough
15 different from each other.

16 So, you could make the case for using
17 it, rather than discriminating individual
18 facilities one from another, discriminating the
19 top and the bottom quartile. So, could you kind
20 of address those two issues? The issue of the
21 real missing data, you know, on response issue.

22 And then, the issue of this, could you

1 put standard error bars on Figure 2, and give us
2 some evidence that there's some compelling
3 differences here? At least interpretable
4 differences between quartiles?

5 MEASURE DEVELOPER: Yes. I don't
6 think standard error bars are an issue that we,
7 you -- Yes, we could add that to that table. And
8 then, the non response bias adjustment, and the
9 selection bias. Josh, would you be able to
10 respond to that?

11 MEASURE DEVELOPER: Well, it, yes.
12 The reason, I think what we're, we're always
13 facing the potential for selection bias due to
14 non-response in, you know, in all of our work.

15 We do a non response adjustment. And
16 we, you know, it's only as good as the variables
17 that you have in your dataset that might be
18 driving non response, the selection.

19 In this case we happen to have a very
20 rich dataset, because we know a lot about the
21 veterans before. So, you know, we're not relying
22 on just the basic demographics for our non

1 response adjustment.

2 But we have all of their clinical
3 administrative data that I think that we can.
4 And we could go to that non response adjustment.
5 So, I think that we provide a pretty rich set of
6 variables to, you know, I think.

7 Again, we can only adjust for what we
8 measure here. But we have more measures than our
9 typical for surveys of this kind, to adjust for
10 potential bias and non-response.

11 CO-CHAIR CELLA: Thank you. Jack.

12 MEMBER NEEDLEMAN: Yes. I do not want
13 to get into an extended argument with the
14 developers about this. But I will simply say
15 that as a voting member of the Committee, my
16 attitude is, sign is not sufficient.

17 Magnitudes matter. That at least if
18 you're trying to argue construct validity, I'm
19 not looking for R squares of .8. I've considered
20 construct validity demonstrated with Rs, where
21 it's well below that. But here the R square is
22 really low, as measured by the coefficient.

1 And frankly, all the measures of
2 patient, and even sign is hard to interpret. All
3 the measures of appropriate end of life care
4 basically are built around doing less, when it's
5 not going to have any effect on the patient,
6 other than torturing them.

7 And I agree with them. But if you
8 have in the VA a substantial number of families
9 that wanted more intensive care, and they got it
10 at the end of life, you would have the wrong
11 side, as they've interpreted it, on this
12 coefficient, because more was better. While the
13 other measures of good care say less is better.

14 So, sign is not sufficient. I do
15 think the magnitude of the, if you're going to
16 argue correlated, correlation proves, validates
17 the measure, you've got to have some correlation
18 at an appropriate level. And this one doesn't.

19 So again, on the face validity I've
20 got no problem with the measure. It's the other
21 measures that are here, partly driven by the need
22 by NQF to have some other measure beyond face

1 validity, that has led to the inclusion here of
2 these measures.

3 I am still concerned. So that, I just
4 wanted to get that on the record. And I do have
5 concern about both the risk adjustment model, and
6 how low response rates are being handled in the
7 adjustment.

8 CO-CHAIR CELLA: Now, I think -- Okay.

9 MEASURE DEVELOPER: Can I get a
10 follow-up on more specific, on what are your
11 concerns specifically about the non response
12 adjustments?

13 MEMBER NEEDLEMAN: Well, it's just a
14 matter of how it's, you know, it introduces a
15 substantial level of potential bias in the
16 results. And you're handling it through a
17 propensity model, which I'd like to, you know, I
18 think is okay. But I'm not sure I've gotten
19 enough data to fully assess it.

20 CO-CHAIR CELLA: Okay. Christine?

21 MEMBER TEIGLAND: Yes. I just want to
22 make another quick comment about the social risk

1 adjustment. And taking your logic, you know, to
2 the factors that you did adjust for, are you
3 saying that you can excuse for age for old
4 people? Because you did use that as a risk
5 adjuster.

6 MEASURE DEVELOPER: I thought, would
7 you --

8 MEMBER TEIGLAND: Age.

9 MEASURE DEVELOPER: Age? Sure.

10 MEMBER TEIGLAND: Yes. Why use age,
11 but not race, ethnicity? Yet --

12 (Simultaneous speaking.)

13 MEASURE DEVELOPER: Yes. Age being a
14 very good proxy for clinical complexity. It's
15 not a perfect proxy. But age being a very big
16 risk factor for --

17 MEMBER TEIGLAND: But do you have --

18 (Simultaneous speaking.)

19 MEASURE DEVELOPER: -- and that's the
20 complexity.

21 MEMBER TEIGLAND: Do you have co
22 morbidities for, and primary diagnosis?

1 MEMBER NEEDLEMAN: So, since you
2 didn't say --

3 MEASURE DEVELOPER: Correct. And,
4 right. And age in addition to those.

5 MEMBER NEEDLEMAN: Okay. You didn't
6 say it in any of your documentation. Is your
7 argument that it is inherently harder to satisfy
8 people, families in end of life care when the
9 patients are more clinically complex? Because
10 that's what's implied in your risk adjustment
11 model.

12 MEASURE DEVELOPER: I think we need to
13 think about that. So, yes, I think --

14 MEASURE DEVELOPER: Yes. VA hospitals
15 vary on the clinical complexities, based on the
16 hospital.

17 MEMBER NEEDLEMAN: Yes.

18 MEASURE DEVELOPER: And it is harder
19 to, yes, it can be more complicated. So it
20 isn't, what you're arguing is correct. We are
21 saying that implicitly we mean it explicitly.

22 They have, the more that is being

1 done, the more acute the care up to the point of
2 death, is a potential risk factor for being less
3 satisfied with end of life care, versus if it's a
4 required hospice death.

5 CO-CHAIR CELLA: Okay. Thank you.

6 MEASURE DEVELOPER: We could make that
7 more --

8 CO-CHAIR CELLA: Thank you.

9 MEASURE DEVELOPER: -- and actually
10 back the --

11 CO-CHAIR CELLA: Thank you. We're
12 going to open it up now to the full Committee.
13 And I'm going to ask the developers, if there's
14 more than one full Committee response or comment,
15 please take notes, and have one response at the
16 end.

17 So, let's go around and see how much
18 we have from other people, and then have one
19 response back from the developer. Okay? Go
20 ahead.

21 MEMBER GLANCE: Quick process issue,
22 Karen. When I try to bring up the source

1 documents on the web page, most of them give me
2 an error, the PDF documents. So, it becomes very
3 difficult to sort of like look, you know --

4 CO-CHAIR CELLA: Look at it while
5 we're talking?

6 MEMBER GLANCE: Yes, exactly. So,
7 that may be something we can fix. A couple of
8 things. You know, I think when you're evaluating
9 score level validity, risk adjustment really is
10 central to doing that. Because you're looking at
11 predictive validity.

12 It would be very difficult to look at
13 construct validity. Because you're trying to
14 compare one concept to another concept. You're
15 not really sure how well, you know, if there's a
16 really good argument, that they're correlated or
17 not.

18 But at the end of the day if you can,
19 if you have risk adjusted measure, and it has
20 good predictive validity, meaning that the
21 statistical model used for risk adjustment, if
22 it's a logistic regression model, has good

1 discrimination, has good calibration, then you
2 have a way, in a sense, of looking at, of
3 predicting what the outcomes for a particular
4 patient should be, conditional on their risk
5 factors.

6 And then, if you have that for all the
7 patients that a hospital treats, then you can
8 compare the observed and the expected. And I'm
9 really over simplifying things. Because there
10 are different ways of doing this. It doesn't
11 have to be an O to E ratio. It can be a P to E
12 ratio.

13 But anyway, the point is, at the heart
14 of score level validity is predictive validity.
15 Okay? So here, what I'm not hearing very much
16 about is, how well does this risk adjustment
17 model perform?

18 And I couldn't get, it looks like the
19 outcome is binary, right? So, I assume that this
20 is a logistic regression model? What was the C
21 statistic for the model? What was the HL
22 statistic? What did the calibration graph look

1 like? Did they do this in a validation dataset,
2 independent from the development dataset? That's
3 my first question.

4 The second one is with regards to
5 whether or not we should be adjusting for
6 clinical complexity. That's really an empiric
7 question. Whether or not this is important or
8 not, you'll see it from the data. You'll see it
9 from the risk adjustment model itself.

10 And then, the third comment I would
11 make is, as we talk about reliability, or score
12 level reliability today, I think there are lots
13 of different ways of doing this. And something
14 that we've talked about extensively at our
15 meetings.

16 Okay. I'll look at it. But one of
17 the ways is to look at the signal to noise ratio.
18 Another one is to do split sample test, retest.
19 A third measure, and I think that, you know, this
20 is where it gets a little confusing, and I don't
21 think it should be used to look at score level
22 reliability.

1 Is when you construct a hierarchical
2 model or a mixed effect model, and based on that
3 model itself you calculate the intraclass
4 correlation coefficient. And that's a very, it's
5 very, very different from the ICC that we
6 calculate when we do the split sample test
7 retest.

8 And so, that ICC, the latter one where
9 you're looking at just the intraclass correlation
10 coefficient, based on the mixed effect model,
11 it's not what we should be looking at, to look at
12 reliability. Okay.

13 When we talk about the signal to noise
14 ratio, based on hierarchical modeling, what we're
15 doing is essentially we're looking for the signal
16 portion. We're looking at the variance for all
17 the provider effects.

18 And then, for each provider we're
19 dividing it by the noise for that individual
20 provider. And then, that gives us a signal to
21 noise ratio for each provider. And then, over
22 the entire sample we look at the median. And

1 that gives us the signal to noise ratio.

2 I mean, I don't mean to spend too much
3 time. But I think this is really important.
4 Because these issues are going to come up over
5 and over again.

6 So, I guess my questions for the
7 developers is, can you tell us a little bit about
8 the performance of the risk adjustment model?

9 And can you tell us how you went about
10 looking at reliability? Whether it was signal to
11 noise, or was it split sample test retest
12 approach? But how you did that, and what the
13 results were.

14 MEMBER KAPLAN: Can I intervene?
15 Because this is going to get us into a tangled
16 discussion about what NQF is going towards, and
17 where NQF is providing guidance now.

18 Because when they did that in the 18
19 submission, the 125.18 submission, the ICCs
20 turned out very low reporting for --

21 MEMBER GLANCE: But how did they --
22 (Simultaneous speaking.)

1 MEMBER KAPLAN: As far as I can tell
2 they did it the correct way, Larry. And if that
3 --

4 MEMBER GLANCE: Did they do a signal
5 to noise ratio?

6 MEMBER KAPLAN: They did. And when
7 you include that extra denominator term the
8 variance between facilities is not, versus
9 within, across patients within facilities, it
10 probably is, that's going to get us into a more
11 complicated discussion about the magnitude of
12 that ICC, the ruling set going forward is.
13 Because --

14 MEMBER GLANCE: But, but --

15 MEMBER KAPLAN: When people have done
16 it the right way with HCAHPS, it turns out
17 exactly --

18 MEMBER GLANCE: But --

19 MEMBER KAPLAN: -- the same way. It's
20 very low.

21 CO-CHAIR CELLA: Let's park that.
22 We'll hope to have time at the end of the meeting

1 for --

2 MEMBER KAPLAN: But the risk
3 adjustment thing --

4 CO-CHAIR CELLA: Let's --

5 MEMBER KAPLAN: -- is Larry's
6 question.

7 CO-CHAIR CELLA: Let's keep the focus
8 now on what developers of this measure need to
9 answer, which, and you've asked three questions,
10 Larry.

11 Are there any other comments from
12 anyone on the Committee? Or we'll turn to the
13 developer for their final comments. Okay. So,
14 that's it. So, back to the VA developers. If
15 you could respond to Larry's questions?

16 MEASURE DEVELOPER: I mean, we have
17 published our risk adjustment method. And we
18 provide these statistics, and the calibration,
19 and things like that. So, I would just have to,
20 I would just need some time to pull up that
21 publication and send all that data.

22 MS. JOHNSON: I can tell you what it

1 is. And I don't know if it's too late for you
2 guys to pull it up or not. See statistic --

3 (Simultaneous speaking.)

4 MS. JOHNSON: .535. They also did a
5 EP information criterion, 36128.58. And for
6 calibration they did Hosmer-Lemeshow. And got a
7 P value of .1827.

8 CO-CHAIR CELLA: What's the sample
9 size, Karen?

10 PARTICIPANT: Small.

11 MS. JOHNSON: Good question.

12 PARTICIPANT: Oh, wait a minute. You
13 have 146? So, it would be a level of --

14 MS. JOHNSON: Sample size, I don't --

15 PARTICIPANT: You can figure two for--

16 MS. JOHNSON: Yes, 146.

17 PARTICIPANT: That's really small.

18 MS. JOHNSON: 146 facilities.

19 (Off microphone comment.)

20 CO-CHAIR CELLA: Any final comments
21 from the developers?

22 MEASURE DEVELOPER: I do just want to

1 say in our case model for, I think there was a
2 concern about the primary diagnoses that were
3 associated with the system performance measure.

4 And then, in our prior work we have
5 shown that, you know, that certain diagnoses, you
6 know, that are associated with the performance
7 measure.

8 And so, those are, that's the reason
9 why we include that principle diagnosis in our
10 case risk adjustment model, and why it's even
11 more important when you're making facility level
12 comparisons.

13 When you have higher proportion of
14 patients such as with cancer, for example, and we
15 know that cancer is associated with the
16 performance measure, you're going to want to
17 include that in your risk adjustment model. So,
18 I just want to point that out.

19 CO-CHAIR CELLA: Thank you.

20 MS. JOHNSON: And, John, this --

21 MEASURE DEVELOPER: And just -- Oh, go
22 ahead. Sorry.

1 MS. JOHNSON: Sorry. This is Karen.
2 Just one more question. I think we still are a
3 little confused. You did say that you do take
4 into account the low versus high complexity.

5 We just don't know how you're doing
6 it. Because it wasn't one of the five risk
7 factors that you mentioned. And you said you did
8 a non response adjustment. So, did you just mean
9 to say you had six risk factors? Or are you
10 doing it some different way?

11 MEASURE DEVELOPER: We just meant we
12 just excluded it. But mistakenly excluded the
13 variable complexity level in our original
14 submission.

15 MS. JOHNSON: Okay. So, it should be
16 six factors, not five?

17 MEASURE DEVELOPER: Correct.

18 (Off microphone comment.)

19 MEASURE DEVELOPER: And we also, with
20 our statement that we submitted last week, we do
21 say that we tried to follow other NQF endorsed
22 surveys for choosing our risk factor variables.

1 And we included a reference in our response.

2 But the CAHPS, I guess that
3 methodology, we tried to follow that as closely
4 as possible with the variables that we had
5 available to us.

6 And race, ethnicity, which is one of
7 the social risk factors we all were very
8 concerned about, was not included in that CAP
9 adjustment methodology.

10 MEASURE DEVELOPER: Yes.

11 PARTICIPANT: Got it.

12 MEASURE DEVELOPER: Yes. And that's
13 in direct, there's a reference that we included
14 in our response. It's a direct link to AHRQ
15 guidance on making adjustments to healthcare
16 quality for us.

17 And so, we followed that guidance as
18 closely as possible. And those were where they
19 said, you know, include age. Co-morbidities,
20 those are a good idea. But it's not considered
21 appropriate in most circumstances for other
22 socio-demographic characteristics, such as race

1 and ethnicity.

2 Because again, for the reasons that we
3 laid out in our response, that would essentially
4 bury information that could reveal what we might
5 think is unacceptable disparities. So, we
6 followed AHRQ's guidance on the--

7 MEMBER TEIGLAND: Can I respond to
8 that? AHRQ uses race, income, education to risk
9 adjust all of their CAHPS measures, which are
10 survey based measures, which are listed. So, I
11 disagree. I think you misinterpreted it.

12 MR. CARTER: Patrick, do you have a
13 comment? Thank you, Christine.

14 MEMBER ROMANO: Yes. I was just going
15 to point out that education is explicitly
16 included in all the CAHPS risk adjustments. So,
17 I'm not sure that race ethnicity is--

18 MEMBER TEIGLAND: It is.

19 MEMBER ROMANO: But certainly
20 education is. And it's been well validated as a
21 measure that is predictive of scores on these
22 types of instruments. So, I don't know if that's

1 something that was outside the realm of the
2 developers's success. But certainly --

3 MR. CARTER: Can I --

4 CO-CHAIR CELLA: Okay.

5 MEASURE DEVELOPER: Yes.

6 Unfortunately education is not a valid variable
7 as corrected in the VA in the patient's medical
8 records.

9 CO-CHAIR CELLA: Okay. Thank you to
10 the developers. I think we have no other
11 comments or questions. Yetunde will set up the
12 Poll Everywhere for the subgroup members to vote.
13 And everyone else, SurveyMonkey.

14 And while we are doing this we are
15 going to start our compressed ten minute break
16 right now. So, because we're --

17 (Off microphone comment.)

18 CO-CHAIR CELLA: -- falling behind
19 even more. And we're going to, we're determined
20 to catch up. So take, make your vote, and take
21 your break. And we'll be back in ten minutes.

22 MS. WILBON: So, I think we're

1 actually going to take our lunch early.

2 CO-CHAIR CELLA: Oh.

3 MS. WILBON: We're --

4 (Laughter.)

5 MS. WILBON: So --

6 CO-CHAIR CELLA: All right. I had a
7 different plan to, I'm meeting with Sherrie and
8 Dave, and we're going to -- Go ahead.

9 MS. WILBON: Oh, okay. Sorry if I'm
10 --

11 CO-CHAIR CELLA: We have to eat now?

12 MS. WILBON: Well, they're getting
13 lunch ready for us.

14 CO-CHAIR CELLA: Yes.

15 MS. WILBON: I think they'll be ready
16 for us very shortly.

17 (Off microphone comment.)

18 MS. WILBON: If everyone has submitted
19 their vote, do we read the results?

20 PARTICIPANT: I haven't even started
21 yet.

22 MS. WILBON: Oh, okay. So, once we do

1 that, I think by the time we get everyone's
2 votes, get the results on record, we'll release
3 everyone for lunch.

4 We may need a couple of minutes,
5 because we are a little bit early to give our
6 support staff an opportunity to get the lunch
7 ready. But let's take a 30 minute break for
8 lunch when we do that.

9 We do also need to go out for public
10 comment. And I do think there has been a couple
11 of comments that have come in through the chat
12 feature, that we want to address. I think by the
13 time we do that we actually may be on track to go
14 to lunch around 12:30 p.m.

15 PARTICIPANT: Yes.

16 MS. WILBON: So, if you guys would
17 just bear with us a bit, I think for, you know,
18 powering through the morning, we'll try to get
19 ourselves back on track this afternoon. So --

20 CO-CHAIR CELLA: : So, what are we
21 going to do between now and 12:30 p.m.?

22 MS. WILBON: We're going to vote.

1 We're going to do public comment.

2 CO-CHAIR CELLA: : Public comment's at
3 12:30 p.m. We can do it early?

4 MS. WILBON: Yes. We'll do it a
5 little early.

6 MS. OGUNGBEMI: All right. So, we are
7 now voting on 1623, the overall rating of
8 validity. Your options are high, moderate, low,
9 and insufficient. We are looking for six votes
10 of the subgroup panel members, and the full
11 everywhere. And the shadow vote can come from
12 the SurveyMonkey.

13 MS. JOHNSON: So, subgroups are
14 Sherrie, Zhenqiu, Jack, Jen, Christie, Terri.
15 Everybody else will be SurveyMonkey.

16 MS. OGUNGBEMI: So, we have five
17 participants.

18 (Off microphone comments.)

19 MS. OGUNGBEMI: So, we have zero votes
20 high, 20 percent moderate, 80 percent low, and
21 zero insufficient. So, the measure fails
22 validity.

1 MS. WILBON: So, let's take this,
2 hopefully everyone else has submitted their
3 shadow vote via SurveyMonkey. Thank you for
4 doing that.

5 And at this time we'll open it up for
6 public comment to those in the room. Okay. Is
7 there anyone on the phone who would like to make
8 a comment? And we'll also be checking our chat
9 box, to see if there's any other comments that
10 have come in for the Committee to consider. Do
11 we need to open up the lines?

12 MS. OGUNGBEMI: No. They're already
13 open.

14 MS. WILBON: Okay. If you are on the
15 phone, and you'd like to make a comment, please
16 just unmute yourself. Or send a chat if you're
17 not able to get through.

18 MEASURE DEVELOPER: Is the public
19 comment open to everyone, including the
20 developers? Or is that section over?

21 MS. WILBON: Sure. You can make a
22 comment.

1 MEASURE DEVELOPER: Okay. I just
2 wanted to make a basic comment that it seems,
3 just based on the discussion on 1623 that we just
4 had, that all of the panel members may not have
5 seen the most updated testing attachment, or at
6 least evaluated it thoroughly, in addition to our
7 response to their concerns.

8 So, I guess I just, it just seemed
9 like, from the conversation that we just had,
10 that we've already answered those questions. And
11 a lot of people weren't aware.

12 MS. JOHNSON: So, this is Karen from
13 NQF. We did make sure that the panel knew and,
14 yes, Christie is nodding her head. They did see
15 the most recent one, and your comments. And as a
16 matter of fact, in the discussion guide that we
17 made available we have it in there as well. And
18 --

19 MEASURE DEVELOPER: Okay.

20 CO-CHAIR CELLA: I think, just to say,
21 I mean, as Chair, that discussion, I think what
22 we heard was a difference of, was disagreement,

1 difference of opinion, and not lack of
2 information.

3 MEASURE DEVELOPER: Okay.

4 MS. WILBON: Any other public
5 comments?

6 (Off microphone comment.)

7 MS. JOHNSON: Okay. One quick
8 question before we let you guys go for break. We
9 didn't set up a formal dinner tonight. Would any
10 of you, and if so, how many of you would be
11 interested if we set up a dinner at a local
12 restaurant?

13 Would you, is this something you'd be
14 interested in going to? Or do you have your own
15 plans for tonight, and really don't care what the
16 rest of us --

17 MS. WILBON: If so, raise your hand --

18 MS. JOHNSON: Yes. Raise your hand --

19 MS. WILBON: -- so we can see how many
20 people --

21 (Simultaneous speaking.)

22 MS. WILBON: -- to make a reservation

1 for.

2 MS. JOHNSON: One, two, three, four,
3 five, six, seven, eight. Eight?

4 CO-CHAIR CELLA: Good group. Good
5 crowd.

6 MS. JOHNSON: Okay. Okay. We will
7 set up something tonight for those of you who
8 want to go. We'll make it for eight, or ten, or
9 12. So, there will be a little room if somebody
10 changes your mind. Thank you. Thirty minutes?
11 Come back at --

12 MS. WILBON: Yes. Let's come back at
13 --

14 MS. JOHNSON: 12:50 p.m.?

15 MS. WILBON: Ten til.

16 CO-CHAIR CELLA: Okay. Let's say a
17 quarter til. So, you really, we really start at
18 ten til.

19 MS. JOHNSON: We're shooting for
20 quarter til. Yes.

21 CO-CHAIR CELLA: Sherrie, can you meet
22 with Dave and me for just a sec?

1 MEMBER KAPLAN: Sure.

2 CO-CHAIR CELLA: Thanks.

3 (Whereupon, the above-entitled matter
4 went off the record at 12:19 p.m. and resumed at
5 12:51 p.m.)

6 CO-CHAIR CELLA: So here's our catch-
7 up strategy, which is going to -- we're going to
8 succeed. Know it already. The measure
9 developers, NCQA, are here joining in the
10 discussion. We are talking -- we're going to
11 talk about three measures: 0575, 0059, and 0061.

12 And we're not -- they all passed, so
13 we're not necessarily going to revote here. It
14 was voted forward for discussion. Sherrie's
15 going to lead that -- or Jack will have something
16 to say, but Sherrie was the person -- I'm sorry
17 if I outed you, Sherrie. I wasn't supposed to.
18 But wanted to discuss something and it probably
19 does not have implications about the vote itself.

20 So, Sam is going to start, lead us off
21 by talking about the three measures, give a
22 little background, and then we'll hear from

1 Sherrie and Jack and then have a discussion.

2 MEMBER SIMON: Very good. Thanks,
3 Dave. I'm going to use my outside voice so
4 everybody can hear me, I hope.

5 So, just a couple of things to
6 highlight. So Measure 0575, which you'll see
7 here on the screen, comprehensive diabetes care.

8 Just want to briefly go over the
9 measure descriptions. This is the percentage of
10 patients ages 18 to 75, this page, with either
11 diabetes Type 1 or Type 2 whose most recent HbA1C
12 level is less than 8 during the measurement
13 period.

14 So this measure incorporates a number
15 of data sources, both claims using prescription
16 claims or otherwise, HR data, electronic health
17 records, as well as paper medical records.

18 So when this initially reviewed by the
19 panel, we got a pass, as was mentioned, both for
20 reliability and validity, which were ranked, on
21 the aggregate level, as moderate. Next slide,
22 please.

1 And you'll notice this companion
2 measure was similar. So, this is 0059,
3 comprehensive diabetes care, HbA1C poor control,
4 which would be greater than 9. So this is simply
5 a percentage of patients from the same age group
6 category, 18 to 75, with diabetes Type 1 or 2
7 that were above 9 percent.

8 It follows a comparable pattern. In
9 terms of the data sourcing, it's exactly the
10 same. And it achieved moderate ratings on both
11 reliability and validity in the aggregate voting.

12 And lastly, Measure 0061,
13 comprehensive diabetes care blood pressure
14 control, less than 140 over 90. Same patient
15 categories, similar numerators and denominators
16 in terms of the structure, but this time we're
17 looking at blood pressure being less than 140
18 over 90. The reliability and validity rankings
19 in aggregate were moderate and high,
20 respectively.

21 I just wanted to mention that the
22 reliability and validity testing was very

1 comparable between these three measures, but the
2 reliability testing, they used the traditional
3 methodology outlined by Adams with a signal-to-
4 noise beta-binomial methodology. And for the
5 validity testing we're looking at correlations
6 between the measure of interest and four or five
7 measures of a comparable quality domain using
8 Pearson correlations between them.

9 I'll go ahead and hand it over to
10 Sherrie, at this point, to discuss further.
11 You're up, Sherrie.

12 MEMBER KAPLAN: So this is not for
13 immediate voting purposes, just to reiterate,
14 because the measure's already passed. This is a
15 sort of opportunity, I'd think, for NCQA and NQF
16 to kind of lead the way in maybe improving the
17 way we're thinking about these kinds of measures.

18 In I believe it was -- or, I forget,
19 1990-something or other, NCQA had this provider
20 recognition program going, and they looked at,
21 and we looked at with them, 210 physicians and
22 7,400-odd patients and actually started to look

1 at what it would take to get a provider level
2 estimate of quality for diabetes care.

3 As Daniel and I were discussing, all
4 measures have measurement error. Glycemic
5 control, I mean, hemoglobin A1C has measurement
6 error. Blood pressure has a lot of measurement -
7 - lipid level measurement error.

8 Well, when you start thinking about
9 these kinds of measures at the patient level,
10 most of them is not considered when you're sort
11 of thinking about the dichotomy. You're either
12 over or under the hemoglobin A1C value of 8
13 percent. You're either over or under the value
14 of this.

15 But there's error associated with
16 this. And when we dichotomize like that, we
17 don't think about that category in the middle
18 where there is measurement error. So we don't,
19 beyond these thresholds, we don't put a
20 confidence interval, for example, to take into
21 account measurement error at this level.

22 Well, what NCQA and we were able to do

1 at that point, and this is like from 2000-and --
2 it was published in 2009, so I think I'm beyond
3 the seven-year where they may have been a
4 conflict of interest. But this is the kind of
5 thing where, when thinking about these kinds of
6 dichotomous measures, if they're all measuring
7 the same thing, diabetes quality, this is an
8 opportunity.

9 One of the ways to improve precision
10 is to measure more things about the patient. We
11 do that naturally when we do CAHPS surveys and
12 other kinds of surveys. We add up different
13 things that are supposed to be measuring the same
14 concepts. This would be an opportunity to create
15 a composite construct where you could actually --
16 because at the patient level this is dichotomous.
17 It's either zero or one.

18 You can't really think about finding
19 the partition variance associated with patient
20 level of error because it's zero-one. But if you
21 created an index, you're either zero-one on this
22 measure. You're at zero-one on the lipid

1 measure. You're zero-one on the glycemic control
2 measure.

3 They're all measuring diabetes
4 quality. You could create a composite that then
5 you could estimate the patient level variance on.
6 So when you're comparing between --

7 (Simultaneous speaking.)

8 CO-CHAIR CELLA: Hello? Is someone
9 trying to talk on the phone? Go ahead.

10 MEMBER KAPLAN: Anyway, so when you're
11 comparing between plans on diabetes quality, you
12 could actually look at the valid patient level
13 variance and between-plan variance and get more
14 of an estimate of how good the diabetes quality
15 is across measures of what you think is the same
16 thing.

17 So this little diatribe was more on
18 the lines of going on from where we are in
19 helping us consider how you'd consider working
20 forward to look at plan performance with that
21 standard error var around patient level variance
22 within plans, you know, across these measures and

1 so on, and really think more broadly about can we
2 improve precision for the purpose these measures
3 are now being put to, which is discriminating
4 between different plans?

5 So that was my bid. Did I make it,
6 Dave?

7 CO-CHAIR CELLA: Great. Thank you.

8 MEMBER KAPLAN: For a moving forward
9 argument.

10 CO-CHAIR CELLA: Jack, did you want to
11 make a comment since you're a reviewer for the
12 first one?

13 MEMBER NEEDLEMAN: Yeah, I actually
14 rated this one insufficient, my first one. And
15 it's not because I don't think the measure has a
16 lot of positive things about it. There were two
17 issues that I think NCQA needs to think about as
18 they move measures forward.

19 One of them is they clearly have some
20 method of treatment of missing data. It did not
21 get clearly explained. My understanding of the
22 NCQA process is the plans implement the measure

1 and send summary statistics up to the NCQA.
2 That's different from CMS which is running it all
3 through their claims databases so they have a lot
4 of control over the way the analysis is done and
5 the risk adjustment is easy.

6 So, missing data is supposedly dealt
7 with. I would like to know how on the next set.
8 I'd like to know how on this one, actually.

9 But the other thing is the risk
10 adjustment. And they did not do any -- they did
11 stratification by plan size. So the Medicaid
12 plans are looked at together. The privately
13 insured plans are looked at together. And
14 there's a fair amount at SES discrimination and
15 just by the type of plan, but I'm not sure it's
16 enough.

17 And NCQA argued that site-to-site
18 without any detail showed no variation and
19 appropriate care within the plans by SES, and
20 implied that meant no need for SES adjustment.

21 But the other argument for SES
22 adjustment is that things outside of the control

1 of the providers are influencing outcomes. So,
2 the lack of ability to exercise, or limitations
3 in your neighborhood related to food
4 availability, might well influence the ability of
5 a patient with diabetes to control their
6 diabetes. And that will be differential by
7 neighborhood, not because of anything the
8 providers are doing. Quite the contrary.

9 The usual argument against SES
10 adjusting is you don't want to let the providers
11 off the hook for poor performance with
12 populations. But here the issue is there may be
13 some elements of the neighborhood or family or
14 work circumstances of patients in different SES
15 status that influence the outcome that are
16 outside, truly outside the control of the plan.

17 And so I am not completely convinced
18 that that's the case as plans move to more
19 population health initiatives. But I do think
20 that the simple dismissing of the need for SES
21 adjustment beyond the stratification by plan size
22 is a little facile. It makes it easier for the

1 plans because NCQA doesn't have to give them a
2 risk adjustment model to apply in their data
3 analysis.

4 OPERATOR: I'm sorry. There's been an
5 internal error. You will be disconnected now.

6 (Laughter.)

7 (Simultaneous speaking.)

8 CO-CHAIR CELLA: Are you really done
9 there or --

10 (Laughter.)

11 MEMBER NEEDLEMAN: No, it's just that
12 -- again, it's the simple issue of it feels to me
13 a lack of risk adjustment in the NCQA measures
14 are driven in part by the fact that the
15 calculations are decentralized to the plans and
16 they try to reduce the complications to the plans
17 to do the analysis. And the rationality here
18 feels a little facile, and I'm not sure it's
19 right. So I'd like to see some more discussion
20 of that with future NCQA measures, even though we
21 passed these ones on this iteration.

22 CO-CHAIR CELLA: So let's go ahead to

1 Christie and then maybe give NCQA a chance to say
2 something. Go ahead, Christie.

3 MEMBER TEIGLAND: I just had two quick
4 comments on that. One is that these are actually
5 medical record reviews, so I think up to 400 is
6 the maximum number of patient records that they
7 pull, because you're not going to find these
8 HbA1C levels in claims data, right? So that's
9 where the data comes from.

10 And I just want to make another point
11 about the lack of risk adjustment for social
12 factors, is that CMS is now actually paying for
13 non-medical benefits, recognizing that if, you
14 know, you live in a food desert it's going to be
15 harder to control your HbA1C, you know, all those
16 reasons. So they're paying for it because they
17 recognize the impact on quality but not yet
18 recognizing the impact on claims.

19 CO-CHAIR CELLA: Okay, so, keeping in
20 mind the context, which is that these passed, and
21 yet Jack has raised an issue, you're welcome to
22 comment on that, particularly if you feel that

1 what Sherrie is suggesting, which is moving more
2 towards some kind of unified composite, can be
3 enabled or perhaps can include down the road some
4 more consideration of social risk analysis.

5 MS. BARTON: Thank you very much,
6 Dave. I'm Mary Barton, Vice President for
7 Performance Measurement at NCQA, and I want to
8 thank Sherrie for that thoughtful set of issues.

9 And I think, you know, there are a
10 couple of composite measures. Of course,
11 Minnesota has one, and then our comprehensive
12 diabetes care, which I think the person on the
13 phone was trying to suggest, is also a composite.
14 It's not exactly a composite, but I think I would
15 like to talk more in the future about how the
16 individual error ties into how a composite could
17 be a better reflection. And I'm curious as to
18 how much this depends on measuring clinicians
19 versus groups versus plans. But I would welcome
20 the opportunity to talk more with you about that.

21 MEMBER SIMON: Excellent. By the way,
22 I wasn't soliciting consultation from NCQA --

1 (Laughter.)

2 MEMBER SIMON: That's not me promoting
3 business. But, so, the idea that, you know, that
4 plan level issues -- the whole nest of
5 environment of the whole healthcare system, it
6 creates problems for us interested in
7 measurement, because at each level there's error.

8 The question is, there are a couple
9 ways to improve the precision that can actually
10 make maximum use of multiple things measuring the
11 same thing. And it actually helps you and
12 reduces the standard error. When you get, you
13 know, the adjustors in right, and all that other
14 stuff, but it really does -- these are the kinds
15 of things that, going forward, people with rich
16 data sets like you have, that many people don't;
17 claims databases don't have that kind of rich
18 data; you can actually test and see at what point
19 a measure becomes more characteristic of a
20 provider or more characteristic of a plan and
21 make adjustments in the kind of performance
22 profile you create using different measures.

1 So it's just an opportunity, I think,
2 to kind of help the whole field move forward in
3 how we're thinking about the attribution of
4 quality measures to a unit of analysis. Thank
5 you.

6 CO-CHAIR CELLA: Well, I'll take you
7 in one second. I apologize. I should have given
8 you the chance to introduce yourselves to us.
9 And I gather there's somebody else on the phone
10 that we heard a little bit from. So just a quick
11 introduction there.

12 MS. BARTON: Oh. Vice President of
13 Performance Measures at NCQA, and I've been in
14 that role for about eight years. And so I just
15 wanted to talk a little bit about the other
16 concern about case management --

17 CO-CHAIR CELLA: Before you do, there
18 are others.

19 MS. BARTON: Oh, I'm sorry.

20 CO-CHAIR CELLA: You're with other
21 people.

22 MR. REHM: Hi. I'm Bob Rehm. I'm the

1 Assistant Vice President for Performance
2 Measurement. I've been with NCQA for nine years.
3 I've been in NQF land for nine years, enjoyed
4 every minute of it. And we have presented,
5 Mary and Dan and I, at almost every standing
6 committee that NQF has pulled together.

7 So, we really appreciate it. This is
8 a great opportunity for us to get feedback and to
9 help us, as we mentioned in the opening comments,
10 to stay ahead of the puck as opposed to chasing
11 it. Thank you.

12 MR. ROMAN: My name is Dan Roman. I'm
13 a director with Performance Measurement. I've
14 been with NCQA for just over seven years.

15 CO-CHAIR CELLA: And there was someone
16 on the phone?

17 (Simultaneous speaking.)

18 CO-CHAIR CELLA: Okay. Go ahead, ZQ.

19 MEMBER LIN: I just had a technical
20 question and I --

21 CO-CHAIR CELLA: Can you speak up a
22 little, ZQ?

1 MEMBER LIN: I just had technical
2 question about your measure, how you determine
3 numerator comprised. So you based on two data,
4 so one's administrative code, one is medical
5 chart review, right?

6 For administrative code, it's okay,
7 based on three categories. For medical chart
8 review, you require a distinct numerical result.
9 So I just wonder why you require a distinct
10 numerical result from chart side, but it's okay
11 from coding side.

12 MR. ROMAN: Sorry, is the question why
13 -- so, the administrative codes we allow for this
14 are CDT Category 2 codes that are specific to
15 HbA1C results that either qualify or don't.

16 MEMBER LIN: Right.

17 MR. ROMAN: And then the results we
18 look for in the record, it's the same set of
19 requirements for what counts or doesn't. I'm
20 sorry, maybe I didn't understand the question.

21 MEMBER LIN: So in a medical
22 information form, say, when you're getting

1 information from medical chart you require, you
2 know, a hospital provide these things in
3 numerical results. So it kind of a different
4 standard when you're getting information from
5 medical chart compared to when you're getting
6 information from an administrative claim.

7 MR. ROMAN: Okay, maybe this is
8 helpful. Before PQRS or before PQRI and now PQD,
9 which is the programs creating these Category 2
10 codes or G codes, quality measures, to make it
11 simpler, primarily for clinicians who would be
12 looking at their A1C of 6.9 or whatever. And
13 then they would code. That would be coded as a G
14 code or a CPT-2 code.

15 So you're right. It's capturing two
16 degrees of separation from the actual lab value
17 for the A1C and the chart, if they did a chart
18 review.

19 The reason -- and it's just a few
20 years ago that we accepted CPT codes. It has a
21 certain -- there's a lack of -- they see this as
22 check-the-box measures, as we agree in part. But

1 on the other hand, clinicians who are involved in
2 the QPT program now -- and many people who record
3 these measures -- they just say it's just so much
4 easier if you'll just give us credits back.

5 So even though these measures are not
6 provider level measures, they are at the health
7 plan, we do accommodate that. We don't get a lot
8 of this, as I understand it, necessarily from
9 that, but it's to accommodate providers' burden,
10 essentially. I hope that helps.

11 MEMBER LIN: Okay.

12 CO-CHAIR CELLA: Any further
13 discussion? Patrick?

14 MR. ROMANO: Yes, hi, Patrick Romano.
15 Obviously, NCQA has been the leader in this field
16 of population health management measures for
17 diabetes, so I have to give NCQA a lot of credit
18 for really developing these measures and
19 maintaining them over time.

20 But, you know, obviously, the bar
21 keeps getting higher as we go through years and
22 years of this process. And I think all of

1 understand that some patients with diabetes are
2 just easier to manage than others. And, in some
3 cases, it's fairly easy to get the A1C down under
4 9 percent, 8 percent. In other cases, it's
5 extremely difficult, and we effectively can't do
6 it within the range of what's tolerable to the
7 patient in terms of medication side effects and
8 medication burden and so forth.

9 And particularly in the Medicaid
10 market, we see -- I don't mean to be critical of
11 plans, but we see that these are very high risk,
12 vulnerable patients. And there are incentives to
13 skim the claim, so to speak, where certain plans
14 cater to patients or enrollees in communities
15 where they have access to more resources, where,
16 frankly, it's easier to manage the diabetes.

17 So I would join with others in
18 encouraging you to consider ways of incorporating
19 risk adjustment into these sort of intermediate
20 clinical outcome measures going forward. You
21 know, if not this cycle, but the next cycle and
22 beyond.

1 MEMBER SIMON: This is like pie-in-
2 the-sky stuff, but as we're considering these
3 kinds of opportunities, there are a broad -- we
4 actually looked at nine measures in the 2009
5 article in Medical Care, nine measures of
6 performance, including did you look in the eyes,
7 did you check the feet, blah-blah-blah-blah-blah.

8 So, a suite of measures that you could
9 then look at the attribution at the plan level,
10 adjusted for whatever risk factors that are
11 reasonable at given units of analysis, and you
12 could actually help the field understand which
13 are right for which purposes and which are not so
14 good for other purposes, and do it empirically in
15 a way that I don't think very many other folks
16 can, because you have market, the medical
17 records.

18 CO-CHAIR CELLA: Well, that was a
19 great discussion. Thank you from our side as
20 well for all the work you've done in this area.

21 So I think we don't have an action
22 item here for this committee. The measure's

1 passed. But we are referring this to NQF and to
2 the Standing Committee to work with you and
3 encourage this kind of enhancing of the measures
4 over time. Thank you for coming.

5 (Simultaneous speaking.)

6 CO-CHAIR CELLA: Then I'll turn it
7 over to Dave N. for the afternoon.

8 CO-CHAIR NERENZ: All right, well,
9 I'll try to continue this run of being on-time.
10 Sherrie, thank you. This was a good way to tee
11 this off, a good way to efficiently discuss it in
12 the context of the three measure. Appreciate
13 that.

14 Okay, so we're actually staying in a
15 similar vein. We are moving now to Measure 0425,
16 if you want to bring that up. This is functional
17 status change for patients with lumbar
18 impairments.

19 I think, again, I might be corrected
20 here by staff, we're in a similar situation in
21 that this has passed, but it was brought up by
22 request of one of the members to discuss a

1 particular point about it. We didn't bundle it
2 with the previous three because it's a different
3 point.

4 So, I wonder, is it worth just a very
5 brief staff flyover this one just so we get all
6 calibrated? But I emphasize brief, because we're
7 not revoting this one again, as far as I know.
8 And then we'll turn to Sherrie as to discussion
9 later.

10 MS. JOHNSON: Hang on. I had confused
11 Bob and Mary and myself completely. Which one
12 are we on? I'm trying to tell them whether they
13 should or shouldn't go. Which one are we on?

14 MEMBER FABIAN: It's a FOTO measure.

15 CO-CHAIR NERENZ: This is a FOTO
16 measure.

17 MS. JOHNSON: Okay. I'm so sorry, yes.

18 CO-CHAIR NERENZ: Sorry about that.

19 MR. STOLPE: No worries. Thanks,
20 NCQA. And Daniel's in the hot seat now.

21 MEMBER DEUTSCHER: Do you want me to
22 sit over there?

1 MR. STOLPE: I think you're probably
2 in a good way now, Daniel. If you'd like to
3 move, you're welcome to.

4 Okay, just some high level overviews
5 per request of the Chair. This is a measure of
6 functional status change for patients with lumbar
7 impairments. But I'd like to read the measure
8 description, because it is a little complicated.

9 So this is a self-report outcome
10 measure of functional status for patients 14
11 years-plus with lumbar impairments. A change in
12 functional status assessment using FOTO lumbar
13 PROM is adjusted to patient characteristics known
14 to be associated with functional status outcome -
15 - that means risk-adjusted -- and used as a
16 performance measure at the patient level, at the
17 individual clinician, and at the clinic level to
18 assess quality.

19 So, this is a PRO-PM. So, as such,
20 the data isn't from an instrument and needs to
21 undergo a little bit more rigorous testing than
22 some of our other quality measures that are

1 brought to NQF for consideration.

2 This was evaluated as high for both
3 reliability and validity. I'll stop shy of going
4 through all of the data elements and score level
5 testing that were performed. But suffice it to
6 say there were many tests that the developer put
7 forward, as well as some fairly robust analysis
8 at both levels for both reliability and validity.

9 And let's go ahead and leave it at
10 that and hand it back over to the lead
11 discussant.

12 CO-CHAIR CELLA: Sherrie?

13 MEMBER KAPLAN: Ready?

14 CO-CHAIR CELLA: Yes.

15 MEMBER KAPLAN: Okay, so I have, first
16 of all, in terms of reliability specs, Section
17 S-6 states that the target population is age
18 greater than or equal to 14; and then S-15 has
19 the inclusion of patients under 8.

20 So, first, can you clarify the measure
21 specifications? Which population are we talking
22 about? Is 14 and over? Or do you actually

1 include both, under 8 --

2 MEMBER DEUTSCHER: Yes, I think we
3 also responded to that in the response to --

4 MEMBER KAPLAN: Oh, and I didn't read
5 it?

6 MEMBER DEUTSCHER: But it's a simple
7 explanation.

8 MEMBER KAPLAN: Okay.

9 MEMBER DEUTSCHER: So I think what's
10 in the specs relates to the general FOTO
11 instructions when using a proxy. Actually, -- so
12 it's not relevant for this measure, in the sense
13 this measure is for patients 14 or above.

14 MEMBER KAPLAN: Okay.

15 MEMBER DEUTSCHER: So we suggested in
16 our response to add a note to that effect, to
17 specify that this relates only to 14 and above,
18 just to avoid this confusion.

19 MEMBER KAPLAN: And we came up on that
20 faster than I was able to scroll down.

21 So the other question I had about
22 reliability -- and this has already passed, so

1 this is not going forward again -- is that when
2 you have multiple items per patient there's a
3 within patient, across items error term.

4 And then you have, when you're folding
5 it up across patients within a unit, you have
6 another error term in the denominator. And then
7 you've got the between -- the signal, between
8 units.

9 So, going forward -- and a I don't
10 think this is part of the guidance yet, so this
11 is not fair -- but going forward, when you've got
12 multiple item measures, that denominator error
13 term has to include the patient across items when
14 there are multiple items.

15 And it will come up in composites, no
16 matter whether it's clinical or these kind --
17 doesn't matter what the source of the data is.
18 Any time you create a composite you're -- if
19 you've got a patient level composite this is a
20 problem going forward in terms of precision and
21 reliability. So, not for this analysis, but for
22 going forward.

1 Then I had another question, and
2 apologies if I missed it, Dan, because I --

3 MEMBER DEUTSCHER: Can I just comment
4 on this before you go ahead? So, for a patient-
5 reported outcome in general, the way the
6 measurement works is, especially when you're
7 using IRT and computerized adaptive testing. So
8 we have an item bank and we do not administer all
9 items to the patients. And there's a provisional
10 estimate after each response. And so we
11 accumulate those provisional estimates, and at
12 the end we have all of these, and we can
13 calculate a standard for measures which is the
14 error associated.

15 One thing I wanted to point out, at
16 least to my view, this is very similar to any
17 measurement based on an instrument, whether it's
18 a patient-reported outcome or not. So I'm not
19 sure if the term composite is the one we want to
20 use for a patient-reported outcome measure that
21 has multiple items.

22 But anyways, as, you know, we

1 discussed just a few minutes ago, when we measure
2 weight there's an associated error. When we
3 measure blood pressure, there's an associated
4 error. So I think your discussion point is
5 relevant for any instrument that takes measure,
6 not specific to a patient-reported outcomes with
7 multiple items on it.

8 MEMBER KAPLAN: Doesn't have to be
9 instrument-based the way the NQF uses instrument-
10 based. It's any measure that uses a composite
11 has associated error. And when you create a
12 composite you just have to keep track of what
13 that's doing to the standard error of measurement
14 at the patient level, and then you fold it up at
15 the next level, across patients within a unit and
16 then between units.

17 And so what I think NQF is going to
18 have to come to terms with is what constitutes
19 the threshold of passing once you consider that
20 level of error that's not really, right now,
21 reflected in the ways that NQF has approved
22 approaching reliability instruments.

1 But when the purpose of measurement is
2 changing, and I know you're agnostic to the
3 purpose of measurement, but when the NCQA's
4 studying them, CMS starts adjusting compensation
5 based on these measures, and the attribution to
6 individuals units hasn't been well tested, I
7 think that's a real caution that we need to
8 express to folks who are using these for
9 different purposes.

10 And that's where -- if you're just
11 using these for quality improvement, you know,
12 okay, we can all accept that there's error. But
13 when you're starting to adjust compensation,
14 that's when these estimates really matter because
15 you've got to be fair about it. And that's where
16 I think it's maybe time to start working with
17 folks who are out there trying to do this the
18 right way.

19 And I think the opportunities here may
20 also exist for FOTO to make some, you know,
21 testing --

22 (Simultaneous speaking.)

1 MEMBER DEUTSCHER: I guess the
2 practical implication would be that, if we add an
3 additional component to that denominator, we're
4 probably just going to have to raise the bar in
5 terms of number of patients assessed to make the
6 measure reliable at the provider level.

7 I mean, from a practical perspective,
8 that's going to be --

9 MEMBER KAPLAN: Well, it depends on
10 whether each patient is giving you unique
11 information. You know, if they're not, then
12 that's not going to help you. But another way to
13 do that is to add more measures.

14 You know, well, maybe the precision of
15 the estimate you can improve by adding more
16 measures. IRT doesn't allow you to do that, but
17 there are kind of other approaches to measurement
18 that do.

19 MEMBER DEUTSCHER: Right. And in this
20 case, I'm not sure if this is an avenue --

21 MEMBER KAPLAN: Right. You know, you
22 got what you got. And to Patrick's point -- can

1 I make one more comment? To Patrick's point,
2 which I, you know --

3 CO-CHAIR CELLA: He stepped out.

4 MEMBER KAPLAN: So I'll make this in
5 his absence. To Patrick's point, you know, we
6 don't test the attribution, the amount of the
7 variance explained. We actually did that in a
8 2009 article within the NCQA.

9 The attribution, at what point a
10 measure in a value-driven analysis becomes more
11 explained by patient level variation versus the
12 unit, the doctor variation, for example. We did
13 test that, and the hemoglobin A1C value came out
14 8, and the LDL came out 120. And so we fed that
15 information back into NCQA and said, here's what
16 it looks like when you actually test this.

17 We can empirically test this for most
18 continuous level variables. Now, why wouldn't
19 you do that kind of analysis, too? There are
20 opportunities that folks have out there to begin
21 to understand these thresholds and what they mean
22 if you're going to use the measuring not for

1 taking care of patients, but actually for
2 attribution for performance.

3 Those are different purposes when
4 they're tested for patient care and empirical
5 data guidelines and so on, but they're not tested
6 on quality.

7 CO-CHAIR NERENZ: I just have
8 clarifying and vocabulary question, mainly for
9 Sherrie. It's about the word composite. And I
10 want to make sure we're all on the same page,
11 because I'm not sure I'm hearing it the same way.

12 My understanding of the word composite
13 as used in this room is that there are two or
14 more measures that have standing as measures.
15 They may even be endorsed in their right. And
16 they are combined, then, in some mathematical way
17 to create a composite. So a composite is the
18 combination of two or more measures.

19 Now, in this discussion, I'm not
20 hearing that. The FOTO is a measure -- or this
21 measure using that scale. There are a number of
22 survey items, but they are not measures. So the

1 word composite, I'm trying to figure out how it
2 bears on this discussion. I just want to be
3 clear.

4 MEMBER DEUTSCHER: Well, this is what
5 I mentioned before, that I'm not sure the term
6 composite fits this discussion because --

7 CO-CHAIR NERENZ: No, I don't think it
8 does, but I --

9 MEMBER DEUTSCHER: But I understand.
10 (Simultaneous speaking.)

11 MEMBER DEUTSCHER: I understand the
12 concept that you're raising using the idea of a
13 composite.

14 MEMBER KAPLAN: Yeah.

15 MEMBER DEUTSCHER: But, basically,
16 relevant for this measure, it's maybe not the
17 composite part of it but it's the error within
18 the patient --

19 MEMBER KAPLAN: Yeah, but, so, this is
20 really TMI for people who aren't fascinated by a
21 measurement, but there's two arms of measurement
22 models, a formative and a reflective model.

1 So, a formative model, say the
2 stressful life mix. So, did you lose your
3 mortgage, you know, did your spouse die? Did
4 your kid go to jail? All of those things are
5 individual components of something that's
6 actually, if you add them all up, they shouldn't
7 correlate with each other, you hope, at the
8 patient level. But if you have one of those,
9 it's bad. So that's like, when things cause
10 stress. Those things cause stress.

11 But if you say, okay, my pulse is
12 fast, I'm sweating, I'm this and that, you know,
13 I have a racing heart and all of that other
14 stuff, that's a reflection of stress.

15 The assumptions you make, measurement-
16 wise, are different in how you approach those
17 measurement models from a reliability and
18 validity standpoint are different. But you're
19 still adding them up. And so if you have a
20 global concept called "I'm adding up a bunch of
21 stuff," that's a composite. How you test the
22 composite is different.

1 MEMBER DEUTSCHER: Well, but, again,
2 I'm nervous about this, because adding up stuff
3 can come in very different ways.

4 So, for example, if I have individual
5 measures that have properties of reliability and
6 validity and what not and I add them to make a
7 composite, there are certain mathematical things
8 that are happening and something of that involves
9 the reliability and validity of the component
10 measures.

11 Now if I take a bunch of survey items
12 and created a score, and that score becomes a
13 measure, I don't presume that each one of those
14 individual survey items, itself, has reliability
15 and validity. I generally don't test that. I
16 may not even want to know that.

17 So it's different. It's not just
18 adding up stuff. It's what you're adding. And
19 I'm just -- all this is in service. I'm just
20 trying to understand the point, which I believe
21 is important, about the error variance, like
22 which error variance and when does it matter and

1 when doesn't it matter. That's what I'm trying
2 to set up.

3 MEMBER KAPLAN: Yeah, well, somebody
4 like me, adding up stuff means something very
5 specific. I think all of that stuff makes a
6 construct. So I think all of that, those
7 individual things, are related to some higher
8 order construct, like stress.

9 You know, if you lose your mortgage,
10 that's one thing. If your kid goes to jail, you
11 know, you've broken your shoe lace for the 29th
12 time, whatever all those things, those things, if
13 you add up more of those, it's bad with respect
14 to construct stress.

15 Like you're adding up stuff. But they
16 have to have this underlying construct, otherwise
17 there is no point in adding them up. You know,
18 why would you do that?

19 On the other hand, and if you think
20 about a math test, two trains left Chicago, you
21 know, and then you've got a bunch of questions
22 about some things, all of those things are

1 theoretically supposed to measure your math
2 ability.

3 And, you know, I don't know if that
4 helps us out of the conundrum of what is a
5 composite, but for somebody like me, you'd better
6 have a good rationale, theoretical rationale, for
7 why those things should have come together. I'm
8 sorry.

9 CO-CHAIR CELLA: This is -- maybe this
10 is addressed mostly to the newbies as a welcome
11 to the carousel. We've been around this carousel
12 a few times and just jumped right on.

13 You know, I have had to induce some
14 sort of self-inflicted electric shocks, in my
15 terminology, as I've gotten acclimated to this
16 committee.

17 So, for example, I think now, here, in
18 terms of data elements and measures. And
19 everything I used to call a measure is not a
20 measure. It's a data element. Because I used to
21 call patient-reported outcome measures, measures.

22 But I try not to do that here. They're

1 data elements. They're elements that go into a
2 measure. And only measures, in this room, for me
3 -- only measures, not data elements -- can be
4 composites.

5 So, in this room, Sherrie.

6 (Laughter.)

7 CO-CHAIR CELLA: That's why I looked
8 over there as I said that. I thought you might
9 like it, but at least it's helped me. So if
10 you're anything like me, maybe you were helped by
11 that.

12 I think the point Daniel was trying to
13 make is that the data element that is in the FOTO
14 submission is more like hemoglobin A1C and blood
15 pressure than it is like an SF-36 PF-10, because
16 it's one number that keeps getting re-estimated
17 each time you ask a question, maybe the same way
18 that the laboratory configures out the hemoglobin
19 A1C.

20 They've all got error. That was the
21 point. All these data -- and you made that point
22 -- all these data elements have error, but

1 there's not a multi-item in an IRT framework --
2 and Sherrie knows this -- in an IRT framework
3 there's not a multi-item error, you know,
4 Cronbach's alpha equivalent. It's one score.

5 I don't know if that's helpful or if
6 that just spins the carousel more. But, for me,
7 at least here, it's data elements are the things
8 that go into the performance measures that
9 sometimes are composites. I'll stop. Jack?

10 MEMBER NEEDLEMAN: Okay. I'm shocked
11 that I'm the outlier here. But I am not
12 incomplete on reliability. Insufficient on
13 reliability.

14 I don't think we need to re-open the
15 argument with respect to the endorsement of this
16 measure. It's fine. But I do think this measure
17 and the data that's been presented to us raised
18 some long-term issues for the committee, both in
19 terms of guidance -- in terms of our standards
20 and in terms of guidance to developers.

21 So, one of the issues is that
22 increasingly we're seeing measures that rely upon

1 the signal-to-noise ratio that John Adams put
2 forward in an article, and we'll often cite that
3 .7 standard in that Adams article.

4 But as John pointed out, in a simple
5 binary classification, .7 produced 25 percent
6 misclassification. So this committee needs to
7 really figure out a way to say what level of
8 signal-to-noise reliability actually we should
9 expect to hit the standards that we expect for
10 the uses of these measures?

11 And that's a long-term discussion.
12 We're not going to get it done in the next two
13 days. But we need to figure out a way to have
14 that conversation and to move that forward. The
15 white papers have been one of the vehicles for
16 doing that. We should continue to do that.

17 But also we approved measures as
18 specified, including the minimum number of cases.
19 And what we're seeing in this measure, as we're
20 seeing with others, is that the reliability is
21 much lower, typically, for clinicians who have
22 smaller numbers of cases.

1 And I think we need to also visit the
2 reliability question with respect to minimum
3 levels of reliability for clinicians or
4 facilities with different numbers of cases in
5 terms of assessing whether the cut-off for the
6 number of cases is the right cut-off in terms of
7 the specification.

8 And this measure raises those issues,
9 I think, quite clearly. And that's one of the
10 reasons why -- that's the principal reason why I
11 said I'm not satisfied that I have sufficient
12 information to make a judgment.

13 The other issue that this raises is
14 about SES testing again. And this is something I
15 would tell the committee to -- I would encourage
16 the Standing Committee to reflect on.

17 We don't any direct measures -- we
18 don't have a lot of measures in here of SES, but
19 the acuity measure which shows to be very
20 sensitive in the risk adjustment is time between
21 the -- is actually what's called the QE is
22 actually the time between onset of symptoms and

1 the initial evaluation.

2 And I can make up all kinds of stories
3 about why that is SES-related. The developer
4 doesn't discuss it. And perhaps the acuity
5 measure as a risk adjuster sort of covers the sin
6 of not analyzing more specifically the SES
7 factors associated with delays in access to
8 treatment. But somebody ought to think about
9 delays in access to this treatment and how it's
10 affecting our measurement of the effectiveness of
11 the treatment.

12 The other thing, and this is a
13 technical issue, was the treatment of the
14 education variables in the SES test. And I read
15 through the comments that were provided in
16 response to that. They have left me now a little
17 bit confused because what was said in the
18 comments does not reflect what I saw discussed or
19 the way the discussion was in the documentation.

20 So you've got these categorical
21 variables for education. And, clearly, they're a
22 bloc that's been broken up into categories. But

1 the assessment of do they come into the model or
2 not is an assessment of each individual
3 coefficient, each individual way.

4 I did not see any data on the testing
5 of the educational variables as a bloc coming in
6 or out of the SES measure. Now, the response is,
7 that's what was done, but that's not what's
8 reflected in the presentation.

9 And clearly, when you've got these
10 kinds of categories, we ought to be seeing
11 analysis of them as a bloc with expectations. So
12 I also sort of comment that we don't see a trend
13 to the data.

14 (Simultaneous speaking.)

15 MEMBER NEEDLEMAN: Well, it's not a
16 perfect trend, but I do see a trend in the data,
17 which suggests that those of higher education
18 seem to have better resources than those of lower
19 education. It's not perfect. The numbers are
20 not moving consistently up across the levels as
21 you move to higher level education. But I think
22 if I did a regression line in that, I would not

1 get a slope of zero.

2 So, again, I think we ought to be
3 giving our developers more guidance on what to
4 say to us when they've got a categorical, and
5 particularly categorical ordered variables, in
6 terms of what analysis we'd like to see of those
7 when they're talking about putting it into a risk
8 adjustment model.

9 Those are my comments.

10 CO-CHAIR CELLA: Thank you. Again, we
11 don't have a revote thing in front of us. These
12 are general comments. If I could just take a
13 second and make one quick observation and move on
14 to the next measure also.

15 I really appreciate it, as I look at
16 the discussion guide, looking at page 60, for
17 those of you that have it up in PDF form. The
18 column that shows variance explained at the
19 provider level. To me, this is a nice capture of
20 measurement property here of reliability. It
21 also conveys to my non card-carrying statistician
22 mind that we're talking about something here

1 that's about 6 percent signal and 94 percent
2 noise.

3 Now, others may not view it the same
4 way. And I'd also say that this is not unusual.
5 The hospital readmission measures have
6 essentially the same property. And others, too.
7 But, as we continue our work and go forward and
8 work with developers, I think we just want to
9 develop a starter consensus about, you know, what
10 should a number like this look like?

11 And I reflect on Mary's excellent
12 comment at our most recent face-to-face meeting
13 about how, you know, this signal that we've got
14 here is sort of everything about the provider,
15 quality and some other stuff. And unless the
16 risk adjustment is perfect, these are essentially
17 high end estimates. Mary pointed out that if the
18 risk adjustment isn't perfect for something, much
19 of what you think is signal, in fact,
20 statistically is signal, is not really quality.
21 It's just something you haven't adjusted for.

22 So none of this changes, I think, what

1 we should do about this. I'm happy to see it
2 expressed that way. And I just think we, as a
3 group, working in collaboration with developers
4 to try to move this whole field forward, should
5 try to sense of is it a good measure. Is it
6 useful, is it informative, is it fair when it's 6
7 percent signal and 94 noise? We'll see.

8 Sherrie?

9 MEMBER KAPLAN: I think one of the
10 things that FOTO did well is they actually also
11 look at residuals. And I think the unexplained
12 variance here is key to kind of understanding
13 much of the concerns that we've been raising.

14 I think this 94 percent business is
15 it's going to have to come back to NQF and what
16 we will tolerate for attribution at a certain
17 level when it's useful for some things but not
18 others. And that's what I was talking about
19 earlier to NCQA, about, you know, maybe these
20 measures aren't so good at the plan level.
21 They're great at certain levels, but not at other
22 levels. And will the field tolerate that? You

1 know, can we say, "Not so fast, CMS"?

2 CO-CHAIR CELLA: All right, Jack, and
3 then, to stay on time, we should probably move on
4 since we're not revoting on anything. Jack?

5 MEMBER NEEDLEMAN: So, I approach --
6 I often approach these measures from the
7 perspective of information and usability for the
8 users. You can have measures with 6 percent
9 variation explained that nonetheless work. And
10 so the other things I'm looking for, which are
11 also captured by the reliability measures, but
12 not perfectly, is how much variation is there
13 between, once you've sorted people on the
14 measure, how much variation is there between the
15 lowest and the highs? How much room for
16 improvement is there?

17 And the other is -- which also relates
18 to the sort of inherent variability here -- how
19 stable are the rankings and the orderings that
20 are implied in this data? If they are so
21 unstable that, by random chance or just by the
22 bad luck of the draw this year, you wound up in

1 the bottom quintile versus and next year in the
2 top quintile because it's the luck of the draw,
3 we don't have a reliable measure.

4 So I think we need to start
5 correlating some of these summary statistics with
6 issues of stability of the measure, coupled with
7 an understanding of how much variability there is
8 from the top to the bottom or the top quartile to
9 the bottom quartile, or something to give us a
10 sense about how much -- what this variation
11 explained is actually translating to in terms of
12 the raw numbers.

13 CO-CHAIR NERENZ: All right. Thanks,
14 everybody. And I guess now we're putting
15 Subgroup 1 in the rearview mirror. Thanks to all
16 of you for that discussion and background.

17 We move on, now, to a couple measures
18 -- actually, there are more than two -- coming
19 from Subgroup 2. So you folks can get caffeine
20 and alert and reading to talk.

21 The first one we have -- in fact,
22 we've got two before the scheduled afternoon

1 break, maybe a half-hour each. We'll see how we
2 do it.

3 The first one is 0696. This is from
4 the Society of Thoracic Surgeons. A candidate
5 composite score. There's the word composite.
6 And we will have Michael tee this one up for us.

7 MR. ABRAMS: Good. And I'm page 18 of
8 the PDF for those of you who are following along
9 on the discussion guide.

10 So, this is a maintenance measure.
11 And, arguably, both a hybrid of some outcomes as
12 well as a number of process measures. And,
13 indeed, it is a composite. And I think a very
14 clearly defined one, as it involved putting
15 together the scores from 11 individual NQF-
16 endorsed measures.

17 So let me quickly refer you to those
18 11 measures. It's broken up into four domains,
19 the first one being the absence of operative
20 mortality. Because of the use of mortality and
21 morbidity in a measure, that's why I'm calling it
22 a hybrid. But there's also some process measures

1 in there.

2 So, the absence of operative mortality
3 is Domain 1. Absence of major morbidity across
4 five different measures: reoperation for cardiac
5 reasons, renal failure, deep sternal wound
6 infection, prolonged ventilation/intubation,
7 cerebrovascular accident, all negative morbidity
8 outcomes that are each individual measures.

9 And then, in Domain 3, in the process
10 area, use of internal mammary artery as part of
11 the grafting procedure being one of the process
12 measures that lies beneath this composite.

13 And then, finally, for additional
14 measures that are process measures that involve
15 different pharmaceuticals, all indicated for a
16 typical CABG procedure: beta blockade therapy,
17 antiplatelet therapy, discharge on beta blockade
18 therapy, and then antilipid medications.

19 So all of these 11 are rolled up into
20 what might be considered an all-or-none kind of
21 approach. So, all 11 have to be hit in order for
22 the numerator to be endorsed, and thus for this

1 measure to be considered accounted or included as
2 a successful, positive outcome/process.

3 All the measures are based on registry
4 data.

5 Some brief notes about the
6 specifications. They did do a weighting
7 procedure. So even though there are 11 measures
8 that lie beneath, they give much more weight to
9 mortality. Eighty-one percent of the composite
10 measure that's reported is based on the mortality
11 score; only 10 percent on the morbidity; 7
12 percent on this mammary graft and only 3 percent
13 on medications. So they did some weighting there
14 in order to create the composite, not a simple
15 sum.

16 The way that they derive the data,
17 from registry, as I said. Level of analysis is
18 group practice. Exclusions or contraindications
19 for this mammary artery graft use, perhaps
20 because it's not the first time the individual
21 had surgery, for example. And also
22 contraindications for any of the pharmaceuticals

1 that were under the final domain that I
2 described. So there are some exclusions,
3 although they report that these exclusions
4 accounted for only about a three percent
5 reduction in the something like 143,000 cases
6 that they used to do their testing.

7 The subcommittee gave it a moderate
8 rating on reliability. So, passed there. It's a
9 Bayesian model. Signal-to-noise ratio was
10 reported at .68. In any case, not what we need
11 to discuss today as the committee gave it at a
12 solid moderate rating.

13 But with regard to validity, that was
14 a "consensus not reached." And here are some
15 points about that. And I'll try to signal some
16 things for discussion and then hand it to Jeff to
17 discuss that further.

18 But the measure gap actually was quite
19 narrow, one could argue. The performance from
20 2014 data that they reported directly in one of
21 their tables gave a performance rating of
22 something like .97 percent with a very small

1 standard deviation running about a .0092, so
2 there's some question about is there a
3 performance gap related to this.

4 Another point, the way that validity
5 was demonstrated was with a Pearson's correlation
6 between, not the measure itself and an external
7 validator, but the measure at two different time
8 points using stability in the measure as a
9 suggestion of its validity, that Pearson's and
10 Spearman's reported for that type of analysis
11 between two annual periods was .6, .63.

12 They talk about face validity, as
13 well, being relevant to the creation of their
14 measure. And then, finally, they do something
15 that -- they use star ratings to cluster the
16 performance of the different facilities into one
17 of three categories.

18 And I put in the discussion guide a
19 table. Actually it's on page 19 now. And if you
20 look at that, or I'll describe it to you as well,
21 most of the observations are falling into Group
22 2.

1 So, from their 2012 data, 76 percent
2 of their facilities were performing at the two-
3 star rating. When you get to 2013-2014, that
4 number increases to 84 percent. So perhaps
5 there's some question about discriminant validity
6 and the way that they've set that up and compared
7 it to their actual scores. There's not a lot of
8 difference between the star ratings, I think, is
9 the point there.

10 And then, finally, I can point out,
11 with regard to validity, were two final points.
12 Creating of the concept, the committee had no
13 concern with regard that, so there's no reason to
14 discuss that further. There was a lot of
15 underlying measures, presumably, were persuasive
16 to you all. And as I said previously, missing
17 data is quite a small issue.

18 So the thrust of the discussion will
19 probably be on this validity piece. So, with
20 that, I'll had it to Jeff next.

21 CO-CHAIR NERENZ: And just as a
22 process reminder, because it's consensus,

1 obviously, there will be a revote on this one.

2 So, Jeff, if you want to sort of focus
3 to steer the subgroup and the rest of us on the
4 key issues that are then going to be up for
5 revote, that'd be great.

6 MEMBER GEPPERT: So I want to start
7 with this one issue that is kind of a focus of my
8 evaluation. And this may reflect some confusion
9 on what was submitted or may reflect some
10 confusion about NQF guidance around evaluations.

11 So, in many respects, the methods and
12 the reporting of the results are really
13 exemplary. You know, some best practices,
14 really, in my regard. A lot of the methodology
15 has been published in peer-reviewed literature
16 and vetted through some great significant actual
17 use.

18 My main concern was that the data that
19 was submitted for evaluation was from the 2012 to
20 2014 time period. And so that sort of raised a
21 question in my mind about whether -- you know,
22 does this sort of meet the criteria that the data

1 being used in testing really sort of reflects the
2 data that is intended for the specification?
3 Which, presumably, would be now, or approaching
4 2020 through 2022.

5 So it's just the time period.

6 Normally, we talk about that in terms of does it
7 cover the same patients or does it cover the same
8 providers, but also does it cover the same kind
9 of time and space as what we're actually going to
10 implement in practice?

11 And we've talked about at various
12 times that too often reliability and validity are
13 treated as sort of static properties of measures.
14 But, really, they're not. They're the properties
15 of measures that are context dependent. And one
16 of those aspects of context was actual use. And,
17 over time, through actual use, either reliability
18 or validity could change over time. And so it's
19 difficult to assess today what the reliability or
20 validity of a measure is based on data from
21 seven years ago after some significant use.

22 So that was sort of my main question,

1 my main concern. But then the developer, in the
2 response, pointed out some guidance from NQF
3 about this. And so that made me look at that.
4 And there's quite a bit of discussion in the
5 guidance document about shifts in emphasis for
6 maintenance measures.

7 So it turns out that, for maintenance
8 measures, in evaluation of the measure, there's a
9 shift of emphasis in terms of the criteria that
10 are considered. It says, for maintenance
11 measures there's less emphasis in maintenance on
12 evidence, reliability, and validity. There's no
13 change in emphasis on specification and
14 feasibility. But there's more emphasis on use
15 and usability, you know, demonstrated improvement
16 in a particular performance gap, is my way to
17 sort of describe it.

18 So then if you actually read, you
19 know, what the guidance says about sort of the
20 shift of emphasis for reliability and validity
21 testing, it says that the Scientific Methods
22 Panel will provide the Standing Committee with

1 evaluations and rating of reliability and
2 validity for new measures or for previously
3 endorsed measures with updated testing.

4 So it seemed like the data that was
5 submitted was probably from a prior -- from the
6 initial sort of measure submission. That could
7 be wrong, but that was sort of my assumption.

8 But if that's true, if the data that
9 was submitted was from a prior measure
10 submission, the prior endorsement process, and
11 the developer is simply asserting that there
12 hasn't been a change, then according to this
13 guidance, you know, we shouldn't even be looking
14 at this.

15 So that was my first question.

16 MS. JOHNSON: Okay, yeah.

17 MEMBER GEPPERT: Sort of topic of
18 discussion.

19 MS. JOHNSON: So, a couple things.
20 You are correct. Right now, we do not have any
21 requirement that says that every so often the
22 testing has to be updated. So, we don't have

1 that requirement right now. And that might be
2 something that you guys want to suggest that we
3 re-look at.

4 So, this particular measure, I'm not
5 exactly sure why you are looking at it in terms
6 of what's new. There's a couple things that
7 could have happened.

8 One is this may have been one that
9 originally they didn't give us the composite
10 information that we needed. And this time they
11 did, so now you have new stuff to look at that
12 was not looked at before. That might be it,
13 because I know that's happened a couple times.

14 The other thing is it could have been
15 we also -- and I didn't list it in all the things
16 of the complex measures -- but we also have a
17 little out to where we say, "and, on occasion,
18 NQF staff may want you guys to look at a
19 measure." So it could have been that.

20 And I don't know, Michael, if you have
21 any intel on which of those two, as to why it's
22 coming to the Methods Panel. Do you know which

1 is it?

2 MR. ABRAMS: Yeah, I don't know. I
3 think it's the latter, though, because it was a
4 composite measure --

5 MS. JOHNSON: That the staff just
6 tasked the Methods Panel to do?

7 MR. ABRAMS: Yeah, for that reason.

8 MS. JOHNSON: Okay. It could have
9 been that.

10 So, back to your question, do we
11 require, you know, they did, looks like 2014 is
12 the most current data. We can't right now, with
13 their requirements, say that that's not good
14 enough.

15 Most of the time what we see -- not
16 all measures, but a lot of measures that are
17 currently in use often get recalibrated every
18 year anyway. The CMS measures, for example, they
19 recalibrate those risk models and those kind of
20 things.

21 So, by definition, those are always
22 going to come back because there's always new

1 data and new loadings, that kind of thing.

2 I am assuming that STS had not
3 recalibrated these models since 2014. And we did
4 ask that. Does that help? It may not be
5 satisfactory, but --

6 MEMBER GEPPERT: Yeah, I just, from a
7 plain reading of what the guidance says, if in
8 fact these results have not changed since the
9 prior submission, it seems like, according to the
10 guidance, that would be enough. There's nothing
11 in the guidance that says we'll be making an
12 exception if staff think it's the right thing to
13 do.

14 MS. JOHNSON: Yeah, it's a different
15 spot. So, yeah, we can. And sometimes we might
16 do that if we are feeling a little bit like we
17 need the extra oomph of the SMP to help us look
18 at a measure, even if it has gone through before.

19 But we'll find out why. I don't
20 exactly know.

21 MS. WILBON: Yeah, I think, yeah, I
22 think this might have been a staff.

1 MS. JOHNSON: Okay, so this, Ashlie is
2 thinking that this is probably a staff pull, that
3 we wanted you guys to look at it for us.

4 MEMBER GEPPERT: Despite that, one of
5 the areas of emphasis has to do with performance
6 gap and sort of where we pointed out that it
7 seems problematic even in the earlier data. The
8 2014 data performance gap was not large if you
9 sort of looked at, you know, extrapolated a
10 trend, you might think that now there's probably
11 no performance gap whatsoever. And so that, by
12 itself, would be sort of enough to call it into
13 question.

14 MS. JOHNSON: And let me interrupt.
15 I'm sorry, Jeff. I know in the discussion guide
16 the term performance gap, but I'm assuming that
17 information came from the Meaningful Differences
18 Section. Is that where that came from?

19 MEMBER GEPPERT: Yes.

20 MS. JOHNSON: Okay.

21 CO-CHAIR NERENZ: Okay, let's open now
22 to the -- just to remind you, the subgroup

1 members here are Daniel, Jack, Larry, Joe Hyder,
2 Alex, and I guess we have Eric on the phone.

3 So this is now our eligible
4 discussants. And let's see who is up. Daniel
5 was up first, then I got Larry second, and then
6 Alex third.

7 MEMBER DEUTSCHER: So I guess my first
8 point is also a question to NQF, and it regards
9 empirical validity testing. So for such a
10 composite measure that is up for re-endorsement,
11 is that a new requirement that might not have
12 been there when it was submitted previously? Is
13 that something we do need to look into more
14 deeply, or not?

15 MS. JOHNSON: This one, no. That
16 would not have been new. No. So the only thing
17 that's changed with validity is we have said that
18 we used to take face validity kind of across the
19 board and it didn't matter when. But now we say
20 face validity for maintenance measures, we really
21 don't like that very much. We'd really like to
22 see empirical, but this is kind of the typical

1 way that STS does their validation. So I'm
2 pretty sure that this is how they had done it
3 last time, so this is not different.

4 MEMBER DEUTSCHER: So I guess my
5 follow-up question is: is there any concern about
6 the method used here for testing empirical
7 validity, which is more of a longitudinal
8 stability over measure than a validity against a
9 different measure.

10 Now I looked at the response from the
11 developers, and they give some explanations on
12 why that happens, and if I understand correctly,
13 their main point was that we kind of exhausted
14 the other measures that we could look at because
15 they're all within the composite. So I guess
16 that might be a valid point in that case.

17 Is this longitudinal stability
18 something that holds, or should they be looking
19 at other ways of looking at validity, like known-
20 groups validity, or other validity testing?

21 MS. JOHNSON: And I suspect that that
22 is part of the reason that this was a stack pull,

1 that we wanted you guys to talk about that
2 methodology, and weigh-in on whether you think
3 that's a valid methodology for validity.

4 CO-CHAIR NERENZ: Okay, just a quick
5 response. I'm going to put out for hypothetical
6 --- you could probably have a totally invalid
7 measure, meaning it didn't measure what you
8 thought it did, but it measured something, and
9 that would be stable over time.

10 MEMBER DEUTSCHER: Right.

11 (Simultaneous speaking.)

12 CO-CHAIR NERENZ: So okay, that's just
13 my quick response there.

14 MEMBER GLANCE: So you know, I wanted
15 to echo the comments that Jeff made about, you
16 know, the STS measures are some of the best
17 measures that we have that we've seen on this
18 panel. They really do follow best practices.
19 This is sort of an editorial comment. But a
20 couple of the issues that were brought up, in
21 terms of validity testing, first about the
22 measurement gap, or lack thereof.

1 I think it's important to understand
2 that at one extreme, if you have really, really
3 poor risk adjustment, you're going to see a big
4 gap. Okay? Because you're going to have
5 differences between hospitals or providers in
6 cases, so some hospitals are going to have really
7 sick patients, some hospitals are going to have
8 really healthy patients. And so you're going to
9 see very different outcomes just because
10 different hospitals have different severity of
11 disease, and you're not risk adjusting for if you
12 have a bad risk adjustment model.

13 Now, when your risk adjustment model
14 is really good, okay, you're going to adjust for
15 all that stuff, and all that's left is really
16 differences in providers. And it may be that
17 when you're comparing cardiac surgeons or
18 hospitals that provide cardiac surgery, you have
19 a pretty uniformly high level of care. And so
20 there aren't really going to be huge differences,
21 but there are still differences.

22 And as a potential patient, and also

1 as someone who -- CMS, you still want to be able
2 to identify even relatively small differences
3 between providers because that may help you make
4 a decision about which cardiac surgeon or which
5 hospital you go to, even if those differences
6 aren't very big. So the fact that there isn't a
7 really big measurement gap isn't enough to say,
8 you know, this model, this measure is not valid.
9 That's my first point.

10 The second point, in terms of using
11 stability as a way of validating a measure, in
12 some ways, measure stability may be one of the
13 best ways that we have.

14 So the idea is that, you know, you
15 look at your -- say your risk adjusted mortality
16 rates, just to simplify, in 2016, and you look
17 how well they agree with risk adjusted mortality
18 rates in 2017.

19 If they don't agree very well, then
20 you're sort of like thinking, well, you know,
21 what information did those risk adjustment
22 mortality rates in 2016 really give me if from

1 year to year they just fluctuate wildly?

2 If on the other hand, they show a
3 fairly high level of agreement, that I think
4 gives you more confidence in the validity of the
5 outcome measure itself. So I would say that
6 stability is actually a fairly important way of
7 establishing validity.

8 And then the third point is about the
9 fact that this was based on old data. And I
10 agree with that criticism. I actually -- instead
11 of giving this a high for validity, I gave it a
12 moderate based on the fact that it was based on
13 old data.

14 I actually really think that the
15 measure developers have newer data. I'm not
16 really sure why they didn't submit that
17 information. And I think we should just ask the
18 measure developer that question, you know? But I
19 would certainly not fail this measure on
20 validity. This is a very, very good measure, and
21 I think that for all the reasons that I gave.

22 I think, one, the fact that again,

1 there is a measurement gap -- it's not a big
2 measurement gap, but that's not unexpected. Two,
3 stability is a good way to look at measure
4 validity. And three, this is not old, old data,
5 but it's not as recent as it could be.

6 CO-CHAIR NERENZ: Alex?

7 MEMBER SOX-HARRIS: Okay, thanks
8 Larry. So what made me dissatisfied with the age
9 of the data was that they reported some new
10 performance results that were higher than the
11 older data, and also more constrained. So if
12 those things changed, then reliability as
13 calculated has probably changed as well, and I
14 just wanted to see it updated.

15 But I think more importantly is the
16 lack of a performance gap speaking. A number of
17 people have raised that issue. And has the
18 measure really topped out? And so when they
19 translate score to stars, I think there's an
20 overstatement of difference, potentially.

21 So what they do, if I understood
22 correctly, was if your confidence interval for

1 your performance crosses the average, you're a
2 two star. And if your confidence interval is
3 wholly above the average, you're a three star,
4 and so forth.

5 I think the problem with this is you
6 could get two facilities that -- or one facility
7 that's higher, that has a greater confidence
8 interval, that is rated a two star, versus a
9 facility that's quite large and has higher
10 volume, and that's lower rated, but it's tighter
11 and does not cross the average line, and be a
12 three star. And I think that's potentially
13 misleading, and also I think it makes the spread,
14 when you look at the star distribution,
15 potentially bigger than it actually is.

16 So those were my two main concerns,
17 other than the issue that's been brought up about
18 there not being an empirical validity test that's
19 due to some external reference. So I would
20 respectfully disagree, but I think stability's
21 important, but that's reliability. It's how well
22 does something relate to itself? It's not a true

1 measure of validity. Those are my concerns.

2 CO-CHAIR NERENZ: I don't see any
3 other of the name panels up. I'll just sort of
4 make a last call for members of the subgroup,
5 since we've got -- at least in the first pass,
6 three people said low, two said high, one said
7 incomplete. Do you want to ask any additional
8 questions of each other to clarify or expand on
9 anything? Because if not, then we'll open it up
10 to the whole group.

11 (No audible response.)

12 CO-CHAIR NERENZ: Oh, I'm sorry. I'm
13 reminded they have a developer representative on
14 the line. This would be a chance to offer a
15 response. Sorry, I didn't see you sitting here.

16 MR. SHAHIAN: Yeah, Dave Shahian and
17 Mark Antman from STS are on the line, and --

18 (Simultaneous speaking.)

19 CO-CHAIR NERENZ: Okay, thank you.
20 Just one second, we're having horrible volume
21 problems. We can barely hear you, and I'm not
22 sure we can control that, or if you have any

1 chance to speak up more at your end. We're
2 working on it. Just hang on a second.

3 MR. SHAHIAN: Okay.

4 CO-CHAIR NERENZ: Try again.

5 MR. SHAHIAN: Okay.

6 (Simultaneous speaking.)

7 CO-CHAIR NERENZ: Better, thank you.

8 MR. SHAHIAN: Can you hear me now?

9 CO-CHAIR NERENZ: Perfect, thank you.

10 MR. SHAHIAN: Hi, it's Dave Shahian,
11 chair of the Quality Measurement Task Force for
12 STS, and I'd like to respond to some of the
13 excellent questions that have been raised.

14 First of all, we did provide yesterday
15 updated reliability, and what I would consider to
16 be some internal validity testing, and I hope
17 everybody has that. It's based on 2018 data.
18 Did people receive that?

19 MS. JOHNSON: Dave, this is Karen from
20 NQF. No, we weren't monitoring yesterday, so we
21 have not made any of that available to the panel.

22 MR. SHAHIAN: Well, would it be

1 possible for you to look right now in your
2 emails? Because this I think would settle a lot
3 of these issues, if you would want to take a
4 look, and then distribute that very quickly to
5 the group?

6 MS. JOHNSON: Yeah.

7 MR. ANTMAN: And this is Mark Antman
8 at STS. Just to clarify, your staff has just
9 confirmed with us that a document that we sent
10 actually very early this morning was distributed
11 to the panel.

12 MS. JOHNSON: I think we're confused.
13 We distributed something that you sent last week,
14 but we have not distributed anything that came in
15 yesterday.

16 CO-CHAIR NERENZ: How about if we do
17 this? To our STS folks, if there are other
18 points you can speak to, essentially just as a
19 time holder, we'll see if somebody in here who
20 has laptop access to the projector and the screen
21 can connect all those things together.

22 MR. SHAHIAN: Okay. All right. Let

1 me talk while you try to get the data, but I will
2 tell you a little bit about the 2018 data that we
3 sent you. It's based on 152,446 records from 962
4 adult cardiac participants.

5 In 2018, in this particular heart rest
6 period, the number of two star or as-expected
7 programs with 80 percent one star, 4 percent, and
8 7 percent were three star. Over time, what has
9 happened is that exactly what we would hope would
10 happen in a very robust, data-rich environment,
11 where we're providing feedback reports to
12 programs, where we're publicly reporting -- you
13 gradually get a convergence of scores.

14 Having said that, the 11 percent or so
15 one or three star programs, it's still
16 substantially higher, for example, than most CMS
17 measures. It is still a sizable proportion, but
18 as somebody commented earlier, you can't really
19 survive in cardiac surgery unless you're a two or
20 three star program.

21 Those programs either tend to improve,
22 or they just die. And so to me, this number is

1 consistent with the number of high and low
2 outliers in most other measurement programs that
3 I'm aware of. And I think it also demonstrates
4 the fact that we've been at this a long time and
5 really been pushing for exactly what you're
6 seeing here.

7 As a matter of fact, I have often
8 commented that if we could have every program in
9 the country statistically indistinguishable and
10 functioning at a very high level, that would
11 really be the ideal situation.

12 We're not looking to make somebody an
13 outlier, we're looking to improve the quality of
14 all programs in cardiac surgery so that patients
15 then feel comfortable making their choice based
16 on other considerations like geographic
17 convenience and that sort of thing. So that, in
18 terms of number of outliers.

19 In terms of the signal-to-noise ratio,
20 signal-to-noise, reliability -- based on 2018
21 data, if you look at all participants, the
22 reliability is 0.64. If you look at participants

1 with at least 50 eligible cases, which would be
2 almost all programs, it's 0.66, and if you look
3 at participants with at least 100 eligible cases,
4 it's 0.67. If you look at most measures in
5 surgery that I'm aware of -- and frankly, surgery
6 does much better than medicine in this respect --
7 but even if you look at most surgical procedures,
8 certainly most general surgical procedures, this
9 is a very high reliability. And this is -- to my
10 way of thinking, confirms the reliability of this
11 measure.

12 And finally on the issue of the
13 validity, it is correct that we have a bit of a
14 problem in that we've used -- the major markers
15 of priority are all already combined within our
16 composite, so it's a little hard to get a good
17 external gold standard to compare it to. We are,
18 in fact, the gold standard, so one thing we
19 thought to do is to see if in the construction of
20 the composite, whether we have done anything
21 squirrely, would then make the domain scores
22 seem unreasonable, or lacking in validity.

1 And if you look at -- and I don't know
2 if you've received the information yet, but I'll
3 just read it to you. If you look at mortality
4 for one, two, and three star programs, for a one
5 star program mortality is 4.3 percent, two star,
6 it's 2.3 percent, and three star programs, it's
7 1.2 percent. Though it's really a threefold
8 variation in mortality between one and three star
9 programs. It's exactly the same for morbidity.
10 It goes from 18.7 percent for one star programs,
11 11.2 percent for two stars, and 6.7 percent for
12 three stars.

13 Even more striking for IMA use, one
14 star, no IMA, 3.3 percent -- and for three star
15 programs, it's 0.4 percent. So they're really an
16 eightfold difference. And for use of all four
17 NQF-endorsed medications -- one star programs, 19
18 percent did not receive at least one of those
19 medications, and for three star programs, only
20 1.9 percent, so a tenfold difference.

21 So we think that in the construction
22 of the composite, we certainly have retained a

1 kind of spread that we wanted to see in
2 mortality, morbidity, IMA use, and medication
3 use. There's a very substantial spread between
4 one and three star programs.

5 Granted, there is some circularity in
6 that argument because it is these measures that
7 make up the composite, but I think, as all of you
8 know, when you construct a composite, sometimes
9 some untoward things happen, and you may not have
10 the kind of relationship within the individual
11 domains that you wanted. Here, I think we've
12 demonstrated that we do.

13 CO-CHAIR NERENZ: Thank you.

14 MR. SHAHIAN: So I think I'll stop
15 there.

16 CO-CHAIR NERENZ: No, that's good,
17 thank you. That was very much on point. I'm
18 just looking around the room, particularly at the
19 subgroup members. Does anyone have any specific,
20 additional questions for the developer?

21 (No audible response.)

22 CO-CHAIR NERENZ: I don't see any

1 hands up. Then let us then open it up to anyone
2 else in the room wanting to discuss, make a point
3 -- yeah, back to Larry.

4 MEMBER GLANCE: Just one more question
5 for the measure developer. One of the issues
6 that came up here in the discussion regards to
7 the data that was used that -- how old the data
8 was for the individual measures, in terms of
9 their performance. So this is a composite
10 measure that has mortality, that has morbidity.
11 Did you look at the performance of those
12 individual components?

13 So for the binary outcomes, did you
14 look at the c-statistic and calibration in
15 validation data sets using more recent data than
16 the data that was used to create these models
17 originally?

18 MR. SHAHIAN: Well, we have --- we've
19 redone all of our risk models, and the
20 performance of those models has all been very
21 high. I'm not sure what else I can say. We work
22 constantly doing that, and we just published the

1 2018 update of all our risk models. And in every
2 case, except for I think internal infection, the
3 c-statistic was improved over the previous models
4 upon which we originally developed this
5 composite.

6 And somebody had asked about re-
7 calibrating the models, too, and I just want to
8 point out that our statistical team does re-
9 calibrate our models every harvest period, so
10 that's at least twice a year. And they're re-
11 calibrated to get an ODE ratio of 1. Usually
12 that re-calibration factor's very small. It's,
13 you know, 1.00-something. But they are re-
14 calibrated with each harvest.

15 CO-CHAIR NERENZ: Thank you. And so

16 --

17 (Simultaneous speaking.)

18 MR. SHAHIAN: And the other thing I
19 forgot to mention was that our statistician has
20 looked at the correlation between composite score
21 estimates over two successive time periods, and
22 that correlation is 0.63, if that helps.

1 CO-CHAIR NERENZ: Yeah, it helps.

2 MR. ANTMAN: This is Mark at the STS.
3 May I just add to what Dr. Shahian said that the
4 updated adult cardiac risk models that were
5 published recently, we did send those papers from
6 the STS annals of thoracic surgery, along with
7 our templated response tied to the Methods Panel
8 staff, a couple of weeks ago. So the staff and
9 hopefully the panel should have those updated
10 risk models available to you.

11 CO-CHAIR NERENZ: Got it, yes. Yes,
12 thank you. All right, I don't see hands up or
13 raised eyebrows or name tags up, so I think we
14 may be ready then to call the question here.

15 So if you're on the subgroup -- oh,
16 Sherrie?

17 MEMBER KAPLAN: Just one point of
18 contention with Larry, that we've been back and
19 forth about, but stability is not a measure of
20 validity because my bathroom scale tells me the
21 same thing every moment. It is wildly wrong, but
22 it's completely stable. So just to note that --

1 MEMBER GLANCE: How do you know it's
2 wildly wrong?

3 MEMBER KAPLAN: It's wildly wrong
4 because I go to the doctor, and he tells me how
5 much I weigh.

6 CO-CHAIR NERENZ: All right, well,
7 let's keep that in mind as we go ahead. So would
8 members of the subgroup -- and you know who you
9 are -- go to one link and one polling place? The
10 rest of us go to SurveyMonkey, and let us do this
11 then.

12 MS. JOHNSON: And let me remind you we
13 are only voting on validity for this measure.
14 This is the one where CNR reliability had passed,
15 so we don't need to re-vote that one.

16 MS. OGUNBEMI: Okay. We are voting on
17 Measure 0696, the STS CABG composite score. We
18 are voting on validity. The voting is active for
19 subgroup members. Your options are high,
20 moderate, low, and insufficient.

21 So our votes are 33 percent high, 67
22 percent moderate, 0 percent low, and 0 percent

1 insufficient. And the counts are two votes high
2 and four votes moderate. Measure 0696 passes on
3 validity.

4 CO-CHAIR NERENZ: Thank you,
5 everybody. All right. Pause to take a breath.
6 Move on before our break.

7 We are now moving to -- same subgroup,
8 Measure 3537. This is a measure of
9 intraoperative hypotension. It comes to us from
10 Mathematica. Staff name is on my agenda.

11 (Laughter.)

12 MR. LYZENGA: So yes, the 3537. This
13 is a measure of the percentage of non-cardiac,
14 non-emergency surgery cases involving general
15 anesthesia, or monitoring anesthesia care, in
16 which mean arterial pressure fell below 65
17 milligrams -- milliliters -- I actually don't
18 know what that measure is -- for a cumulative
19 total of 15 minutes or more. So this is sort of
20 an intermediate clinical outcome, looking at a
21 particular measurement within the surgery, making
22 sure it -- of hypotension.

1 This is a registry-based measure
2 intended to apply at the individual clinician
3 level. They did a signal-to-noise analysis for
4 reliability of the measure score using the Adams
5 method. They provided the distribution of those
6 reliability statistics by clinician denominators,
7 sample size, and by quartile -- had, you know,
8 some fairly high scores. One of the concerns
9 that the panel members raised was they wanted to
10 see that those reliability statistics were
11 reported by case volume, and the developers did
12 provide that in their follow-up material. We can
13 discuss that in a moment.

14 For validity, they did a couple of
15 types of validity testing. One was predictive
16 validity, by which they examined the association
17 between unadjusted measure score in several
18 negative outcomes, and then linked to
19 intraoperative hypotension.

20 Their results were as they expected.
21 Patients who experienced those negative outcomes
22 had significantly higher rates of hypotension

1 than patients that did not experience these
2 outcomes. And then their second way of assessing
3 validity was in known-group validity assessment,
4 in which they tested whether anesthesia cases
5 involving patient subpopulations known to be at
6 greater risk for intraoperative hypotension had
7 significantly poorer measure scores than those
8 cases not involved with those high-risk
9 subpopulations.

10 Their results were consistent with
11 what they expected, with the exception of
12 patients who were 65 or older, who had slightly
13 but significantly lower intraoperative
14 hypotension rates than patients who were under
15 65, which was contrary to what they were
16 expecting. And with that, I will turn it over to
17 our lead discussant, who I think is Jeff Geppert
18 --- oh, Larry.

19 MEMBER GLANCE: Okay, thanks. Thanks
20 for that really good summary. So this is a
21 really interesting measure, and basically the
22 idea is that if you have a low blood pressure

1 during an operation, you're more likely to have a
2 bad outcome, you're more likely to die, you're
3 more likely to have a heart attack, kidney
4 failure, et cetera, et cetera. And to surgeons
5 and to anesthesiologists who practice out there,
6 I mean, this has a lot of face validity. You
7 know, you don't want to go out there and be
8 really hypotensive for a long period of time.

9 In terms of the empiric evidence
10 supporting that, so far there's not a huge
11 amount. Even though it really, really makes
12 sense to most of us, the reality is that there is
13 very limited evidence to support this. Most of
14 this from observational studies, which really do
15 not establish causality. There is one randomized
16 control trial that was published in JAMA, but
17 that looked at sort of standard blood pressure
18 control versus -- which they defined as keeping
19 the blood pressure within 40 percent of what your
20 normal is, versus keeping it within 10 percent.

21 So very few of us would let the blood
22 pressure drop to below 40 percent of what it

1 normally is, so that really wasn't a fair trial.
2 This is sort of by way of introduction.

3 So this is a risk adjusted outcome
4 measure. It's a very parsimonious model, and
5 there's nothing necessarily wrong with a
6 parsimonious model. But in this case, one of the
7 -- basically it has age, sex, ASA physical
8 status, how long the surgery lasts, and body mass
9 index. Okay?

10 So one of the most important
11 predictive risk factors is ASA physical status.
12 And for those of you who are not
13 anesthesiologists or surgeons, which I take it is
14 the vast majority of us -- of you, not me. So
15 ASA physical status, one, you're a normal,
16 healthy patient. Two, you have mild systemic
17 disease, like you're a smoker, you have some
18 well-controlled hypotension. Three, you have
19 severe systemic disease, so you have poorly
20 controlled diabetes, or you're end-stage renal
21 disease. And then four, you have severe systemic
22 disease that is a constant threat to life.

1 So why am I going over this? Well
2 because the ASA physical status is not as
3 objective as it sounds. Basically, I as an
4 anesthesiologist code that at the very beginning
5 of the case. So if I know that my performance is
6 going to be measured, that maybe, you know,
7 people who are a lot sicker are expected to have
8 a higher incidence of low blood pressure. And
9 maybe I don't do such a good job every day, maybe
10 all my patients have a low blood pressure, but I
11 don't want to be singled out as being a low
12 performance outlier. So I'm going to upcode all
13 of my patients.

14 So this particular measure in terms of
15 the risk adjustment is really, really sensitive
16 to upcoding because the people whose performance
17 is being measured are the people who are making
18 the determination of the ASA physical status,
19 which is one of the main risk factors in this
20 model. So that's a big problem with this model.

21 The other thing is that it doesn't
22 really account for the complexity of the surgery.

1 So if you're doing a mastectomy, you know, that's
2 a relatively superficial procedure. People
3 aren't likely to get hypotensive. If you're
4 doing an open abdominal aortic aneurysm repair
5 surgery, those are a lot sicker patients, there's
6 a lot more volume shifts, much more likely to get
7 hypotensive. That is not at all captured in this
8 model. Okay?

9 So the model itself is a little crude,
10 and to my way of thinking, it's not quite yet
11 ready to be released in the wild. Okay? The
12 second thing is that not only is the model
13 probably not quite as good as it needs to be when
14 you look under the hood, but it was developed
15 using just two different centers, two different
16 hospitals. Okay?

17 So if you look at the typical risk
18 adjustment measures that we look at, the good
19 ones -- you know, the STS measures 1,000
20 different hospitals, you know, CMS outcome
21 measures, you know, 2,000 hospitals -- this one
22 is based on two hospitals. Okay? So it is very

1 unlikely that you can generalize anything about
2 this measure and about its performance, and its
3 validity, and its reliability to anything outside
4 of the very limited data set that was used to
5 develop the measure.

6 And those were really the main issues
7 that I had with this. I think that the
8 reliability was quite good; it's just there are
9 major problems with validity, and mostly around
10 a, the risk adjustment model, b, the
11 generalizability, and c, the very real potential
12 for gaming.

13 CO-CHAIR NERENZ: Okay, thanks. We're
14 going to do a couple comments, and then if we do
15 have developers available on the line, ask them
16 to respond. Let's do either building on those
17 comments, challenge those comments. Alex, and
18 then Joe.

19 MEMBER SOX-HARRIS: To build on the
20 comments related to the contents of the risk
21 model, there's another variable that I had a
22 question about, which was the length of the

1 operation. Things that go in risk models should
2 be before and related to the outcome, and not
3 gameable. It's a clinical question, I'm not a
4 clinician, whether length of the operation could
5 be related to the outcome in a way that was, you
6 know, in both directions.

7 So the longer the operation, the more
8 opportunities would be for having low blood
9 pressure, which might make the operation longer.

10 MEMBER GLANCE: So in a sense, you're
11 right in almost all contexts. You do not want to
12 put things that happen during the episode, like
13 blood transfusion and stuff like that, into the
14 model. On the other hand, in this particular
15 case, if you're doing a really long operation,
16 it's more complex possibly, and you are maybe
17 more likely to have episodes of hypotension.

18 So if you were comparing someone who
19 routinely does really long, complex procedures to
20 someone who does 30 to 60 minute procedures, you
21 would want to take into account for the
22 complexity and the duration of the surgery. I

1 don't think that's completely unreasonable.

2 MEMBER SOX-HARRIS: Yeah, so perhaps
3 a way around this concern is to have the average
4 length of the procedure -- not the actual length
5 of the specific procedure -- included in the
6 model, which would account for complexity and
7 length, but would not have this issue I'm worried
8 about.

9 MEMBER GLANCE: Agreed.

10 CO-CHAIR NERENZ: Joe?

11 MEMBER HYDER: Larry made some
12 excellent points. I'll make a couple others.
13 This has excellent face validity, but the
14 challenge is really in the details, so one of the
15 issues is that the measure as specified is at a
16 level of clinician, not facility or otherwise.

17 For most anesthetics given in the
18 United States, they're provided under a care team
19 model, so there may be one or multiple
20 anesthetists, one or multiple anesthesiologists.
21 The developers have come back and said we would
22 attribute the performance, and encased all of

1 those individuals. I think we'd lose some folks
2 on the validity with that.

3 So even if one person controlled the
4 blood pressure, they would get dinged for others,
5 in the same case not controlling blood pressure.
6 And then Larry made an excellent point about risk
7 adjustment. So as far as the length of surgery,
8 that's something that's determined after the
9 case, so you could come up with a philosophical
10 piece about: should we use something that
11 occurred after the case to risk adjust?

12 Most of us would say no. I think the
13 exception would be looking at what NISQUIP does,
14 and also what STS does, which is they use a
15 surgical CPT to risk adjust. So the CPT may be
16 pre-specified, but the one that's documented in
17 the risk model is the one that was performed. I
18 think there'd be an opportunity to use something
19 other than length of surgery with surgical CPT to
20 try to get at a much more meaningful risk
21 adjustment.

22 I think what happened in their

1 reliability calculations here -- and I could be
2 completely wrong -- is that inadequate risk
3 adjustment put variability in the hands of
4 individual clinicians rather than back into the
5 case. And clinicians take care of certain kinds
6 of patients for certain kinds of cases in a non-
7 random way, so you're going to have a falsely
8 elevated reliability for those clinicians.

9 And then another minor point is I
10 think there's some exclusions here. They talk
11 about monitored anesthesia care, general
12 anesthesia, and so forth. Some of our surgeries
13 require induced hypotension, and it's not a rare
14 thing. This includes, for some surgeons, all
15 their joint replacements, a very common surgery,
16 spine procedures, also very common surgeries.
17 There's no exclusion or a way to get around
18 induced hypotension at the request of the
19 surgeon.

20 So I think there's some important
21 limitations that may have affected the
22 reliability and the validity for this one.

1 CO-CHAIR NERENZ: Thank you. I'm just
2 going to make a quick observation just to kind of
3 guide us as we keep going here, and then we'll go
4 to Daniel, and then I'm going to go to
5 Mathematica.

6 Jeff points out -- and I think it's
7 good for us to keep in mind -- there's this
8 really narrow hair split distinction in some of
9 these areas, say of risk adjustment, where
10 whether it's our call, or is it the Standing
11 Committee's call? And I just want us to be
12 thinking of that -- that although it's sometimes
13 hard to know exactly, we've often said let's
14 focus on the math, let's focus on the statistics,
15 let's focus on model construction, that kind of
16 thing.

17 If a certain variable should or should
18 not be in because of its clinical meaningfulness,
19 or is it specified a certain way, we typically --
20 at least in our young history so far, have said
21 that's maybe something up to the Standing
22 Committee. So I don't think anything to this

1 point has been inappropriate, but as we go from
2 here to the voting point, let's make sure that we
3 don't put ourselves in the position of the
4 Standing Committee to say, you know, conceptually
5 or clinically or medically the right things are
6 in there.

7 And I realize it's a hard thing to
8 keep, but that's -- okay, so Larry, you want to
9 speak directly to this point? And then I'm going
10 to go to Daniel.

11 MEMBER GLANCE: So you know, I think
12 this is a bit of a philosophical point. And I
13 think sometimes it's very difficult to separate
14 out methodological expertise from content
15 expertise. So I think in this particular case,
16 certainly some of us have very, very specific
17 content expertise.

18 But, even in a more general sense,
19 when you're looking at the validity of the
20 measure itself, I think part of that involves
21 looking under the hood and looking at the risk
22 factors that were included, whether they were the

1 right risk factors or not the right risk factors.
2 So we talked a little bit about this. You know,
3 if you're going to look at an episode, are you
4 going to include complications or not? Should
5 you be including hospital characteristics, or
6 not?

7 So you know, in this case, should you
8 be including a variable that we know is very easy
9 to game? And we're telling you that right now
10 because we have that content expertise. So I
11 actually think that we ought to be careful about
12 not making a strict kind of black and white, sort
13 of like, divide. You know, I think we ought to
14 be looking at the risk factors. In some cases,
15 it's very appropriate to do so.

16 CO-CHAIR NERENZ: And the process
17 allows the Standing Committee to overrule us
18 anyway. So okay, Daniel, and then Jack.

19 MEMBER DEUTSCHER: And just a quick
20 note about reliability. They did provide some
21 additional information that we requested. And so
22 I'm looking at this additional table that splits

1 the clinicians by sample sizes. And if I'm
2 reading this correctly, although the overall
3 reliability was very high, I think probably one
4 of the reasons was that most clinicians have very
5 large volumes.

6 But there was still one group of
7 clinicians with one to 30 cases that had an
8 average reliability of 0.5. So and it wasn't a
9 very small group. It was about 12 percent of the
10 sample. So I think maybe for reliability it
11 should be noted that the measure isn't reliable,
12 but above this threshold.

13 CO-CHAIR NERENZ: Yes, thank you.
14 Jack, and then back to Joe.

15 MEMBER NEEDLEMAN: Daniel, where was
16 that report of the reliability for cases one to
17 30?

18 MEMBER DEUTSCHER: It's in the PDF in
19 the discussion guide.

20 (Simultaneous speaking.)

21 MEMBER DEUTSCHER: In the discussion
22 guide.

1 MEMBER NEEDLEMAN: Because that's not
2 in the original evidence package.

3 MEMBER DEUTSCHER: Right.

4 MEMBER NEEDLEMAN: My comment about it
5 was not in the original evidence package. They
6 only report reliabilities for the whole sample
7 going down -- and again, that represents an
8 inability to provide data that's useful for
9 assessing whether the cut point for minimum
10 number of cases. And that made the evidence
11 package insufficient for making appropriate
12 decisions. And this table just reinforces and
13 confirms that.

14 MEMBER DEUTSCHER: Yes.

15 MEMBER NEEDLEMAN: The conclusion
16 should draw from the table on page 22. It's very
17 different from what you would draw from the
18 evidence package.

19 CO-CHAIR NERENZ: True. Yes, thank
20 you. Joe, and then back to Larry.

21 MEMBER HYDER: I want to speak to your
22 point because my interpretation is that it may be

1 deceiving. So if Larry and I both take care of
2 very sick people, and he takes care of them for a
3 really big surgery, and I take care of them for a
4 really small surgery, and we don't risk adjust
5 for that, what will happen is that it will appear
6 with higher reliability that he's a lot worse
7 than I am.

8 And so I think that the adequacy of
9 the risk adjustment or the inadequacy of the risk
10 adjustment in this case may be contributing to a
11 falsely elevated reliability estimate. I could
12 be wrong, but that's my distinct impression.

13 CO-CHAIR NERENZ: All right, Jeff?

14 MEMBER GLANCE: Just one quick note.
15 This is actually something that we talk about in
16 our white paper. The fact that before you look
17 at reliability, you should be looking at risk
18 adjustment because if the risk adjustment is
19 inadequate, then you're going to have falsely
20 elevated reliability. And I think that Joe spoke
21 to that very well.

22 CO-CHAIR NERENZ: All right, Jeff?

1 And then I do want to let Mathematica get a
2 chance here.

3 MEMBER GEPPERT: I'll be quick. I
4 don't know, for some reason not feeling very
5 positive today.

6 (Laughter.)

7 MEMBER GEPPERT: The way that, you
8 know, the reliability and validity results are
9 reported even -- you know, we asked for some
10 additional results. Those were provided. Very
11 illuminating. I really liked the way they did
12 the validity. And I'm looking at some -- you
13 know, finding the implicit quality construct with
14 our measure, but then I'm looking at some
15 downstream outcomes. You know, we don't see that
16 very often. This is one of the few cases where
17 the developer actually looks at, you know, the
18 relationship with downstream outcomes, so I
19 think, you know, in a lot of respects, they've
20 done an exemplary job.

21 CO-CHAIR NERENZ: All right, on that
22 happy note, Cindy from Mathematica -- oh no,

1 Patrick, but you're not in the subgroup. Are you
2 directly on one of these points?

3 MEMBER ROMANO: I'm not in the
4 subgroup, so I'll --

5 (Simultaneous speaking.)

6 CO-CHAIR NERENZ: Okay, let's do
7 Mathematica first, and then we'll see where we
8 go.

9 MEMBER ROMANO: Okay.

10 CO-CHAIR NERENZ: Cindy?

11 MS. CULLEN: I'm going to hand it over
12 to our principal investigator, Dr. Anna
13 Christensen.

14 MS. CHRISTENSEN: Hi, yes. This is
15 Anna Christensen. Thanks for giving us a chance
16 to comment. Let me start by talking about some
17 of the statistical results that we provided, and
18 focus more first on some of the more traditional
19 things that the Scientific Methods Panel
20 reviewed.

21 So as the discussants have mentioned,
22 we did provide new reliability. People showing

1 reliability results above 0.8, and in many cases,
2 above 0.9 for the vast majority of clinicians in
3 our sample. As mentioned, we only have two
4 hospitals in our testing data so far. That's
5 because this is a measure that is not yet in use.
6 It's under consideration for use at this point.

7 And we use data from the anesthesia
8 information management system, so we don't have
9 larger amounts of data at this point to test the
10 measure. But in the sample that we did look at,
11 it's high reliability for the vast majority of
12 clinicians.

13 And then the last commenter mentioned
14 the new validity testing data. I hope everyone
15 had a chance to see that. We provide a graph
16 that shows that the clinician level risk adjusted
17 measure is very strongly associated with
18 downstream adverse outcomes for patients.
19 Clinicians with the worst two quintiles of this
20 measure have higher rates of acute kidney injury,
21 cardiac surgery, and death in hospital.

22 In terms of the risk adjustment -- the

1 items in the risk adjustment measure, the
2 discussants mention the ASA status, which yes, is
3 something that is assigned by either a nurse
4 clinical anesthetist or the anesthesiologist. We
5 were told on various site visits that we went on
6 that that was something that, you know, although
7 there is some subjectivity in assigning it, it's
8 something that clinicians feel like they're
9 mostly on the same page on. There's some
10 research showing some EquIS inter-rater
11 (phonetic) reliability on ASA status.

12 In terms of the surgical length, and
13 that being something that is determined after the
14 case, the length of the case is something that is
15 used for billing purposes. So it's very reliably
16 reported, and trying to mess with that length of
17 a case between anesthesia start time and end time
18 would amount to billing fraud. So we were
19 reassured that that would be something that
20 wouldn't necessarily change, or couldn't be
21 gamed.

22 In terms of the induced hypotension,

1 that's something, right, the measure does not
2 deal with, but some of our clinician consultants
3 had mentioned that that is not something that is
4 very common. Let me check with my team and see
5 if there are other points that they wanted to
6 address. Okay. Hearing none, if there's
7 anything else that I have forgotten to address,
8 please let me know. We'd be happy to talk
9 through some more of our position.

10 CO-CHAIR NERENZ: All right, thanks
11 Cindy. Our process here is now we open up to the
12 entire panel for comments or questions. Patrick
13 had the first crack at this.

14 MEMBER ROMANO: Yeah, I mean, two
15 things. I mean, one unfortunately is that I
16 certainly understand that the developers are
17 trying to use the duration of the surgery as a
18 proxy for the complexity of the surgery.
19 Unfortunately, it sort of violates the rule, that
20 it's endogenous, you know, because clearly a
21 period of prolonged hypotension is going to
22 affect the total length of the operation.

1 Either it'll lead to a termination of
2 the operation, it may shorten in some cases, or
3 it may lengthen in other cases because of the
4 maneuvers that are being made to address that
5 hypotension. So clearly, that is not an
6 acceptable theory. Now, it seems to me that the
7 developers have access to measuring the average
8 duration of operations of that type, which would
9 be exogenous. So if you took it away from the
10 length of that particular operation in that
11 patient, and used instead the average length of
12 operations of that specific type, then you could
13 resolve that problem.

14 The other thing I wanted to point out
15 is that they cite Kendale's paper for predictive
16 analytics, and the most important risk factor
17 that was identified in that paper was actually
18 the baseline blood pressure level. So I know
19 there was some discussion in the documents
20 about why that could or couldn't be included, but
21 that would be an important thing to consider.

22 CO-CHAIR CELLA: All right, thanks.

1 Any other comments by other members of our group?
2 Jack, you look like you're thinking about it.

3 MEMBER NEEDLEMAN: Yeah. I'm looking
4 in the documentation. I'm not finding it
5 immediately, so I'll ask the developer. In light
6 of your reliability findings, is there any
7 minimum number of cases that are specified for
8 inclusion in this measure?

9 MS. CHRISTENSEN: Right now, we don't
10 have a minimum case volume. The testing is all
11 done with clinicians of all numbers of cases.

12 MEMBER NEEDLEMAN: Okay. Yeah, that
13 might be a decision you want to reconsider, given
14 the reliability numbers that you've presented to
15 the committee.

16 CO-CHAIR NERENZ: Karen, let me just
17 ask you, the general measure endorsement process
18 --- clearly this matters. We all see it in the
19 table. There's no mystery here. If there should
20 be a minimum, is it up to the developer to state
21 the minimum at the front-end of this? Can we, in
22 our process, state a minimum? How does this work

1 now? Because the table says what the table says.
2 It's not so hard to figure out.

3 MS. JOHNSON: You could suggest that
4 they might want to consider a minimum, but they
5 would be the ones who would actually --

6 CO-CHAIR NERENZ: So that's not up to
7 us to declare?

8 MS. JOHNSON: Correct.

9 CO-CHAIR NERENZ: Okay.

10 MS. CHRISTENSEN: Yeah, we would be
11 happy to make that change. It was our
12 understanding that that would be made at the
13 point of the program at which the measure was
14 included, but we could also make that suggestion
15 in our specification.

16 CO-CHAIR NERENZ: Yeah, I think part
17 of the concern we've had, at least looking back
18 historically, is that a measure gets NQF-endorsed
19 under certain conditions, so then the users and
20 programs go off and do whatever they want to with
21 it. Different setting, different minimum sample,
22 they do whatever they want. So the feeling here

1 is things have to be a little tighter than that.
2 But that's okay. Christie?

3 MEMBER TEIGLAND: Just quickly. I
4 don't know if you've looked at, you know, any
5 ranges below 30, because it might not be 30. I
6 don't know how you got, you know, those cutoffs,
7 but it could be 20, it could be, you know, 10
8 maybe. But you might want to just do a little
9 further investigation of that bottom number.

10 CO-CHAIR NERENZ: Okay. All right.
11 I'm sensing a movement to call the question, and
12 then break. That's good. Larry?

13 MEMBER GLANCE: I just wanted to make
14 just a general comment to the measure developer.
15 I actually think that this measure -- although in
16 my judgment, I don't think it's quite ready to be
17 released -- I really like the concept because it
18 is very likely that there is an association, a
19 causal relationship between hypotension
20 intraoperatively and mortality, and major
21 morbidity.

22 But I think that this measure needs a

1 little bit more work. I think you need to
2 develop your models a little bit better, and you
3 need to have more hospitals in your data set. I
4 think that you need to consider other risk
5 factors besides the ones that you've included,
6 but I don't know how this group is going to end
7 up voting. But if it ends up voting not to
8 endorse this measure, I don't think in any way
9 should that be seen as our group saying this is
10 not something that has some promise.

11 I think this is potentially a very
12 important measure. There are not a lot of
13 measures out there that really look at what
14 perioperative physicians do in the operating,
15 what anesthesiologists do. So this is a really
16 interesting measure, and I think it needs to be
17 pursued.

18 MS. CHRISTENSEN: Thank you.

19 CO-CHAIR NERENZ: All right, let us
20 proceed then. Subgroup members to your voting
21 domain, and the rest of us SurveyMonkey, and
22 let's do the business.

1 MS. JOHNSON: And we'll be voting on
2 both reliability and validity on this measure,
3 which --

4 MS. OGUNBEMI: So we are voting on
5 3537, reliability. The options are high,
6 moderate, low, and insufficient. Voting is open.

7 Okay, voting results --- oh, it's
8 moving. I'm going to close the responses now,
9 thank you. The measure still passes, but the
10 results for Measure 3537, reliability, 33 percent
11 high, 50 percent moderate, 17 percent low, and 0
12 percent insufficient. And the count is two votes
13 high, three votes moderate, one vote low, and
14 zero votes insufficient. Measure 3537 passes on
15 reliability.

16 And now we move to validity. The
17 voting is open for validity of Measure 3537.
18 Voting is closed. Let's see. So we have 0
19 percent high, 33 percent moderate, 67 percent
20 low, and 0 percent insufficient. The counts are
21 zero votes high, two votes moderate, four votes
22 low, and zero votes insufficient. Measure 3537

1 fails on validity.

2 CO-CHAIR NERENZ: All right. Well
3 thanks everyone for the discussion. Good work.
4 We are now at a scheduled break time. The agenda
5 says we're back at 3:00. That is a little
6 challenging. We're close, though. How about if
7 we try for five after, and I'll try to get us
8 going as close as we can to that.

9 (Whereupon, the above-entitled matter
10 went off the record at 2:53 p.m. and resumed at
11 3:09 p.m.)

12 CO-CHAIR NERENZ: Our speakers need to
13 go green. All right, getting ready to go here in
14 just a second.

15 Just to get us oriented, we have three
16 measures to talk about in a little over an hour
17 and a half, so I think we can do that. We are
18 still under the auspices now of Subgroup 2,
19 although we'll switch eventually to 3. We are now
20 talking about Measure 0018. This is also an NCQA
21 measure about controlling high blood pressure.
22 This is actually in front of us because on

1 validity, it was a consensus not reached. So,
2 Ashlie will tee this one up for us.

3 MS. WILBON: Yes. Thank you, Dave. As
4 we've mentioned, we're looking at Measure 0018,
5 Controlling High Blood Pressure, from NCQA. This
6 is a maintenance measure. The description reads,
7 the percentage of adults 18 to 85 years of age
8 who had a diagnosis of hypertension and whose
9 blood pressure was adequately controlled less
10 than 140/90 during the measurement year.

11 We have categorized this measure as an
12 intermediate outcome. It is a health plan level
13 measure, as you are aware. It does not contain
14 risk adjustments, and there is no analysis of
15 social factors. And the developers described
16 using plan type as a bit of a proxy for income
17 and socioeconomic status.

18 As we mentioned, reliability passed
19 with a rating of high. They did do the testing
20 for reliability using the beta-binomial approach,
21 signal to noise analysis. Overall reliability
22 ranged from .98 to .99 across the three types of

1 plans.

2 Again, while it passed, there were a
3 few concerns expressed by reviewers about the
4 clarity and consistency of the specifications and
5 various age ranges used throughout the
6 specifications that seem to be inconsistent, and
7 some clarity around how -- which target was used
8 for blood pressure. But I think maybe we could
9 get some clarity from the developers a little bit
10 later on that. But overall it passed on
11 reliability so we won't spend time there.

12 For reliability, work consensus not
13 reached -- I'm sorry, for validity, work
14 consensus not reached, so we'll focus our
15 discussion here, I'll just do a brief summary of
16 some of their testing approach and then means,
17 and some of the concerns, then we'll turn it over
18 to John for a brief summary as well.

19 So the validity of the health plan was
20 demonstrated using -- with construct validity,
21 the entire heated beta sample. The validity was
22 conducted in correlation with another measure,

1 which was the comprehensive diabetes care blood
2 pressure control measure, which looked at the
3 percentage of adults 18 to 75 of age with
4 diabetes, whose most recent blood pressure level
5 was taken during the measurement year, was less
6 than 140/90.

7 The Pearson correlation, they did a
8 Pearson correlation between these two measures
9 and across the three types of health plans. Those
10 scored ranged from .75 to .93. Medicare was the
11 lowest and commercial plans with the highest
12 correlation score.

13 The concerns around validity are
14 related to the lack of analysis around the
15 multiple data sources, the exclusion of lack of a
16 risk adjustment, and the comparative measure that
17 was used to demonstrate construct validity. So,
18 I'll stop there. John?

19 CO-CHAIR NERENZ: Daniel?

20 MS. WILBON: Actually, it's John, but
21 if Daniel, I don't know if --- oh, I'm sorry, I'm
22 looking at the wrong measure. Daniel. Sorry. My

1 agenda was on the wrong side. You're the lead
2 discussant?

3 MEMBER DEUTSCHER: I'm not supposed to
4 discuss this ---

5 MS. WILBON: Oh, okay. I can keep
6 going.

7 MEMBER DEUTSCHER: Yeah, go ahead. I'll
8 say what I know.

9 MS. WILBON: I'll start with the
10 concept validity. There were concerns over the
11 method that was selected to test the correlation
12 demonstrate construct validity.

13 The concerns were around the fact that
14 they both have, potentially have the same data
15 elements around blood pressure measurements, as
16 well as the overall measure, so that the diabetes
17 population eventually would be a part of the
18 overall population as it's measured in the packet
19 of the measures that we're looking at. So there
20 was concern that the measures aren't actually
21 independent measures themselves, and that there
22 may be some completing there with comparing those

1 measures and the direction of the quality
2 performance score.

3 The next concern around risk
4 adjustments, that there was not any risk
5 adjustment, there was concern about this and
6 whether the stratification alone of the health
7 plan types was enough to account for the
8 differences in the population that is generally
9 factored with the different health plan types.

10 Additionally, there was some notes
11 from reviewers around whether or not, in addition
12 to socioeconomic differences, that there may be a
13 need to adjust for additional clinical factors
14 that may come into play with certain populations
15 that may be more challenging than others to
16 control blood pressure.

17 Multiple data sources, again, the
18 measure as specified identifies at least three
19 sources for collecting data for the measure
20 claims, electronic health data, electronic health
21 records and paper medical records. There was not
22 any analysis in the submission, the initial

1 submission around how there may be differences in
2 reliability or validity based on where the data
3 was extracted from for the measure.

4 And then finally, some concerns were
5 kind of questions from the reviewers about
6 additional analysis for the exclusions to
7 determine kind of a sensitivity analysis to
8 determine that the percent of cases that were
9 included actually aligns with what you might see
10 in the literature or that they don't overall
11 impact the performance scores in some other way.

12 So with that, I will pause and open it
13 up to the subgroup.

14 CO-CHAIR NERENZ: Yes, why don't I
15 invite anyone from the subgroup who wants to make
16 a comment or questions to the measure developers.
17 Okay, Daniel, yeah.

18 MEMBER DEUTSCHER: Yes, so I think a
19 lot of the people -- what you've stated already,
20 I think some of the information was provided
21 about validity, which looked good to me. I looked
22 at it yesterday. Especially regarding the

1 circularity of the comparison data with the
2 sample of patients that was essentially part of
3 the larger sample, which the measure measures,
4 right.

5 Then you went on and provided some new
6 analysis, comparing this measure to a different
7 measure again, so maybe you want to explain that.
8 From what I saw, it seemed satisfactory to me as
9 a solution for this circularity problem.

10 MR. ROMAN: Sure. So we recognize the
11 comment that was made about it kind of being
12 circular in some ways, or one population being a
13 subset of the other, and the target of the
14 measure exactly the same. So we went back and we
15 compared the blood pressure measures to two of
16 our diabetes Hb1c measures instead.

17 And the results all had moderate to
18 strong correlation so for looking at the blood
19 pressure measure comparing this to our Hb1c
20 control measure where we had Hb1c values of less
21 than an eighth, there was a .81 correlation for
22 the poor control measure --- I'm sorry, I just

1 said that backwards.

2 MS. BARTON: This is commercial.

3 MR. ROMAN: Oh, sorry.

4 MS. BARTON: And so then the poor
5 control measure is negatively correlated, which
6 you would expect. So I take it, .824.

7 MR. ROMAN: Right. And in Med -- so in
8 the Medicare line, the same thing with the good
9 control it was .5, and with the poor control it
10 was .57 and in Medicaid it was .79 for the
11 control measure and negative .8 for the poor
12 control measure.

13 CO-CHAIR NERENZ: Larry?

14 MEMBER GLANCE: So I appreciate the
15 comments that you all are making and there
16 certainly may be some evidence to support
17 construct validity but I think that in terms of
18 the utilization of this measure, we all recognize
19 that some hypertensives are more difficult to
20 control than others, and there can be a big
21 difference between somebody who is requiring one
22 anti-hypertensive and somebody else who is

1 requiring three anti-hypertensives to control
2 their blood pressure.

3 And this measure does not recognize
4 the difference between those types of patients,
5 so I think if you're going to look at the
6 outcomes of primary care doctors in terms of
7 their ability to take care of their patients, you
8 absolutely have to have risk-adjustment. To my
9 way of thinking, this measure needs to go back
10 and needs a little bit of work.

11 I think it's a very important measure,
12 I think it's an important outcome, but I don't
13 think it should be used to measure the
14 performance of physicians and other providers
15 without some form of risk adjustment.

16 CO-CHAIR NERENZ: Larry, just a
17 question clarifying question that I have to bring
18 up. This is a plan-level measure only, right?
19 Okay. I understand, but I just ---

20 MEMBER GLANCE: No, thank you.

21 CO-CHAIR NERENZ: Okay, Daniel again?

22 MEMBER DEUTSCHER: Yes, just again, a

1 similar comment which was the second comment, the
2 main comment that I had was about risk
3 adjustment, so it also comes back to the general
4 discussions we've been having about risk
5 adjustment and the voice that we need to raise
6 here or later on in the process in extending
7 communities, so I guess that there's a question
8 on that as well.

9 But you mentioned, I think that you
10 did not risk adjust, you mentioned, I think,
11 social risk factors that you did not want to
12 adjust for in order to not over-adjust, but I
13 think there's a wide range between no risk
14 adjustment and over-adjustment, and I think
15 there's still things to discuss so I join the
16 comments here about looking more deeply into
17 those factors that might be important to adjust
18 for so to not misclassify too many providers for
19 this measure.

20 CO-CHAIR NERENZ: Any other comments?

21 Okay, Jeffrey.

22 MEMBER GEPPERT: Sort of in a similar

1 vein, you're looking for, in terms of the
2 characterization of the patients, I'd like to see
3 us delve more deeply into what the quality
4 construct of this measure actually is. What are
5 the behaviors that these plans are engaging in
6 that are resulting in the outcome that we're
7 measuring.

8 Because then I think you can actually,
9 if you do sort of a correlation like this, where
10 you can tie it more specifically to actual
11 behaviors, then it's a lot more compelling than
12 to just do the correlation without any
13 justification or explanation for why we think
14 these are correlated, and in fact provide some
15 empirical justification for why you think those
16 things are correlated.

17 We used to talk about creating flow
18 charts and things, we don't really do that so
19 much anymore, but I think in these cases,
20 especially where you don't have explicit measures
21 of quality construct, having a pretty detailed
22 flow chart of why one health plan performs better

1 than another, having some understanding of why
2 that is would be helpful.

3 MR. REHM: Thanks for that. So this
4 measure is probably by its number, 0018, one of
5 our oldest measures. The leverage that a health
6 plan can pull to ensure over a long period of
7 time, this measure's probably been in place 25
8 years or so, are many and they are varied.

9 And one of the things that is the way
10 of the operating premise, which is in a sort of
11 ecumenical way, there is the target, you figure
12 out what resources you can commit to it, you
13 figure out what the different things are that
14 would be effective in the communities you serve.
15 The primary one is to understand your members. If
16 you don't understand your members, you're not
17 going to make much traction on any of the
18 interventions.

19 There is no one intervention that is
20 wildly successful across all health plans. I've
21 worked with health plans and depending on your
22 angle of attack, your approach to that whole

1 population of health management of chronic
2 disease could be quite different.

3 More than likely, what works for
4 diabetes blood pressure is probably going to be
5 working for hypertension. Not always, but there's
6 similarities, which is why we chose that measure
7 to help support your review. You were looking for
8 another level of analogous, so that's why we
9 responded. I think, in principle, I think that's
10 kind of where we're at.

11 And I just add one other thought. When
12 we've taken this to the steering, standing
13 committees, five, six times now, one of the
14 things they like, one of the things that our own
15 governance likes, we have three panels that meet
16 on this particular measure, is its broad use to
17 improve population health. And not getting into,
18 if you will, the credible detailed clinical
19 guidelines and how to measure, absolutely bury
20 that, you know, patient profile by patient
21 profile.

22 Do we need measures to do that?

1 Absolutely. But from a population health, if you
2 think about health plans that we're trying to
3 hold them accountable for, at a national level,
4 by having benchmark data that helps 450
5 commercial plans compare themselves.

6 We do think there's value in that. We
7 also know that the needle's moving on it. That's
8 kind of where our perspective has evolved. Your
9 comments are all forward thinking, and I look
10 forward to addressing them. Thank you.

11 CO-CHAIR NERENZ: Sherrie?

12 MEMBER KAPLAN: The age of the patient,
13 I'm not a clinician so I'm way out on a limb
14 here, but it strikes me that plans that serve the
15 diagnosis of hypertension in an 18-year-old in
16 terms of its ideology are wildly different from
17 the diagnosis of, you know, in a 75-year-old.

18 So do you think, is the argument for
19 not risk-adjusting the plans that serve 18-year-
20 olds are more homogenous and plans that serve 65-
21 year-olds are more homogenous, and adjustment for
22 plan type is enough? Or do you think that is the

1 ideology so mixed that age is one of those things
2 that leaps out at you apart from diagnoses and
3 other things, is an easy one for you guys to deal
4 with but you didn't?

5 MS. BARTON: So age is interesting,
6 because I thought that you might say a health
7 plan isn't going to take care of the 18-year-old
8 long enough to see the stroke that's going to
9 happen ten years down the road?

10 MEMBER KAPLAN: Well, that.

11 MS. BARTON: And certainly that's true.
12 That's why we think that it's important to hold
13 everybody accountable for blood pressure control,
14 because while there is going to be a handful
15 compared to the number of hypertensives who are
16 60, there's only going to be a handful who are
17 18. But the importance of controlling their blood
18 pressure so that they don't have a stroke when
19 they're 40, is extreme.

20 And so having the plan be accountable
21 for that understanding that they're accountable
22 because there's a measure, somebody's looking to

1 check that they're doing this right. I think that
2 that's actually an important thing to have, not
3 to say that there should be some kind of, you
4 know, we have to figure out how many of the 18-
5 year-olds have a pheochromocytoma and how many of
6 them are this or that ---

7 MEMBER KAPLAN: And renal disease or
8 whatever.

9 MS. BARTON: Yeah, that that would be
10 getting more in the weeds than a national
11 benchmark would want to, given that you're
12 comparing plans that have thousands of members to
13 each other.

14 MEMBER KAPLAN: Can I ask one follow up
15 question? So a 75/80-year-old after a blood
16 pressure of 140/90, right, and therefore would
17 technically, or 145, if it was a digital thing,
18 over 95, or 93, who's on at least one medication
19 and on a bazillion others and you're fighting to
20 keep everything else under control, you're still
21 being held accountable for that 85-year-old's
22 wacko hypertension. Your argument then is that if

1 there's not enough of those, or if there's too
2 many of them, you're messing up?

3 MS. BARTON: Well, the measure only
4 tracks to up to 85. So there's nobody over 85.
5 And, you know, the problem of measures that use a
6 threshold, I'm not going to make a big case for
7 measures that use a threshold because I think
8 that the future of measures that use electronic
9 data, that use digital insights, will be able to
10 do much more, be much more powerful. And I wish
11 that we were there today, and we're not there
12 today.

13 A measure that says, well, how many of
14 your people with a blood pressure of 190 did you
15 drop by 20 points systolic? That would be a good
16 gold star to have, for clinicians. So for today,
17 what we have, as Bob mentioned, this measure's
18 been around for a long time. It's a measure that
19 holds health plans accountable so they can be
20 compared one to the other on a standard, using a
21 standard definition.

22 CO-CHAIR NERENZ: Okay. I see three

1 name tags up. This is now opening to the full
2 panel, I'm going to go Jack, Sean, Eugene and
3 we'll see who else gets on.

4 MEMBER NEEDLEMAN: Since I'm not quite
5 sure I was heard earlier, I'm going to be very
6 aggressive here, and I'm speaking only for
7 myself, but I've known the NCQA measures from
8 long before I became active on any of the NQA
9 activities. And I deeply appreciate the general
10 philosophy that the plan should be held
11 responsible for figuring out strategies for
12 getting everybody's health under control. I
13 really do. I also appreciate from that
14 perspective the no excuses approach.

15 On the other hand, risk adjustment is
16 an integral part of any, virtually every outcome
17 measure this committee has looked at and
18 endorsed, it is a standard part of the process,
19 and as I said earlier, there's also an element in
20 the NQF stand which is convenience, in that NQF
21 does not have to go to the individual plans and
22 ask for more analysis than the baseline rates by

1 asking them for risk adjustment.

2 And frankly, risk adjustment's going
3 to remain a major element of our assessment of
4 whether the measures get the relative rankings
5 right, get the absolute values across different
6 providers right, and if NCQA wants to continue to
7 come in here without a risk adjustment because of
8 the argument all plans should be held responsible
9 across the board, I think you're going to have to
10 show us that you've done the risk adjustment
11 makes de minimis difference in the rankings of
12 the plans.

13 Or you're going to have to show us
14 that the underlying factors in a risk adjustment,
15 age distribution, illness distributions, are
16 similar enough across your plan that even if we
17 did risk adjust at the individual patient level,
18 we wouldn't see it at plan level because the
19 factors that are in the risk adjustment are
20 similar enough across the plans.

21 But we really need to see some effort
22 to look at the effect of risk adjustment in these

1 measures to be comfortable with your general
2 approach of not requiring it of the plans.

3 CO-CHAIR NERENZ: Clearly stated. Thank
4 you. Sean?

5 MEMBER O-BRIEN: Dr. Needleman, very
6 glad you make your argument for risk adjustment
7 very forcefully articulately is no longer needed.
8 I was just curious, is this measure classified in
9 a way that makes it not required to be adjusted,
10 or are we assessing whether their rationale for
11 not providing a risk adjustment is an acceptable
12 rationale?

13 MS. JOHNSON: Yeah, this is an
14 intermediate clinical outcome so it does fall
15 under that outcome nomenclature, so we would like
16 to have the rationale as to why. And that could
17 be conceptual or it could be empirical.

18 CO-CHAIR NERENZ: Well, for example,
19 somebody could say, I'd love to do it but I can't
20 get the right data on this. Sorry, I just can't
21 do it. There are a number of approaches, but we
22 just have to judge, for those of you who are

1 voting, is this an acceptable rationale. Gene?

2 MEMBER NUNCIO: I want to call your
3 attention to the table you provided, 2E4.2, which
4 looks at the three different types of plans, the
5 commercial plan, the Medicaid plan, and the
6 Medicare plan.

7 Again, I was wondering who is holding
8 these plans responsible? I mean, what's the
9 impact of reporting that commercial has a score
10 of 54 and Medicare has a plan of 69? That's
11 number one. So who's your audience is going to
12 make a difference here.

13 The other thing I wanted to call
14 attention to was there seems to be a fair amount
15 of overlap in terms of the percentile ranges, or
16 the percentile values, in terms of performance.
17 So that the 90th percentile for the commercial is
18 higher than Medicaid. I would see this perhaps
19 more valuable to look at distribution within
20 plans as opposed to across the three types of
21 plans that you're dealing with.

22 That is, I mean, when you look at

1 commercial and the tenth percentile is 9, and the
2 90th is 71, that's a huge difference. Clearly
3 something could be done there. Again, for
4 Medicare it's 57 versus 80. You know, 57 starts
5 at the 50th percentile of commercial. So I'm
6 wondering, you know, who's going to make these
7 plans make a change? Where's risk level?

8 And number two, would you consider
9 looking within plans for your measure as opposed
10 to across plans?

11 MS. BARTON: So NCQA's role as a
12 creditor is to ask health plans who give credit
13 to report quality measures to us. We release them
14 on our website. We have a quality compass where
15 people can come and look. We also release every
16 year ratings of health plans. And if you follow
17 ANCQA on Twitter, you'll see that there's
18 currently a spate of conversations about which
19 states have the most highly-ranked plans.

20 You might be familiar with something
21 that CMS runs, called the Medicare Stars Program.
22 And that has been responsible, I would say that

1 that is what is responsible for the 57 tenth
2 percentile rating among Medicare plans because
3 they pay plans according to their performance on
4 these measures.

5 If you know of an entity that could
6 pay commercial plans to improve their quality, I
7 would be delighted for you to institute that but
8 right now CMS is the only engine, the best lever,
9 for getting plans to pay attention to quality
10 improvement. And there has been an incredible
11 result to that attention.

12 MEMBER NUCCIO: I think we all in this
13 room believe that you get what you measure. It
14 clearly is evidence that that might be the case
15 for Medicare, might be good for Medicaid.

16 Are you looking at all within
17 programs? Are there others that you're reporting
18 domain, your reporting platform?

19 CO-CHAIR NERENZ: Gene, what do you
20 mean by program?

21 MEMBER NUCCIO: I mean within a plan,
22 your rate, ranking or rating or whatever,

1 reporting to the world about commercial plans and
2 which ones have poor performance versus higher
3 performance, and you're doing it based on that
4 sort of table I mentioned.

5 MR. REHM: Right. So in general, I just
6 picked, I'll pick ACME Health Plan, 38 states, in
7 commercial, and ACME, that's a part of the
8 reporting where it's actually happening out there
9 with 38 states represented here.

10 And so those 39 ACMEs get to see that
11 data, because that's how we parse it out. We
12 don't call it ACME, we just want data points. We
13 have 38 ACMEs. And they range. They range all
14 over the place.

15 So that's, you know, this is back to
16 my original premise, which is you look at your
17 own data, and trust me, every health plan has its
18 own data shop that it's grinding this stuff out
19 all the time, probably a very rapid cycle if they
20 care about quality. There's some plans that
21 simply don't. They bills, that's what they do.
22 And shame on them, but that's just an

1 advertisement.

2 So that's a little bit about how we
3 construct this. And I think that, from an
4 accountability model, the more people who are in
5 the mix then clearly the more power you have.
6 It's just our accreditation plans could say, you
7 know what? The bar for NCQA is too bloody high,
8 we're out of here. We're going to go to someone
9 else who looks to see if we have policies and
10 procedures and we'll accredit you that way.

11 That's an option. So in some ways
12 we're trying to add measurement as the guiding
13 force. People don't vary quality in terms of
14 their compliance with the standards, the
15 structural measures. They generally all do very
16 well, because they know exactly what to do.
17 Influencing your members' behavior, influencing a
18 community's health, influencing physician
19 behavior, that's a tougher road to hoe. So that's
20 why we like this spotlight.

21 CO-CHAIR NERENZ: Let's just make sure
22 this stays on decision and comments. I'm starting

1 to wonder here, but go ahead.

2 MEMBER NUCCIO: Just a quick comment.

3 I mean, these data are the long risk-adjusted
4 data. I do support my colleagues in their desire
5 for making sure that we're comparing apples to
6 apples.

7 MR. REHM: Comparing health plan to
8 health plan. So, yeah.

9 MS. BARTON: Well, and I'm sure that
10 your colleagues in Medicaid health plans would
11 much prefer to be compared to other Medicaid
12 health plans. They see that as the fairest way to
13 rank them, to rate them.

14 CO-CHAIR NERENZ: All right, I think
15 points have been made, I don't see any other tent
16 cards up, so let us call the question on this
17 one. Subgroup 2, I think, are still the voters
18 for real. The rest of us, the Survey Monkey.

19 MS. OGUNBEMI: We are now voting on
20 Measure 0018, overall relating of validity, and
21 your voting is open.

22 Okay, we're at zero percent high, 67

1 percent moderate, 33 percent low and zero percent
2 insufficient. The measure passes validity. The
3 counts are zero votes high, four votes moderate,
4 two votes low and zero votes insufficient.

5 CO-CHAIR NERENZ: All right, thank you.
6 All right, we now, last one for Subgroup 2, we
7 are now moving to Measure 3534, 30 Day All-cause
8 Risks Standardized Mortality Odds Ratio. We're
9 only missing two necessary hyphens up there;
10 sorry, that's my pet peeve.

11 (Off microphone comments.)

12 CO-CHAIR NERENZ: Mortality Odds Ratio,
13 and we will have Karen do this one up for us.

14 MS. JOHNSON: Yeah. How well you,
15 that's a long title to get your tongue around. So
16 this measure estimates risk-standardized 30 Day
17 All-cause Risks Standardized Mortality Odds Ratio
18 following Transcatheter Aortic Valve Replacement
19 (TAVR). It uses clinical data available in the
20 SCS ACC TVT registry for risk adjustment.

21 So when they developed the measure, it
22 used site-reported 30 day follow up data in that

1 same registry.

2 So this is an outcome measure, again
3 using registry data. The level of analysis is a
4 facility level. It is risk-adjusted with 41
5 factors. So when it came to our subgroup votes,
6 it did not pass reliability. And for validity,
7 there was not consensus reached on this measure.
8 This is a new measure, so it hasn't been seen
9 before.

10 And, let's see. For reliability, I'll
11 just give you the real basic stuff and then we
12 can go to Alex to get more into the concerns. For
13 reliability, the developer-assessed inter-rater
14 reliability using data from 40 records randomly
15 selected from four randomly selected facilities,
16 I hope I have that down right, so presumably that
17 was ten records per facility but I might not have
18 that exactly correct.

19 For validity, to do data element
20 validation we did two different methods. They
21 looked at record eligibility assessment, so
22 looked at six hospitals. And basically looked at

1 all of their TABT and mitral cases within a
2 specified time frame and then compared that to
3 the registry to make sure that none of the
4 records were being missed. And then they looked
5 at 40 hospitals that had at least ten cases
6 randomly selected for audit.

7 So they looked at ten baseline, ten
8 follow up cases, randomly selected for
9 abstraction, so therefore ended up with 400
10 baseline records, 400 30-day records and quite a
11 few fewer, 289 one-year records. So they did a
12 prevalence-adjusted, bias-adjusted kappa
13 statistic.

14 The key concerns around the validity
15 analysis included exclusion of more than 50
16 percent all hospitals and patients due to missing
17 data, relatively low values for that adjusted
18 kappa for two of the values, lack of data element
19 testing for most of the variables and a
20 relatively small testing sample that may or may
21 not be representative of hospitals and patients
22 included in the measure. Those were some of the

1 main concerns. I think we hand it to Alex. Is
2 that right?

3 MEMBER SOX-HARRIS: I'm going to
4 briefly focus on three out of the four main
5 issues as I saw them. The first being the
6 eligibility criteria for participation in the
7 measure. They dropped a lot of sites for
8 eligibility, then there is what is considered a
9 critical element to be subjected to both
10 reliability and validity item level testing.

11 The item level reliability results, I
12 think we're off the hook to discuss some of the
13 concerning aspects of that methodology, because
14 if I understood earlier, they do item-level
15 validity analysis, then we don't need to consider
16 the reliability analysis, which is nice, so.

17 So I want to thank the developers for
18 responding to some of our initial comments. They
19 provided that data and rationale that were very
20 helpful.

21 To talk about the eligibility
22 requirement for participation in the measure,

1 there are 480-some entities that participate in
2 the registry that the measure is based on. In
3 order to participate in the specific measure,
4 developers have said that all critical elements,
5 all variables, need to be at least 90 percent
6 present in the data set for entities to
7 participate.

8 The effect this has is it drops out
9 over, I think roughly half of the entities. And
10 so this is, they've provided a nice table, so if
11 you scroll down to the supplemental material
12 they've provided, I think it's figure -- let's
13 see if I can find this quickly -- figure B-1 or
14 46, it shows the tradeoff between if you have
15 different thresholds of allowable missingness,
16 what the consequences are in terms of how many
17 sites you can get included.

18 I think they present this data for our
19 consideration in terms of whether their judgment
20 of 90 percent is the correct tradeoff between
21 saying something potentially more accurate on a
22 sample of the population of entities versus

1 including more entities and having to deal with
2 more missing data. So that's the eligibility
3 question.

4 The critical element question, so
5 their initial submission identified of the 40-
6 some risk adjustment variables, they identified
7 five of them as being critical. When I was
8 reviewing this, I'm a newcomer to this group, by
9 saying, aren't all the risk-adjustment variables
10 critical? I mean, if you have serious reliability
11 problems or validity problems on any of the risk
12 adjustment variables, that seems to be important.

13 So that might be a clarifying thing
14 for NQF, to say when we say, or when NQF says
15 critical elements, does it really mean all the
16 elements that you need to make a measure, or is
17 it some subset of one of the criteria to make
18 that distinction?

19 The developers kindly went back and
20 did 21 or 24 of the variables, subjected them to
21 reliability or validity testing. That's not all
22 of the variables, but it's a lot more than five,

1 so I found that helpful.

2 Last point is on the item validity
3 testing. So again, if you go to their
4 supplemental table, what you'll see is they've
5 done -- so one of the issues was essentially
6 audit, where they took data from the registry,
7 sample registry entries, and then went into the
8 component systems and looked at their records to
9 do an audit to see if the registry was accurate.
10 So it's strong item level validity analysis.

11 One of the questions was, were the
12 selected entities and patients similar to the
13 non-selected ones? They provide a nice analysis
14 to show that there's nothing really concerning
15 about the selection at that level.

16 When they went through and did the
17 prevalence-adjusted kappas for the different
18 elements, most of them looked excellent although
19 there are two that have concerningly low values,
20 including one that may be essential, which is the
21 date of death, since it's a 30-day mortality
22 measure, not having a good measure on date of

1 death to be problematic.

2 I'll take a breath and allow my
3 colleagues on the subcommittee to chime in.

4 CO-CHAIR NERENZ: Just before I go
5 there, could I just ask you a clarifying
6 question? It's on this point exactly, date of
7 death, because I was looking at this and saying
8 holy smokes, how can you have a measure if you
9 don't know the date of death? But actually, I
10 think I have an answer to my own question. I want
11 to know if it's the right answer.

12 In a registry like this, let's say you
13 do a case review in 30 days. You can record in
14 the registry yes/no whether death has occurred,
15 and you can be quite accurate of that even if you
16 didn't know for sure if it was day 25, 24, 23,
17 and so it seems to me theoretically possible that
18 you could be very, very accurate on yes/no, death
19 has occurred, and then you can spin this measure
20 even if you don't know the exact date.

21 So is that what's going on here?

22 MEMBER SOX-HARRIS: I think you're

1 right, but it's hard to check if yes/no is
2 correct unless you know the date. That's the
3 issue.

4 CO-CHAIR NERENZ: Maybe. Well --

5 MEMBER GLANCE: You know, it's funny,
6 when I was reviewing this, I didn't rightfully
7 understand why they went about presenting it the
8 way they did. So, in other words, why did they
9 focus on the data elements, when in instance of
10 data registry set, this is high-quality data.
11 This is STSS. They know how to do really, really
12 great measures. Why didn't they just go through
13 and do the usual stuff, which is to basically
14 present the reliability and the validity of the
15 score measured?

16 I think that part of our job,
17 honestly, as a panel is just to provide feedback.
18 Just like a reviewer would for a peer-review
19 journal. Personally, I think the two things I
20 would suggest would be go back and just do what
21 you normally do which is look at the score,
22 measure of validity and reliability.

1 The second thing, and I think this is
2 probably the more substantive comment, and I
3 think you made this comment, is that if you're
4 going to look at, you're going to use a measure
5 to do bench marking, to do accountability, you
6 can't exclude 50 percent of the patients.

7 I think they did this because they
8 wanted to include these really cool functional
9 measures in their model. And they really are kind
10 of cool, and they may be somewhat important in
11 terms of risk predictions but you know, you can
12 make the same argument for virtually any of the
13 other STS or non-STS measures. But the reality is
14 they were missing them in 50 percent of the
15 hospitals. You can't use it if it's missing in so
16 many hospitals.

17 So I guess our feedback to STS would
18 be, I think it would be really straightforward
19 because I'm sure they have these calculations
20 already done, would be to look at the measure and
21 look at reliability and validity at the score
22 level, number one; and number two, reestimate

1 your model with these two risk factors that are
2 missing in virtually half the patients.

3 But I think at the end of the day,
4 it's hard to pass this measure based on what was
5 presented to us in terms of validity.

6 CO-CHAIR NERENZ: And also, just as a
7 comment to the group, I'm looking up here and I
8 see the main problem actually being in
9 reliability. That's just a flat-out fail. Yeah, I
10 think. And then validity's a consensus in a
11 breeze. So does anybody, particularly in light of
12 this new information, want to argue for
13 rethinking of some of those reliability ratings?
14 Because that's just a straight fail, right there.

15 Yeah, Alex?

16 MEMBER SOX-HARRIS: I had some real
17 concerns with their reliability item-level
18 methodology. But as I said at the outset, I don't
19 think we need to judge that if their item-level
20 validity analysis is convincing, is that right? I
21 think that drove some of the low reliability
22 ratings.

1 CO-CHAIR NERENZ: Okay, so let's make
2 sure we clarify that. Because if somebody rated
3 reliability insufficient, but the rules of the
4 game said they didn't even have to do it, that
5 would be, I mean, I guess you could still vote
6 it, but that's --- what are we doing here?

7 MS. JOHNSON: Yeah. So what you need to
8 do, you can take their updated reliability
9 information if you want to, or you can take their
10 updated data element validity information and
11 apply that.

12 So since they did do data element
13 validation, you can take your rating for that and
14 apply it to reliability. So, and I think as Alex
15 stated, they originally only gave you five
16 variables. They gave you many more after that, so
17 take into account you have more variables than
18 you did, I don't remember if the sample size
19 changed or if it's the same sample size, I don't
20 recall. It's about 400. Yeah.

21 So am I being clear? You guys
22 understand? I suspect that the low numbers on the

1 reliability the first time around had to do a lot
2 with having only five elements. But that was my
3 guess. But you can take what they -- because they
4 updated both, right? They updated reliability and
5 validity, if I remember correctly.

6 CO-CHAIR NERENZ: All right. Not seeing
7 any nametags. Do we have somebody from ACC on the
8 phone?

9 MEASURE DEVELOPER: This is Susan. I'm
10 ACC staff.

11 CO-CHAIR NERENZ: All right, Susan, I
12 assume you've been listening in. Any comment,
13 response that you'd like to make so far?

14 MEASURE DEVELOPER: Well, I think we
15 recognize some of the things that you're
16 expressing concerns about with this measure. It
17 was one of our first toes in the water for
18 something we're attempting to publicly report. We
19 had talked so many times about the, it's -- all
20 the variables are very complete.

21 The mortality date is missing.
22 Sometimes it's a rare occasion, and there is

1 something that attached to our response,
2 actually. We have done a check with CMS data to
3 see if there was any gaining or differences with
4 CMS, so that, we really never saw any mismatches,
5 it's like 20-something percent of the time, over
6 several years.

7 But the, first of all, the inclusion
8 criteria, the having the KCCQ, it's something we
9 kind of felt that sites would man up and start
10 complying. They have improved over time as we
11 just started publishing this measure in our
12 outcomes reports not long ago. We feel like it's
13 important.

14 KCCQ is part of the coverage decision,
15 so the physicians really, and Dave Shavian has
16 worked with us for this and he said, people raise
17 the bar for STS, when STS raised the bar people
18 kind of stepped up to it. Everybody felt like
19 sites would do that for us. So that's one thing.

20 And then the testing, we just decided
21 not to submit this data in the first round and we
22 would, if this measure was endorsed we would

1 submit it a couple of years from now. Because the
2 way I understand this, and I'm not, I haven't
3 really worked with this, but the way I understand
4 it is that it's not something required. If you
5 submit your audit and your interreliability,
6 you're not required for the criteria to submit
7 the testing.

8 So we do typically submit that at STS
9 and ACC for other measures.

10 CO-CHAIR NERENZ: All right. Thank you.
11 I guess I'll defer to staff if they want to
12 respond immediately to that last, it's really
13 sort of a statement about the rules of the game.

14 MS. JOHNSON: Yes, she's correct. This
15 is what we call a health outcome measure, so we
16 ask for either data element testing or score
17 level, and currently we do not require both. What
18 you're hearing is Larry saying, golly, it would
19 have been nice if you had given us both, but he
20 knows that he can't take it down because you
21 didn't. But he would really like to see it in the
22 future.

1 MEASURE DEVELOPER: Yeah, and we know
2 that and we know, I mean one thing we looked at
3 is there are lower volume sites have lower, have
4 less select reliability in their measure, and if
5 we're publicly reporting it, that's going to have
6 to be something that we need to talk through.
7 Because we don't want a lower-volume hospital to
8 be reported as not as reliable.

9 So the reliability, there's really
10 low-volume hospitals and there's hospitals with
11 really high volumes. So that was one of the
12 challenges with that testing.

13 CO-CHAIR NERENZ: Dan?

14 MEMBER DEUTSCHER: Is there any way the
15 developers could comment on the discussion on the
16 percent of completeness threshold that they set?
17 I found the additional table provided very
18 interesting. From 440, 450 sites, applying the
19 current threshold, only 188 are included, which
20 is a comment that was brought up here before. So,
21 any comments on this threshold and the tradeoff
22 maybe going to a slightly lower completeness

1 threshold?

2 I was looking, for example, at the 70
3 percent or above, seemed to have resolved in a
4 completeness of the three columns here, all over
5 90 percent. Just as an example. But maybe a
6 comment on that would be helpful.

7 MEASURE DEVELOPER: Well, I mean, I
8 think one thing is that the criteria, is that you
9 perform the 30-day follow up and the statement.
10 You have to perform all three of those on 90
11 percent of your patients to get your outcomes.

12 That table that's in your packet is
13 from model development, and in the application of
14 the testing, I think I showed from model
15 development until our most recently published
16 report how that has increased over time, the
17 number of sites included, because they are really
18 trying to work on that.

19 But from what I know about those two
20 variables is we could drop the variables, and we
21 wanted to see if we can keep them. But you can't,
22 if a site has incomplete KCCQ or incomplete Five

1 Meter Walk, you impute a median score. That might
2 be good or it might be bad for a patient. It may
3 make a flight's risk adjustment artificially
4 higher or lower.

5 Those are two tools that it's just
6 more difficult to impute the median, the median
7 score, which is what you would do on a survey
8 with a Five Meter Walk if the patient didn't have
9 this assessment. So that is kind of challenging
10 in just lowering the inclusion criteria but
11 imputing the missing patients to a median score.

12 MEMBER KAPLAN: I have a question about
13 NQS position on imputation because, you know, to
14 the extent that you have more opportunities for
15 missing data, you have more missing data. So
16 multiple imputation is sometimes indicated,
17 sometimes not.

18 For example, if it's associated more
19 closely with a dependent variable of whatever
20 quality measure, you might not might want to
21 impute rates, for example. It depends on
22 circumstances. What is your position on

1 imputation, and what's called for in certain
2 circumstances, or does NQF have a policy on this?

3 MEASURE DEVELOPER: Actually, NQF to my
4 knowledge has never made a policy on imputation,
5 so we don't have any statements at all. Or if we
6 do, it's in the back of time, before I started.
7 As far as I know, we have not made any statements
8 about imputation.

9 MEMBER KAPLAN: Can we put that in the
10 parking lot for tomorrow?

11 MEASURE DEVELOPER: Yeah, maybe you
12 guys can make some statements.

13 CO-CHAIR NERENZ: I agree. It's, I was
14 maybe going to use a little bit terminology and
15 not so much the imputation, but what do you do in
16 real life, but in measurement as we're judging
17 it. If you've got a complex risk-adjustment model
18 but a lot of data elements are frequently
19 missing, do you just exclude all cases that have
20 any variables missing, which is what my own
21 statisticians do. It drives me crazy.

22 Or, you know, do you come up with some

1 sort of way in which you can use what you have
2 and argue that that's better than nothing. I
3 don't know the answer to that. Somebody has to
4 know more than I do, but this is something that
5 we probably shouldn't speak to.

6 MS. JOHNSON: Or you do a sensitivity
7 analysis to your conclusions, based upon
8 different imputation strategies.

9 MEMBER GLANCE: One thing that we've
10 done in our group is basically you take a sample
11 where you have all the complete data, and then
12 you just basically get rid of the complete data
13 on a subset of the data, then you impute that
14 missing data. Then you see how well your impute
15 data is working.

16 MS. JOHNSON: You do the sensitivity
17 analysis.

18 MEMBER GLANCE: Yes, exactly. You can
19 do that.

20 MS. JOHNSON: But I didn't know if they
21 had a policy on it.

22 CO-CHAIR NERENZ: Interesting. Okay. So

1 this sounds like a, when we're talking about how
2 to make the world a better place tomorrow
3 morning, or early afternoon.

4 Okay. Let's, any other comments from
5 anyone?

6 MEMBER GLANCE: I was just going to
7 say that, I will not take down this measure. I
8 saw that look. I really think we need to talk
9 about this. I think the idea that a measure can
10 pass just because somebody's looked at a hundred
11 copies --

12 MEMBER ROMANO: Can you speak louder?
13 We can't hear you.

14 MEMBER GLANCE: You can't?

15 If you can just --

16 MEMBER GLANCE: I was just going to
17 say that, I think we really need to talk tomorrow
18 about whether or not it's acceptable to only look
19 at the data quality. Because the idea that
20 someone can look at hundred charts and assess
21 validity and reliability at the data element
22 level and that's enough to get any endorsement,

1 that to me kind of is a problem.

2 CO-CHAIR NERENZ: Now let me just
3 check the question. For those of you who are
4 going to vote for Rio, are you okay with these
5 convoluted rules of the game, and validity counts
6 for reliability and the measures disclosed are
7 required? I just want to make sure everybody is
8 okay on this, because it's going to matter here.

9 MEMBER GLANCE: We're supposed to
10 impute our reliability, I --

11 (Laughter.)

12 MEMBER HYDER: Is this like a jury
13 trial? Are you supposed to excuse yourself in
14 front of the jury?

15 MEMBER GLANCE: No, we're just going
16 to nail it. All right, I just want to make sure
17 everybody's okay, those of you on the subject.

18 MEMBER HYDER: I'm okay with it, but
19 there's a new agenda item called "boil the
20 ocean," that I would definitely engage.

21 CO-CHAIR NERENZ: Okay, all right.
22 We'll get to this.

1 MS. JOHNSON: And just for
2 clarification, they did give us updated
3 reliability information, so you can use that.
4 We're not saying you have to use the validity
5 data element, validation, right? So you can look
6 at what they gave you with reliability, that's,
7 you know, you can use that. If that's not enough
8 to pass them, then go ahead and look at their
9 data element validation and see if that is enough
10 in your estimation to give them a passing rate.
11 Does that make sense?

12 MEMBER FABIAN: In order to be a
13 true, unbiased evaluator, you spent, I probably
14 wasn't paying as much attention as I should have
15 been, because I had my preconceived, you spent 90
16 seconds reviewing that updated reliability and
17 validity information on the data? Because I
18 don't have it in front of me for some reason.

19 MS. JOHNSON: Yes, it's --- you might
20 know it faster and better than me.

21 MEASURE DEVELOPER: So it's in there,
22 the supplemental stuff they sent. And let's see,

1 discussion guide, page 95 and beyond. Is that
2 it?

3 MS. JOHNSON: Yes. It's possibly 99.

4 MEASURE DEVELOPER: It's --

5 CO-CHAIR NERENZ: 95?

6 MS. JOHNSON: 95, yes.

7 CO-CHAIR NERENZ: Okay.

8 UNIDENTIFIED SPEAKER: 95.

9 MS. JOHNSON: 95,96, oh, yes. I wrote
10 that down in the --

11 CO-CHAIR NERENZ: Okay. I'll look at
12 it right here. Okay.

13 MEASURE DEVELOPER: I think this
14 validity guidance stuff starts on 100, page 100.

15

16 MS. JOHNSON: Is that clear? It's --

17 MEASURE DEVELOPER: Yes, no, I see it,
18 thank you. Thanks for, you know, --

19 PARTICIPANT: It's page 98. It's the
20 beginning of validity.

21 MS. JOHNSON: So let's start with page
22 95 for reliability. Start with page 98 for

1 updated validity.

2 CO-CHAIR NERENZ: Let's pause just
3 for a couple of minutes, let folks look into that
4 if they want too. I'm sure they'll get it right.
5 Let us move now on to voting. As we've been,
6 Subgroup 2 does it for real, the rest of us on
7 SurveyMonkey.

8 MS. OGUNBEMI: We are now voting on
9 the reliability for Measure 3534. Your voting is
10 open. The options are high for moderate, low and
11 insufficient.

12 So the voting is closed. The results
13 for Measure 3534 are resounding moderate. All
14 six participants voted moderate. So we have zero
15 high, low, and insufficient, six votes moderate,
16 100 percent moderate votes. So the measure
17 passes on reliability.

18 And we are now voting on validity
19 Measure 3534, your voting is open. Your options
20 are, high, moderate, low and insufficient.
21 Voting is closed. The results are: 0 percent
22 high, 83 percent moderate, 17 percent low, and 0

1 percent insufficient. That is, zero votes high,
2 five votes moderate, one vote low, and zero votes
3 insufficient. Measure 3534 passes on validity.
4 And we just move to Subgroup 3.

5 CO-CHAIR NERENZ: All right. Thank
6 you again, everyone. Moving right along, we are
7 now basically on time, I think. We have 35
8 minutes from here to our scheduled next break
9 point for the first measure out of Subgroup 3.
10 So Subgroups 1 and 2 can relax. This will be
11 Measure 3478. This is surgical treatment
12 complications for localized prostate cancer. The
13 issue -- issues plural are that it was consensus
14 not reached on both reliability and validity. So
15 we have to see if we can sort that out. And
16 Ashlie.

17 MS. WILBON: Are the -- is the
18 developer in the room? Okay. Please come have a
19 seat at the bench.

20 MS. ANDEL: Yes. I'm Corinna Anandel.
21 I represent the ADCC Quality Committee.

22 CO-CHAIR NERENZ: Welcome.

1 MS. ANDEL: Thank you.

2 MS. WILBON: You're welcome, Corinna.

3 So just a quick note, Subgroup 3 is John Bott,
4 Marybeth Farquhar, Paul -- I'm sorry, he's not
5 here -- Dave Nerenz, Eugene Nuccio, and Ron
6 Walters. So you guys are on deck starting now
7 for Subgroup 3, and we're looking at Measure
8 3478.

9 So this is a new measure. The
10 description is that the measure analyzes hospital
11 facility level variation in patient relevant
12 outcomes during the year after prostate directed
13 surgery. The measure uses claims to identify
14 urinary incontinence and/or erectile dysfunction
15 among patients undergoing localized prostate
16 cancer surgery. So I'm going to read through the
17 numerator and denominator because it was -- it's
18 a bit tricky. So I think that's important in
19 kind of understanding how the measure works. So
20 we'll have the developer clarify if I miss
21 anything, but we'll just walk through here, the
22 numerator and the denominator here.

1 So we'll start with the denominator.
2 So the denominator is Medicare fee for service
3 beneficiaries, 66 years of age or greater, with
4 prostate cancer who receive prostate cancer
5 surgery -- so open or closed, if you will --
6 after prostate diagnosis and survived at least
7 one year after the surgery.

8 The numerator is -- so the numerator
9 generates a hospital level score of incontinence
10 and/or erectile dysfunction during the year after
11 versus the year before prostate surgery. So each
12 individual patient's change and the number of
13 claim stays for incontinence and/or erectile
14 dysfunction calculated in the year after versus
15 the year before the surgery.

16 The patient's scores are then
17 truncated and then re-scaled from I think
18 negative five to 10 to scale of zero to 100. The
19 hospital score is the mean difference in days
20 among all attributed patients. So that's for the
21 hospital. The claims for incontinence and/or
22 erectile dysfunction during the year after versus

1 the year before. And it uses claims for both
2 inpatient and outpatient encounters. So I just
3 wanted to give that kind of brief overview so
4 folks have a sense of what that measure is
5 capturing. Move back to the discussion guide to
6 summarize some of what the -- some other of the
7 preliminary analysis votes.

8 Again, this is at the facility level,
9 and it's not risk-adjusted. The ratings for
10 reliability, again were, because consensus were
11 not reached. We had three moderate, one low and
12 one insufficient. Score level reliability was
13 demonstrated using a split-half affirmed with
14 Pearson correlations for the minimum sample size
15 of 10, n equals 10, which for 233 hospitals of
16 correlation was about 0.65. For the largest
17 sample size, which was about, which was n of 80,
18 the correlation was about 0.89. I also wanted to
19 note that again, I think this has come up with
20 some other measures, that we only require score
21 or data element reliability testing in order to
22 meet our requirements. I think that came up in

1 some of the reviewers' comments about their
2 concerns about the measure, so I just wanted to
3 clarify that essentially going forward, so we
4 don't kind of conflate those requirements with
5 what you'd like to see. And there was also some
6 concerns over the lack of clarity of this
7 specification, some confusion about how the
8 attribution works, some of the time frames about
9 how the scoring methodology was implemented, if
10 the winterization method is for kind of
11 truncating the scores if you will. I also wanted
12 to note, there was a few reviewers who noted
13 about the age of the data. So they used data
14 that was tested from 2009 to 2013 using ICD-9
15 codes. And we did have kind of prior approval
16 with this developer that they could submit
17 testing using ICD-9 codes based on a waiver that
18 we granted due to some limitations with data that
19 they identified. So if the measure is endorsed
20 and they come back for maintenance, they will be
21 required to submit ICD data, testing on ICD data
22 at that time.

1 For validity, it was also consensus
2 not reached. They did do an assessment on
3 validity doing a systematic assessment of face
4 validity. Their assessment does meet NQF
5 requirements for face validity and is acceptable
6 for demonstrating validity for new measure
7 submissions. So, again, for this concern, I
8 think that some reviewers noted that we wanted to
9 see other types of validity demonstrated for a
10 new measure. The first time in the door, we do
11 accept face validity, although you still should
12 also weigh other threats to validity. But in
13 terms of the testing requirement, they have met
14 that with their face validity demonstration.

15 Other concerns with validity were
16 around the lack of risk adjustments on the
17 analysis of the exclusions and missing data. So
18 with that, I will hand it over to the lead
19 discussant which is John.

20 MR. BOTT: So Ashlie covered things
21 pretty well. I'll just elaborate a little bit on
22 a couple of things that stuck out to me and that

1 other folks on the group hit on as well that are
2 here. So I was the one who voted low regarding
3 reliability, and it was because of the ambiguity
4 I thought in the specification. So while I had a
5 number of them, I'll just point out a couple.

6 One was this concept used in the exclusions and
7 the numerator at a minimum, maybe it was used in
8 that elsewhere as well, that the quantity of
9 days, somehow using claims codes to get at
10 quantity of days, that's new to me. I've been in
11 the game of working with client data for a long,
12 long time.

13 So for example, in the exclusions,
14 there are several exclusions about quantity of
15 days. One example is verbatim, two or more days
16 with code for secondary malignant neoplasm. I
17 don't know how claims codes are used to get a two
18 or more days, I don't understand that, and it's
19 not explained. And numerator also has this
20 concept with number of days where it just says
21 numerator is identified from claims, in
22 parenthesis, days with claims.

1 So I understand what the numerator
2 events are, but I'm not sure how they're getting
3 that number of days based on claims. I would
4 expect if you're using claims, that you somehow
5 count the number of days in a novel way that
6 should be enumerated more than it is here.
7 Another area is this statement about attribution.
8 After the list of the denominator bullets, it
9 states: "Patients are then attributed to the
10 hospital/facility associated to the claim for the
11 procedure code for prostatectomy." But it
12 doesn't talk about -- it's just silent on how
13 that attribution happens. And it seems like with
14 measures like this where you're looking at an
15 event in the hospital which you would sort of
16 call your in-depth submission for other measures
17 where you're counting numerator events post-
18 discharge, measures oftentimes get into
19 attribution like readmission measures. So things
20 that it seems like it should take into account,
21 but I don't know if it does, because it's silent
22 is: what if the person had a qualifying

1 denominator procedure performed in another
2 facility? It doesn't.

3 It's also silent on transferring into
4 that hospital where the procedure is performed,
5 or what if they transfer out to another facility?
6 So it makes me think there -- the attribution is
7 simply the event happened at the hospital. But
8 then the last denominator exclusion states,
9 "patients who could not be attributed to a
10 hospital." So it does make me think that, well
11 it seems like there is some attributional logic
12 if you would state that. But I think that we
13 should be -- we should not be guessing at these
14 types of things. So those were a couple of
15 things that jumped out at me more.

16 A couple other notes related to
17 reliability that others made. Somebody said there
18 is a potential bias here because the procedures
19 for incontinence are medications for erectile
20 dysfunction. There could be a bias that I think
21 the person is saying, and if they want to jump
22 in, those aren't accounted for. Maybe the person

1 is suggesting that these should be exclusions
2 then to level the playing field.

3 Also, I did have a somewhat smaller
4 question related to the winsorization, which I
5 won't get into because I noted my high-profile
6 ones. But somebody else noted that the way the
7 scores are transformed from the range of a
8 negative five to 10 get transformed from I think
9 zero to 100. And somebody stated under
10 reliability that that transformation may define
11 differences perhaps more than is reasonable. So
12 that's the reliability.

13 A couple quick things on validity, but
14 I think I'm risking repeating what Ashlie may
15 have said. One of the concerns expressed by
16 somebody was there's other conditions that could
17 impact incontinence, suggesting that that could
18 have been tested for in risk adjustment. The
19 person noted stroke, Parkinson's, diabetes.

20 I was surprised that those all seem
21 logical, but the measure developer cited they did
22 look at an ICHOM report, they did a lit review,

1 they had a tech panel, so I am surprised those
2 didn't come up and weren't tested for. So again,
3 the other panelists who I noted, they might want
4 to elaborate on if we're aware of evidence that
5 those are needed and related to risk of
6 incontinence.

7 Other complications could be having an
8 impact on the rate. It wasn't -- so again, if
9 somebody else wanted to, if somebody else noted
10 that, they might want to jump in. Lastly, there
11 was a concern about: is this measure really
12 expressing meaningful differences to the point
13 where we could really be measuring variation and
14 attribute it to the hospital?

15 So that's the high-level validity and
16 reliability concerns for the panel. But if
17 anybody wants to jump in with one of the points
18 that they have?

19 CO-CHAIR NERENZ: Yes, and also I'll
20 just sort of reframe little. Of those on this
21 particular Subgroup, I know that's a pretty long
22 list of things for which we need a response.

1 Anybody else with challenges, questions,
2 concerns, let's get them all on the table at
3 once. And then I know you're -- I'm watching you
4 taking good notes here.

5 MEASURE DEVELOPER: I'm taking some
6 notes, I'm going to need a reminder.

7 CO-CHAIR NERENZ: Okay.

8 MEMBER NUCCIO: Yes, I'll only, the
9 question about rescaling from the negative five
10 to 10? When you expand that to 100, you're going
11 to create mathematically significant differences
12 that may not be meaningful. If you really put it
13 that way, okay, mathematically different,
14 probably nothing major. That's number one.

15 Number two, I was confused by the
16 higher equal better in terms of the metric
17 itself, in that it sounded like it, providers
18 that create more E.D after the prostate surgery
19 were rated better, okay. And I don't think
20 that's what you meant. And then it has to do
21 with that, as what I think Ashlie was talking
22 about, the looking at differences. So if there's

1 something you can do to clarify the language
2 there.

3 And in terms of the -- I'm a little
4 concerned about the risk adjustment. You did
5 provide some correlations for potential items.
6 And I understand the lack of data issue, that I
7 understand. But of the potential risk factors,
8 you only have the Gleason scales of which is a
9 severity issue -- who was the only one that had
10 any kind of inkling. And so I think I was
11 surprised that your tech did not come up with
12 something more. And I don't -- maybe we can go
13 back and repoll them or something, but I found
14 that strange that they didn't provide you with a
15 laundry list of things that they could make a
16 difference. But I mean, you know, even if it's
17 where the surgery takes place and that was --
18 John talked about that. How it was possible, or
19 outpatient clinic, or --

20 CO-CHAIR NERENZ: And I'll just sort
21 of -- I'll do it as if I was responding to John's
22 question, but is actually -- you're going to

1 clarify whether I got this right. I as a member
2 of this group wasn't too worried myself about
3 this claim state thing. But now I'm interested
4 in your discussion of this. Well, fundamentally,
5 it seemed to me like situations, like for
6 example, if you're worried about the effect of
7 diabetes, for example, it's a comorbidity, and
8 you want to identify comorbid patients, you're
9 looking for two claims with the code some days
10 apart, just to indicate it's not a false
11 positive. And I sort of then extended it to here
12 to say, the fundamental premise seems to be that
13 if you're accepting one of these two problems,
14 the more it shows up on a claim, the worse it is
15 or the more frequently you're getting treated for
16 it. And that is the fundamental concept of the
17 numerator. And it's also --- it sort of runs
18 negative to positive, in that in principle you
19 can be having codes for these prior to surgery,
20 and then it goes away. And you don't -- okay, so
21 at least that's the concept. Now whether we buy
22 it and say that's right, okay, different thing.

1 But that's at least --

2 MEASURE DEVELOPER: Well put. Yes.

3 CO-CHAIR NERENZ: Okay. Bott, so why
4 don't you go ahead and I'll let you --

5 MEMBER NEEDLEMAN: David? Could I,
6 I'd like to have a little bit more inclination
7 about where the codes are coming from when we say
8 number of days. So there's a claim in October
9 that includes erectile dysfunction, and then
10 there's another claim that the surgery is in
11 November, and then there's another claim in
12 January that includes erectile dysfunction. So
13 you're counting all the days between the surgery,
14 either looking back or looking forward based upon
15 the dates of those claims?

16 CO-CHAIR NERENZ: No, it's --

17 MEMBER NEEDLEMAN: That's what I'm not
18 understanding. How are the actual numerators
19 being calculated?

20 CO-CHAIR NERENZ: Okay. So you've got
21 one before, you've got one after, the change is
22 zero. That's what I thought they were doing.

1 MEASURE DEVELOPER: Yes.

2 CO-CHAIR NERENZ: The day interval is
3 meaningless, right?

4 MEASURE DEVELOPER: Correct.

5 MEMBER NEEDLEMAN: So it's simply the
6 number of times you have been in for a visit, an
7 outpatient visit, or an inpatient visit, for
8 which this the diagnosis that is primary?
9 Secondary?

10 MEASURE DEVELOPER: If the claim ---
11 it's the number of days with claims for either of
12 those conditions, either as an outpatient or an
13 inpatient.

14 MEMBER NEEDLEMAN: Okay. Well, this
15 is what's confusing. If it's the number of
16 claims, then I understand that. But if it's the
17 number of days with claims?

18 MEASURE DEVELOPER: I'm sorry. It is
19 the number of claimed days --- claims-based days.
20 So the number of days with a claim, either of
21 those conditions.

22 CO-CHAIR NERENZ: Well, and -- I

1 shouldn't be in the business of defending, but
2 this is what I'm verifying. I'm not trying to
3 say it's a good event. Let's say you've got one
4 of these problems, you go in in a clinic and you
5 see in sequence three different specialists, just
6 cause. And each one of those generates a claim
7 and a Medicare fee for service. And essentially
8 the idea is that's one visit. That's how the day
9 concept comes in. It only counts once, not three
10 times, but --

11 MEMBER NEEDLEMAN: But we're not
12 looking at the duration, of the --

13 MEASURE DEVELOPER: Primary.

14 MEMBER NEEDLEMAN: -- of the problem,
15 we're looking at the number of days you have gone
16 in for actual diagnosis and treatment.

17 CO-CHAIR NERENZ: Yes.

18 MR. BOTT: Yes, I don't mean to stifle
19 conversation with the measure developer, but I
20 did specifically ask this morning if the measure
21 developer had the opportunity to clarify the
22 questions that we posed, primarily I posed, and

1 failed to -- which the measure developer failed
2 to address these questions in writing. And so it
3 would be in the material that we agreed before
4 the meeting. Karen had said that they will not
5 have the opportunity to allow verbally then to
6 address them in person.

7 MS. JOHNSON: Sir, I didn't --

8 MR. BOTT: Well, maybe it wasn't
9 Karen, it was somebody else, but I thought that
10 it was you who said that.

11 MS. JOHNSON: Yes, they can address
12 verbally. They can't give you anything written
13 today.

14 MR. BOTT: Okay.

15 MS. JOHNSON: So apologies if I said
16 it wrong.

17 CO-CHAIR NERENZ: Go ahead.

18 MEASURE DEVELOPER: Okay. So in terms
19 of attribution, the hospital attribution, so what
20 we did is we first looked for a claim with a
21 procedure code for prostatectomy either in the
22 outside file or in the MedPAR file. Okay. So we

1 start with that and then we identify the hospital
2 or the facility that's associated with that
3 claim. And then we take a look at the patients
4 for whom they had claims for a prostatectomy, but
5 only in the carrier file. So we could only
6 identify the condition. But we could not find a
7 hospital where that procedure took place, and we
8 excluded those. And that was in 275 cases out of
9 more than 10,000. But that's how we wanted to
10 determine where the procedure occurred. We
11 wanted to be able to attribute it to a hospital.

12 The winsorization and the concern
13 about magnifying the differences in the
14 rescaling. So the winsorizing occurred, the
15 cutoff was plus or minus two standard deviations.
16 It was not an arbitrary number, negative 10 or
17 five, it was -- that's what the plus or minus two
18 standard deviation cut off, so that's why we
19 picked that, and that has implications to the
20 rescaling.

21 In terms of magnifying the difference,
22 our impression was that because we were adding

1 constants to all of the numbers, it doesn't
2 magnify the difference. Because you're making
3 that change to every single score at the same
4 time.

5 Let's see, and then in terms of
6 meaningful differences, taking a look at that
7 among the facilities, we do recommend -- and we
8 have provided in the submission form -- that the
9 hospital's claims file score be included so that
10 you can see where the hospitals fall under those
11 sections. And at the very least we can have
12 comparisons among those. So we do note that that
13 would be helpful, and we did detect that they're
14 an issue among the hospitals. We think that this
15 claims-based measure could be useful in that
16 regard in identifying differences between
17 hospitals on either end of the spectrum or across
18 it. Let's see, the risk adjustment, we actually
19 did look at a number of patient variables and
20 hospital factors, and then you looked at what
21 came out and tumor factors and looked at what was
22 significant.

1 And then we ran the numbers. We
2 adjusted them using the significant patient level
3 factors. We also looked at adjusting the scores
4 of the hospital and patient level factors,
5 compared those adjusted scores to the unadjusted
6 scores, and found that there was a correlation of
7 .95 in both cases. And that led us to the
8 decision that risk adjustment was not necessary
9 and added unnecessary complexity.

10 Okay, what else here? In terms of how
11 factors such as stroke or diabetes could impact
12 the results, we also did take a look at
13 comorbidities, and those were not significant.
14 That is in the packet under -- in one of the
15 tables. Also, because the patients serve as
16 their own control, if they have that stroke or
17 diabetes or other comorbidity prior to the
18 prostatectomy, they're going to sit the
19 evaluation out. Let's see, what were some of the
20 other questions I have not addressed yet?

21 MEMBER NUCCIO: I'm sorry to
22 interrupt, but I understand that you truncated

1 negative five to 10 based on two standard
2 deviations.

3 MEASURE DEVELOPER: Yes.

4 MEMBER NUCCIO: That's great. But
5 then how did you convert those values from zero
6 to 100, so that 10 became 100 and negative five
7 became zero?

8 MEASURE DEVELOPER: Yes, okay. So
9 there were a number of steps that we identified.
10 So what we did was we looked at -- we subtracted
11 the difference after we subtracted the
12 complications from prior to the surgery from
13 after a surgery. And then we winsorized, and
14 then we took those different scores for each
15 patient, subtracted 10 and then multiplied by 10
16 over -- 100 over 15, and that created the scale
17 from zero to 100. And we wanted to create a
18 scale from zero to 100 because we found that
19 would be more intuitively interpretable for the
20 average person. We know what a score of 100
21 feels like versus 40, as opposed to looking at
22 negative five to 10. You know, there's no

1 meaningful anchor for that.

2 MEMBER NUCCIO: So then
3 proportionately, the ends expanded more than the
4 scores in the middle?

5 MEASURE DEVELOPER: Well, but you're
6 doing the same thing to all of the scores.

7 MEMBER NUCCIO: Oh, assuming
8 numerically they change. Okay. I understand I
9 think.

10 MEMBER ROMANO: Yes, I'm curious about
11 this formulation with subtraction. I think it's
12 fairly self-evident that if someone has no claims
13 before the surgery for one year and then they
14 have one or more claims after the surgery, that
15 something happened, probably, related to the
16 surgery.

17 But I'm not sure what it means if
18 somebody had, let's say, two claims before the
19 surgery and then they had three or four claims
20 after the surgery. And so the subtraction yields
21 a positive number, but can we really interpret
22 that as a worsening?

1 So I'm curious if you have a sense of,
2 when this indicator flags positive, how often is
3 it because of this increase in the number versus
4 going from zero to a positive number?

5 And have you done or are you planning
6 to do anything to look at the validity of, you
7 know, going from two to three or two to four, is
8 that really a worsening from a patient's
9 perspective?

10 And I say this because I think we all
11 agree that the right way to measure this concept
12 is with a PRO-PF with a patient reported outcome
13 measure. So what you're doing here is a proxy
14 and the question is, how good is it for men who
15 have these problems before and after the surgery?

16 MEASURE DEVELOPER: Well, I think we
17 would argue that if they had more claims
18 following surgery that something happened to make
19 it worse compared to before, prior to that, prior
20 to having the surgery.

21 Your point is well taken about
22 collecting PRO data for this kind of thing. And,

1 in fact, we are working on some PRO development,
2 but that takes a long time and it's going to be a
3 few years before we are able collect the data for
4 such a measure. So --

5 MEMBER ROMANO: So do most of them
6 flagged positive, are they mostly zero before, or
7 are they mostly have some claims before them and
8 some after?

9 MEASURE DEVELOPER: I don't have the
10 answer to that, I can't tell you.

11 MEMBER NEEDLEMAN: Can I follow up?
12 I'm curious to know why you think the number of
13 claims is a better measure than simply the
14 condition is present or absent?

15 What is it that I need to understand
16 about the clinical presentation of the patient
17 with these conditions that says more days
18 visiting the doctor indicates a worse condition?

19 MEASURE DEVELOPER: Well, prostate
20 cancer is associated with a number of
21 complications. And it's possible that undergoing
22 surgery, could actually make them worse instead

1 of better.

2 MEMBER NEEDLEMAN: Yes, I got that.

3 The question is, why do more claims post-surgery
4 before erectile dysfunction indicate that the
5 condition has gotten worse?

6 MEASURE DEVELOPER: It's an inference
7 we're making. It's, I mean it's --

8 MEMBER NEEDLEMAN: I mean it's quite
9 plausible that if somebody has erectile
10 dysfunction, let's say preoperatively, that the
11 surgeon might say, well, let's deal with that
12 after surgery.

13 And so, they would specifically defer
14 dealing with that problem knowing that the
15 patient's going to have surgery. And then all of
16 a sudden after surgery, you'd see a series of
17 visits for that problem.

18 And that was part of the plan. So I
19 think that maybe what we're getting at, and it's
20 not entirely clear that the number of claims is
21 good proxy for how bothered the patient is by the
22 condition. Maybe it is, but it's still a good

1 question.

2 CO-CHAIR NERENZ: Okay, let's keep
3 moving along, because I don't know that there's
4 any way, other than the point being made, it's
5 all on the table. I think we've got Sherrie,
6 Sean, you were up. You still up?

7 MEMBER O'BRIEN: Yes, pretty much
8 asking the same question.

9 CO-CHAIR NERENZ: Okay.

10 MEMBER O'BRIEN: Over time, are there
11 people who are just more likely to interact with
12 the healthcare system for reasons unrelated to
13 the intensiveness of their symptoms.

14 And then those people are going to get
15 flagged because they're going to show some type
16 of secondary diagnosis claim. So is it going to
17 be partly measuring how many visits a patient has
18 for whatever reason?

19 CO-CHAIR NERENZ: Yeah, good point.
20 Okay, Sherrie, and then Dave.

21 MEMBER KAPLAN: The recently completed
22 CEASAR Study, this big national study of prostate

1 cancer, localized prostate cancer and different
2 treatments for it, surgery, radiation, and the
3 act of surveillance, when using Epic, the Epic
4 Measure, patient-reported outcome, you can see
5 that where you start pretty much conditions where
6 you end up.

7 So if you're a surgical patient with
8 coming baseline erectile dysfunction and
9 incontinence measures, you're going to end up
10 about a whole standard deviation off of where you
11 started from.

12 But it's all conditioned of your
13 baseline. So I mean the patient-reported outcome
14 business is relevant in this case. What's
15 concerning to me is the non-adjustment and your
16 no-findings of differences by rates.

17 Because it looks like for, based on
18 our data from the California Initiative of
19 Physician Medicine and the CEASAR data, African
20 American patients, A, are less likely to get
21 surgery and B, if they do get surgery, they have
22 crummier outcomes.

1 And so I'm a little bit concerned that
2 you're not finding a race variable there,
3 especially since African Americans patients tend,
4 for other conditions, to go to lower quality --
5 can you -- have we -- what did you find with
6 respect to race and how is that playing out?

7 MEASURE DEVELOPER: We did test for it
8 and it did not come out significant.

9 MEMBER KAPLAN: Interesting. Even so,
10 within surgical differences across that variable
11 or independent of the other adjustments, you
12 didn't find any differences?

13 MEASURE DEVELOPER: Correct.

14 CO-CHAIR NERENZ: Well, although it
15 could be --

16 MEMBER KAPLAN: Interesting.

17 CO-CHAIR NERENZ: Although it could be
18 one of the data sourced problems and the proper -
19 - that's one, and getting care for it is another
20 thing.

21 And if it's a disconnect between the
22 two then you're going to show up in one data set

1 and not in another data set because the effect
2 will show up in one and not show up in another,
3 and it just --

4 MEMBER GLANCE: Just have a really,
5 really quick point of information. In our other
6 sessions where we look at the impact of SES, of
7 race on a risk adjusted outcome rate, typically
8 haven't seen a really big difference.

9 MEMBER KAPLAN: Yes.

10 MEMBER GLANCE: We've seen a really
11 high ICD --

12 MEMBER KAPLAN: It tends to move the
13 whole distribution and it doesn't show up in
14 people in total to the distribution. I get that.

15 MEMBER GLANCE: Yes.

16 MEMBER KAPLAN: On the other hand,
17 it's kind of surprising with the variable itself
18 because those same analyses, when you do, when
19 you look at the individual variables, they're
20 significant.

21 MEMBER GLANCE: Well, the variables,
22 they're significant but overall the hospital

1 level --

2 MEMBER KAPLAN: Right.

3 MEMBER GLANCE: -- stuff doesn't
4 really change pretty much.

5 MEMBER KAPLAN: Right.

6 CO-CHAIR NERENZ: Okay, Dave.

7 CO-CHAIR CELLA: So, I'm also
8 concerned about the PRO being the sort of a
9 standard that we all want and this being a
10 surrogate for that or a proxy.

11 But I'm looking at the other side of
12 the coin, the other side being, how many people
13 were excluded because there were no claims? Like
14 proportional to the whole -- it started with a
15 population and then you excluded what percentage
16 of people because, there were no claims or
17 adverse events, these two adverse events.

18 Do you happen to know?

19 MEASURE DEVELOPER: No, we do not look
20 at that.

21 CO-CHAIR CELLA: I don't, I'm guessing
22 it's a high number. And, it's probably a lot of

1 people that have erectile dysfunction and/or
2 urinary incontinence and just aren't getting
3 treated for it.

4 And then a related concern that, you
5 know, if you're a urologist that really wants
6 good numbers, you might say well, it's just
7 normal to have that erectile dysfunction.

8 We can help you just learn to live
9 with it and not encourage a visit. I'm worried
10 about that side of the coin, that this could
11 actually tip healthcare away from paying
12 attention to it, because there's a claims-based
13 punishment, a claims-based penalty.

14 So I'm not necessarily expecting an
15 answer. I'd like to know that number because I'm
16 guessing that number of non -- no claims patients
17 might be pretty high.

18 CO-CHAIR NERENZ: Okay. Just to
19 clarify and following on that point and I may
20 have misunderstood. You used the word excluded,
21 if I'm in the denominator of this and in the
22 subsequent year --

1 CO-CHAIR CELLA: You have to have a
2 claim.

3 CO-CHAIR NERENZ: Well, but you have
4 a -- yes, but what kind of claim?

5 CO-CHAIR CELLA: An adverse event
6 claim, right?

7 MEASURE DEVELOPER: Right.

8 CO-CHAIR CELLA: Yes, because they
9 only look at people with claims.

10 CO-CHAIR NERENZ: Oh, thank you, okay.
11 So, no, that's important. Okay. So, if I would
12 have left no claim for complication, I had the
13 test and then the subsequent claims --

14 MEASURE DEVELOPER: In the numerator.

15 MS. WILBON: Yes, the denominator is
16 that they had prostate surgery, open or closed,
17 and survived at least one year.

18 CO-CHAIR NERENZ: Okay, so --

19 CO-CHAIR CELLA: So the denominator
20 claim doesn't have to be in the denominator?

21 MEASURE DEVELOPER: Not in the
22 denominator, only the numerator.

1 CO-CHAIR NERENZ: Okay.

2 CO-CHAIR CELLA: What is that
3 proportion? What is the numerator over the
4 denominator?

5 MS. WILBON: What is the proportion
6 that?

7 CO-CHAIR CELLA: What percentage of
8 the people that are alive for a year after
9 prostate surgery have claims?

10 MS. WILBON: Had any claims at all --

11 MEASURE DEVELOPER: I don't, we can
12 get that information, but I don't have it at the
13 time.

14 CO-CHAIR CELLA: But you see why I
15 think it's important, because if it's low then
16 it's a real underrepresentation of the problem
17 because people just aren't getting treated for
18 it.

19 MEMBER TEIGLAND: And, did you require
20 a minimum pre-index period, pre-surgery period as
21 well?

22 MEASURE DEVELOPER: Yes, one year.

1 MEMBER TEIGLAND: One year also?

2 MEASURE DEVELOPER: Yes. One year
3 before, one year after.

4 CO-CHAIR NERENZ: Okay. We are close
5 to time here. If anybody's got something crucial
6 to a vote? Jack.

7 MEMBER NEEDLEMAN: Yes, just we've
8 been having a lot of discussion about the
9 clinical logic of the way this is measured.

10 And, if the need, if the measure gets
11 to the standing committee, I would encourage
12 either the standing committee or a tech with
13 urologists to really review the validity of the
14 clinical logic behind this measure this way,
15 which I think goes, the clinical issues go beyond
16 our capabilities in this room. Thank you.

17 CO-CHAIR NERENZ: Okay, no cards up.
18 Let us call the question now. This is now
19 Subgroup 3 voting for real, everybody else,
20 Survey Monkey.

21 CO-CHAIR CELLA: I object to
22 referring to the shadow votes as monkeys.

1 MS. OGUNBEMI: We are now voting on
2 the reliability for Measure 3478. The voting is
3 open. Your options are high, moderate, low and
4 insufficient.

5 CO-CHAIR NERENZ: That's the first
6 time I've done this where it says clear last
7 response. Does that mean you want to correct it
8 or it means you're ready to move on?

9 MS. OGUNBEMI: If you clear it, that
10 means you take it away.

11 CO-CHAIR NERENZ: I just wait for you
12 to move us along. Okay.

13 MS. OGUNBEMI: Yes.

14 CO-CHAIR NERENZ: Okay, thank you.

15 MS. OGUNBEMI: So, we have, we were
16 supposed to be expecting five members voting and
17 we have four votes, John Bott, Marybeth Farquhar,
18 David Nerenz, Eugene Nuccio, and Ron Walters.

19 MS. WILBON: Ron, I think --

20 MS. OGUNBEMI: No, we've got Ron. Oh,
21 so we only took the form? All right.

22 MS. WILBON: Ron's here.

1 MS. OGUNBEMI: He's recused from
2 voting.

3 MEMBER WALTERS: Oh, yeah, yeah.

4 MS. WILBON: He's recused?

5 MS. OGUNBEMI: Yes. Okay, consensus
6 not reached. We have zero votes high, zero
7 percent; moderate, 50 percent, at two votes; low,
8 two votes at 50 percent and zero votes
9 insufficient.

10 So Measure 3478 is consensus not
11 reached on reliability. And now we are voting on
12 the validity of Measure 3478. Options are, high,
13 moderate, low, and insufficient.

14 Voting is open. And we have zero
15 percent high, zero votes; moderate, 25 percent,
16 one vote; low, 75 percent, three votes and
17 insufficient, zero votes, zero percent. Measure
18 3478 fails on validity.

19 MEASURE DEVELOPER: Thank you.

20 MS. WILBON: Can I just make one last
21 plug? If -- We are planning to take a look at
22 the shadow votes tomorrow, so if you missed any

1 votes today on the Survey Monkey or subgroups
2 that you, that you were not a part of, if you
3 could just make sure that you have all your votes
4 submitted up to now for all the measures that
5 we've reviewed, that will help us tomorrow.

6 Because we'd like to do some kind of on the fly
7 analysis with you guys to look at, to see how the
8 shadow votes compared to the actual votes and
9 see, have some discussion about how those votes
10 compared and maybe, what some of those
11 differences might have been. So, if you could
12 kind of catch yourselves up if you weren't able
13 to keep up today for some reason.

14 That way tomorrow for the measures
15 that we review, we can kind of pop right in and
16 start looking at those and do a quick turn-
17 around. So, thanks for doing that.

18 MEMBER ROMANO: Do you have any way of
19 knowing which ones we haven't submitted or there
20 isn't any way to know that?

21 MS. WILBON: We would have to do a
22 quick export. And, it also depends on if you put

1 your name in or not, right. So, if you didn't
2 put your name, we won't know who submitted what.

3 So it may be a little bit difficult if
4 some folks chose not to put their name, so.

5 CO-CHAIR NUNEZ: So do we go to public
6 comment?

7 MS. OGUNBEMI: So if anyone is on the
8 line and would like to provide a public comment,
9 now is your opportunity, we'll give you a couple
10 seconds.

11 If your line is muted, you can press
12 Star 7. We also have a chat function available
13 on the web platform if you'd like to submit a
14 comment that way.

15 (Off microphone comments.)

16 CO-CHAIR CELLA: Okay. We're going to
17 wrap up. Aren't we?

18 MS. JOHNSON: Yes. So kudos to our
19 fearless co-chairs who got us out of here on
20 time.

21 CO-CHAIR CELLA: That was you, you
22 cooperated wonderfully.

1 MS. JOHNSON: That was great. So
2 pretty much, I haven't counted up, but we got
3 through all the measures that we wanted to. I
4 hope that the process wasn't too onerous.

5 What we would ask you to do for
6 tomorrow is, if you have identified specific
7 methodological issues that you'd like to talk
8 about a little bit more tomorrow, we've been
9 writing some down, but if there are others, you
10 know, let us know or write them down yourself.

11 We will hopefully have a chance to
12 talk about those tomorrow. We are also planning,
13 I don't know if you heard Ashlie telling Dave and
14 Dave that we're going to try to compile our
15 shadow votes and just kind of see how that works.

16 We're also going to talk about, you
17 know, how the process itself is working. It felt
18 a little new and different, even than our
19 separate pulse did, so we'll talk about that.

20 And then, probably more important than
21 anything else, dinner. We do have reservations
22 at Siroc, which is a, I think it's an Italian

1 place, just right around the corner.

2 I'll give you the address, because I
3 cannot be relied upon to tell anybody how to get
4 anywhere. It is 915 15th Street, so it literally
5 is right up the street.

6 Our reservations are for 5:30, so that
7 gives you time to go to your hotel, do whatever
8 you want. So, if any of you would like to join
9 us for dinner, we'd love to have you.

10 (Off microphone comments.)

11 MS. JOHNSON: Thank you guys, we'll
12 see you tomorrow morning.

13 MS. WILBON: Thank you guys. Have a
14 good night.

15 (Whereupon, the above-entitled matter
16 went off the record at 4:54 p.m.)
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A			
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Before: NQF

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Place: Washington, DC

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