

NATIONAL QUALITY FORUM

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SCIENTIFIC METHODS PANEL

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TUESDAY

OCTOBER 29, 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

JENNIFER PERLOFF, PhD, Institute of Healthcare  
Systems, Brandeis University

PATRICK ROMANO, MD, MPH, UC Davis

SAM SIMON, PhD, Mathematica Policy Research

ALEX SOX-HARRIS, PhD, MS, Stanford University

CHRISTIE TEIGLAND, PhD, Avalere Health

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

NQF STAFF:

MICHAEL ABRAMS, Senior Director  
KAREN JOHNSON, Senior Director  
ANDREW LYZENGA, Senior Director  
NICOLETTE MEHAS, Director  
ELISA MUNTHALI, Senior Vice President

YETUNDE OGUNGBEMI, Project Manager

SAM STOLPE, Senior Director

ASHLIE WILBON, Senior Director

ALSO PRESENT:

KATHERINE ALLEN-BRIDSON, CDC\*

SUPARNA BAGCHI, CDC\*

MARY BARTON, NCQA

SUSANNAH BERNHEIM, Yale-CORE\*

SUSAN CALI, CDC\*

TARA MILLSON, CDC\*

DANIEL POLLOCK, CDC\*

ILANA RICHMAN, Yale-CORE\*

LINDSEY ROTH, NCQA\*

\* present by teleconference

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

2 8:58 a.m.

3 CO-CHAIR CELLA: Good morning. So,  
4 first, we're just going to review the agenda,  
5 which is, you know, the morning up until 11 is  
6 the continuation of yesterday, looking at the  
7 remaining submissions. And then at 11 -- so I'll  
8 do that part, and then Dave will, Dave N. will  
9 facilitate the process review and discussion of  
10 methodological issues. And then we'll get  
11 updates from NQF, and then we'll close by 2:30.  
12 So that's the day.

13 Karen, would you like to introduce  
14 Jen?

15 MS. JOHNSON: We're whispering about  
16 you, Jen. Good morning, everybody. So welcome.  
17 We're going to ask you a couple of things. One  
18 is just to tell us who you are and where you're  
19 from and that good stuff but then also our  
20 disclosures of interest. So I don't know if you  
21 want to do the spiel or have you done this enough  
22 --

1                   MEMBER PERLOFF: I've done it before,  
2 and I think you know it, yes.

3                   CO-CHAIR CELLA: It's not your first  
4 rodeo.

5                   MEMBER PERLOFF: Great. Jen Perloff.  
6 I'm a health services researcher at Brandeis  
7 University. I apologize. Yesterday, I was at an  
8 annual R01 team meeting on nurse practitioner  
9 cost and quality, so I was thinking about quality  
10 measures, just not the right quality measures.

11                   So excited to be here today. And I  
12 have no conflicts to disclose. I'm not a measure  
13 developer, just a consumer.

14                   MS. JOHNSON: Okay. Some reminders  
15 and housekeeping. If you are on the phone and  
16 you're not talking, please mute your lines. We  
17 appreciate that. Also, once you do want to talk,  
18 if you're on the phone, just remind us who you  
19 are, say your name so we know who you are.

20                   CO-CHAIR CELLA: We have one more  
21 measure for Subgroup 3 to discuss. Reminding you  
22 the subgroup members are John Bott, Marybeth

1 Farquhar, Dave Nerenz, Eugene Nuccio, and Ron  
2 Walters. It's also Paul Kurlansky, but Paul is  
3 not here.

4 So we're going to start with 3492,  
5 acute care use due to opioid overdose for Yale  
6 CORE/CMS submission, and Michael is going to lead  
7 us off with the NQF presentation summary.

8 MR. ABRAMS: Very good. Good morning,  
9 everyone. So let's see. Why don't we, can we  
10 get the slide up there? Let me get out my study  
11 guide here.

12 CO-CHAIR CELLA: So while you're  
13 looking for the -- consensus was not reached for  
14 reliability, four high, one low, one incomplete.  
15 And then validity, one high, three medium, three  
16 incomplete. Did I say one before? Two  
17 incomplete for reliability.

18 MR. ABRAMS: Yes. So if you take a  
19 look at your study guide on page 32 it should be,  
20 you'll find a header for this measure, which is,  
21 again, Measure Number 3492, acute care use due to  
22 opioid use disorder. But the actual measure is

1 described because of a little header switch error  
2 that's actually described subsequently on page  
3 35. Okay. So I'm going to be going through the  
4 discussion guide materials there beginning on  
5 page 35.

6 Again, this is acute care use due to  
7 opioid overdose. It's a new measure. It was  
8 actually brought forward to this panel in a  
9 previous cycle and was, it failed passage here  
10 for a couple of reasons, one related to validity.  
11 We'll talk more about that later. The other was  
12 because there was no ICD-10 testing previously.

13 Just to remind you briefly about what  
14 the measure is about, the numerator is incident,  
15 what you might refer to as outcome events defined  
16 as an opioid overdose that results in an  
17 emergency department's use event, okay? Later  
18 during this meeting we're going to talk about  
19 whether or not that constitutes what might be  
20 considered a quality measure or not, but we don't  
21 want you to worry about that now. It is, for the  
22 purposes of our review at this moment, to be



1 considered as an outcome measure as described by  
2 the developer.

3 The denominator for this is rather a  
4 specific population, Medicare Fee-for-Service  
5 beneficiaries, engaged in Part A, the inpatient  
6 benefit, or Part B, the physician outpatient  
7 benefit. Individuals aged 18 or older residing -  
8 - and the measure is reported based on geography,  
9 county or state level. No exclusions, per se,  
10 were described for this measure. It's claims  
11 based, Medicare claims principally.

12 And when you all rated it previously  
13 for this current cycle it was consensus not  
14 reached for reliability. Let me remind you what  
15 the reliability looked like. It was an ADAMS R  
16 score across 25 states that they had data for,  
17 and the ADAMS R for the signal-to-noise score  
18 ranged from 0.92 to 0.99 across those 25 states.  
19 Across Maryland's 24 jurisdictions, counties and  
20 Baltimore city, the ADAMS R scores ranged from  
21 0.6 to 0.99.

22 They also did a split sample analysis

1 with the Pearson's r, at least I'm assuming  
2 that's what they're reporting, and the  
3 correlation coefficients from that analysis were  
4 0.94 and 0.87.

5 For validity also consensus was not  
6 reached. They did validity using a small panel  
7 of physicians from Yale from their institution, a  
8 sort of convenience expert panel, if you will,  
9 and used, you know, Likert scheme of voting to  
10 assess face validity.

11 Then they also did comparisons with  
12 AHRQ and CDC overdose data. The CDC measure is  
13 deaths per 100,000, so, you know, instead of, you  
14 remember the measure is about ED events, okay?  
15 So as a validator, they looked at mortality  
16 events from the CDC and they did that combining  
17 both NEDS and this data, NEDS being ED discharges  
18 and this data being ED-to-inpatient transfers.  
19 And then they looked at AHRQ data, as well, which  
20 was opioid-related hospitalizations.

21 Okay. So that's perhaps a little bit  
22 more related to the ED measure, but, again, this

1 was hospitalizations directly. And compared  
2 those two separate indicators of, you know,  
3 opioid burden, if you will, to the current  
4 measure. For the CDC comparison, the correlation  
5 coefficient was 0.74, simple correlation  
6 coefficient. For the AHRQ measure, as it turns  
7 out the correlation was again 0.74. I don't know  
8 what the P value is for having two correlations  
9 exactly like that. Somewhat of a coincidence,  
10 but that those are the numbers they reported.

11 And then they looked at meaningful  
12 difference using, you know, confidence interval  
13 overlap, did a GLM model with Poisson  
14 distribution where they took into account year  
15 effects, as well, and from that type of analysis  
16 found that there were 12 states below the mean  
17 performance level, three at the mean performance  
18 level, and ten above. So this was evidence for  
19 their suggesting that there were meaningful  
20 differences worth addressing in this measure.

21 So I'm going to pause there and ask  
22 that our discussant then make a comment.

1 CO-CHAIR CELLA: Marybeth is up for  
2 that. Thanks, Michael.

3 MEMBER FARQUHAR: I want to thank the  
4 measure developer for bringing this forward  
5 again. It's pretty hard to do population  
6 measures at this point. I do have some questions  
7 with regard to it. And thank you for sending the  
8 additional information. That was really helpful.  
9 I was one of the people that couldn't make head  
10 or tail out of it after I had seen a few of the  
11 other measures. So I have a question as to why  
12 Medicare Advantage was not included in the  
13 denominator. I'm not sure how come that's not  
14 included when they just did Fee-for-Service and  
15 not do the whole population.

16 So that was one thing I had a question  
17 on. The other thing, they have no exclusions,  
18 and I have a concern with regard to hospice and  
19 palliative care individuals who sometimes need  
20 more aggressive treatment than some of the others  
21 and they really should exclude them from this  
22 population or from the denominator.

1                   What else did I have? I do have  
2                   concern about the face validity and the five Yale  
3                   physicians, which I think introduces bias. We  
4                   have no idea about what their background is,  
5                   whether it's oncology or general physician or  
6                   what. And who knows if they're practicing. We  
7                   didn't get any of that information with regard to  
8                   determining whether that was appropriate or not,  
9                   so, to me, I don't know that that was appropriate  
10                  for the face validity piece.

11                  I do have an issue with the geography  
12                  of the consumer. Now, because we have such a  
13                  mobile society, people often go to other places  
14                  to get care. For instance, I have a friend who  
15                  went to Hopkins, although she lived in Virginia,  
16                  to get her primary care. So to ding the people  
17                  back in Virginia for something that Hopkins may  
18                  have done is not appropriate in my terms. You  
19                  know, we live in the Washington, D.C. area and  
20                  we're so close to the Maryland, West Virginia,  
21                  D.C. border, we want to make sure that we  
22                  appropriately, you know, I believe that holding

1 these providers accountable for these overdoses  
2 in the ERs. So in order to, for instance, if I  
3 live in Loudoun County, if I go to Fairfax County  
4 to get my care done, that means that, if I had  
5 gone to a hospital for an overdose in Loudoun,  
6 they would take me to Loudoun and then, because I  
7 lived in Loudoun, they would ding Fairfax County  
8 for the overdose. And to me, that's just not a  
9 fair comparison if that's what they're planning  
10 on doing, and that's what I gathered. So if I'm  
11 wrong, please correct me on that.

12 CO-CHAIR CELLA: Marybeth, I believe  
13 that there's someone on the phone with the Yale  
14 CORE group. Are you on the phone?

15 MS. RICHMAN: Yes, this is Ilana  
16 Richman for Yale CORE. I can --

17 CO-CHAIR CELLA: We'll come back to  
18 you in a minute. I just wanted to confirm you're  
19 here. Okay, thank you. Keep going, Marybeth.  
20 I'm sorry. I just wanted to --

21 MEMBER FARQUHAR: No, that's okay.  
22 I'm almost done. I just had a couple of

1 highlights after we went through that  
2 information. What else did I have? Again, I  
3 think, you know, at the state level, it might be  
4 fine to do that, but at the county level I think  
5 that's probably a gross injustice to the  
6 providers in that particular area. So those are  
7 the things that I kind of pulled out and wanted  
8 to highlight. I don't know if anybody else on  
9 our team wants to jump in here.

10 CO-CHAIR CELLA: Let's go ahead with  
11 Dave and then maybe give Yale an interim chance  
12 to respond and then if more subgroup discussion  
13 is needed.

14 CO-CHAIR NERENZ: Thanks. Yes, I had  
15 a lot of concerns about this, and they were  
16 mainly conceptual concerns having even to do with  
17 the rules of NQF endorsement, not so much the  
18 technical specs in the measure. I was the one  
19 who objected originally since this isn't even a  
20 quality measure. In fact, when I first saw it in  
21 our packet as a subgroup, I sent it out to Karen  
22 saying, you know, why are we even looking at

1 this? This doesn't fit our template.

2 I specifically didn't know what to do  
3 with the whole area of validity because most of  
4 our approaches and concepts about validity have  
5 to do with some underlying concept of quality.  
6 You look at process outcome relationships and you  
7 validate outcome measures by the extent that  
8 you're quite certain of the processes and you  
9 validate process measures by the extent to which  
10 they influence the outcomes. So there's a whole  
11 frame that simply doesn't apply here.

12 In the original materials presented to  
13 us, there was only a very brief one-sentence  
14 mention of quality that said, like, higher scores  
15 versus quality, but there's no theory, there's no  
16 data, there's no development of any sort of  
17 theory of quality for this measure.

18 Now, what I'm told, though, the  
19 sponsors will go ahead and review it, and, as  
20 Michael just said, we're not supposed to somehow  
21 table it or decline it because it's not a quality  
22 measure. I won't accept that it can be an



1 outcome measure without being a quality measure  
2 because outcome is a subset of the larger domain  
3 of quality. It's just a type of quality measure.

4 I don't know what this is an outcome  
5 of. If you live in a state or county that has a  
6 high rate of this, probably the driving factor is  
7 there's a lot of opioid use. So maybe that's an  
8 outcome of the criminal justice system, it's an  
9 outcome of the education and economy of the local  
10 area.

11 So I'm really stuck to know what to do  
12 with this, particularly in the domain of  
13 validity. Now, if we accept that it is just  
14 simply on its face as it says it is with no  
15 inference about quality and, in fact, no  
16 inference about outcome, I mean, I guess we can  
17 go ahead and raise some validity of it, simply is  
18 this a measure of ED use for opioid overdose.  
19 That's it. No inference beyond that. That's it.  
20 I guess you can assess the validity of that, and  
21 that is, as far as I can tell, what the face  
22 validity process is, at least as I read the

1 materials. The folks at Yale were not asked to  
2 say is this a good quality measure or is it a  
3 good outcome measure. They were simply asked is  
4 this a good measure of the face concept of ED  
5 use.

6 So I'm greatly troubled by this one,  
7 and I, in some ways, don't even know what to do  
8 with it.

9 CO-CHAIR CELLA: You want to make one  
10 of these points --

11 MEMBER NUCCIO: Yes.

12 CO-CHAIR CELLA: Yes. So one more  
13 moment, Yale. Gene Nuccio, a comment.

14 MEMBER NUCCIO: I just wanted to sort  
15 of reiterate my concern about the population  
16 that's being measured here, Medicare Fee-for-  
17 Service. And that's a point that Marybeth  
18 already brought up.

19 It struck me that this was clearly a  
20 population kind of measure, and so I didn't know  
21 why you didn't use population data. It would  
22 seem to me that hospitals in a county report the

1 number of visits to their emergency department,  
2 and they also might collect data on the number of  
3 opioid-related cases. And from that, you could  
4 also identify what the age of the patient is, and  
5 it would seem to me a pretty straightforward  
6 measure of opioid use and overdose, that they  
7 went in the hospital. Why Fee-for-Service for 18  
8 year olds? That's a fairly restricted population  
9 until you get to 65.

10 So I had a fundamental problem with  
11 why this denominator and why this population of  
12 the measure. Also, the point that Marybeth made  
13 about only five people on the TAP from  
14 Connecticut seemed to be a little bit restrictive  
15 in terms of how we mostly form our TAPs.

16 So I just want to support both of  
17 those. I came at it again understanding David's  
18 point about is this a quality measure. If it's a  
19 population measure, you use population data, not  
20 restrictive healthcare data.

21 CO-CHAIR CELLA: Okay. We're going to  
22 pause there and give Yale a chance to respond.

1                   MEMBER NEEDLEMAN: Before we do that,  
2 I just want to follow up on Eugene's point about  
3 population-based data. There actually is a  
4 population-based data set here, not in all states  
5 but many states collect ED data and hospital  
6 discharge data and those are available publicly.  
7 They actually do a correlation of this measure  
8 with the rates from the ED and inpatient  
9 databases, and the correlation is 0.74. In other  
10 circumstances, that would be fine. But it just  
11 feels to me that it's a low correlation. Apropos  
12 of what Eugene is saying, if you want to use one  
13 population measure, use a population measure. A  
14 correlation of 0.74 feels awfully low comparing a  
15 population measure to a Medicare Part A/B  
16 population, Fee-for-Service population only.

17                   So the question is are you getting  
18 good enough measurement of the population here  
19 when we know what the actual population rates  
20 are, and I'm saying I'm concerned about that.

21                   CO-CHAIR CELLA: Okay. Thank you. So  
22 let's ask for a response from Yale to the issues

1 that have been raised so far.

2 MS. RICHMAN: Okay, sure. This is  
3 Ilana Richman from Yale CORE. So thanks for  
4 those comments. Let me begin with the issue of  
5 the population. There were a few issues raised  
6 why Medicare Fee-for-Service or another broader  
7 population, why not include Medicare Advantage?  
8 If it's a population measure, why not use the  
9 national inpatient and national emergency  
10 department sample, for example.

11 So there are a few reasons why we  
12 chose Medicare Fee-for-Service. One is that  
13 we're working with CMMI on this measure, and part  
14 of their model is around engaging Medicare Fee-  
15 for-Service patients. So there was a sort of  
16 reason to focus on Medicare Fee-for-Service  
17 initially because of the contextual arrangement  
18 between the State of Maryland and CMMI.

19 Two, there are practical reasons for  
20 developing the measure in Medicare Fee-for-  
21 Service, namely it's the only population that I  
22 can think of, with the exception of Medicare

1 Advantage perhaps for which there are kind of  
2 limited data, but, anyway, it's the only  
3 population where we know not only numerator  
4 events but denominator enrollment. So, for  
5 example, in the national inpatient sample and  
6 national emergency department sample we used for  
7 validation, one limitation of that data is that  
8 we don't actually know the enrollment period for  
9 all the beneficiaries. So in that data, in the  
10 AHRQ data, the denominator seemed to be the state  
11 adult population, which is probably a reasonable  
12 proxy but it is not exactly the same as the  
13 number of patients who might be couched in the  
14 numerator. So it was sort of a pragmatic reason  
15 for using Medicare Fee-for-Service.

16 I will say that we plan to do  
17 additional testing in an all-payer population,  
18 knowing the limitations. But for initial  
19 testing, we felt we could best count the  
20 numerator in denominator in Medicare Fee-for-  
21 Service.

22 In terms of why the correlation with

1 national inpatient and national emergency  
2 department sample is 0.72 or 0.74, I mean, there  
3 are two reasons why that is the case. One is  
4 that the populations are different. Obviously,  
5 the age distribution between Medicare Fee-for-  
6 Service and an all-payer sample, Medicare Fee-  
7 for-Service skew older. Although we included  
8 patients 18 and older, most patients are 65 and  
9 older. That's one reason.

10           And then the second is that the  
11 measures are actually different. So the measure  
12 that we compare it to in AHRQ data is a much  
13 broader definition of emergency department and  
14 hospitalizations for opioid-related conditions.  
15 So, for example, our measure excludes intentional  
16 overdose, but the AHRQ measure that we compare it  
17 to includes it. It includes also things like an  
18 ED visit for opioid use that's related to  
19 assault. It includes withdrawal. It includes ED  
20 visits for opioid use disorder and not just  
21 overdose. So it includes a much broader set of  
22 conditions, and so we'd expect not to have

1 perfect correlation. But we felt it was useful  
2 to compare the measure to these. We're really  
3 trying to ask, you know, are we getting at this  
4 broader, this broader kind of phenomenon of the  
5 opioid epidemic and opioid overdose.

6 We saw that even in a different  
7 population and even with a different measure  
8 outcome, we saw a relatively high correlation,  
9 and that was true also for opioid, for death from  
10 opioid overdose. Again, a different population,  
11 a different outcome, we still saw a relatively  
12 strong correlation, so we felt like that was  
13 helpful.

14 So that was our rationale for choosing  
15 Medicare Fee-for-Service. We felt we could  
16 really kind of count the measure numerator and  
17 denominator with high fidelity, and it was also  
18 in line with what we had discussed with CMMI in  
19 whom this measure is being developed in  
20 collaboration. And then, yes, the correlation  
21 coefficient is not a one, but I think that's, to  
22 some extent, to be expected.



1                   There was also a question about  
2                   exclusions from the measure. We did end up in  
3                   this measure discussed whether to exclude  
4                   patients in hospice and palliative care, and we  
5                   did not for two reasons. One is that the number  
6                   of patients who would contribute are probably  
7                   relatively small. That's not necessarily a  
8                   reason to not exclude them, but, more broadly  
9                   speaking, I mean, if we have a, if there is a  
10                  patient on hospice or who is receiving palliative  
11                  care who has an opioid overdose, to me, that is  
12                  still considered an adverse outcome. I mean,  
13                  that's not preferable even for patients who are  
14                  receiving those benefits. So we would want to  
15                  include them. That's still an opioid overdose,  
16                  and we consider that undesirable. So we decided  
17                  ultimately not to exclude those patients.

18                  Let's see. There were some questions  
19                  about the validity and the face validity. So I  
20                  will say that, you know, in thinking about the  
21                  validity of this measure, our primary objective  
22                  was to think about, one, is the measure capturing

1 what we think it is capturing, and here we built  
2 on the existing literature which has been shown  
3 in a number of papers that ICD codes for opioid  
4 overdose are highly specific, even though, you  
5 know, population where opioid overdoses are rare  
6 events, the positivity value is still high. So  
7 if you see it, it's really there.

8           Second, we compared the measure, as  
9 discussed, to two other measures:  
10 hospitalizations and ED use for opioid-related  
11 conditions, that's the AHRQ measure, and death  
12 from opioid overdose of CDC data and saw  
13 relatively high correlation coefficients. And in  
14 face validity, you know, we felt like was  
15 reasonable and valuable to discuss. It was  
16 really not kind of the foundation on which our  
17 argument for validity is built. We did it as  
18 sort of an adjunct to the argument that we were  
19 building, which is really based on empirical  
20 validity testing.

21           And, yes, we used a local expert panel  
22 which would not necessarily call it tech. It

1 wasn't intended to be kind of a comprehensive  
2 national expert panel, but we convened a local  
3 expert panel as a way to get some feedback on the  
4 measure. The composition of the panel, it  
5 consisted of -- I'm sorry. So it consisted of  
6 emergency department physicians and general  
7 internists, all of whom have a research interest  
8 in opioid use. And I would say, by research  
9 interest, I mean many of these people are  
10 national experts who have experience measuring  
11 opioid use and overdose in a variety of context,  
12 including in the emergency department. So they  
13 were not sort of, they had focused expertise in  
14 this area.

15 But, again, you know, the face  
16 validity, we thought of this as an adjunct to our  
17 error validity testing, not really the kind of  
18 foundational premise on which our argument for  
19 validity is built.

20 And then, let's see, questions about  
21 geography. So the use case of the measure, the  
22 intended use is in the total cost of care model

1 which is a payment model in which the State of  
2 Maryland and entities within Maryland, geographic  
3 entities, are responsible for the total cost of  
4 care for Medicare enrollees. And patients in  
5 this model are attributed geographically, whether  
6 it's small area geographies or on the state  
7 level.

8           And so it really made sense to define  
9 this measure on the geographic level. Agree, of  
10 course, people move around, but not only, you  
11 know, is this payment model geographically  
12 defined but also, you know, public health  
13 infrastructure is geographically defined either  
14 on the state level or often on the county level.  
15 So it's true people cross counties to receive  
16 services, but often services, particularly in the  
17 opioid treatment world, are kind of structured on  
18 a county level. So counties invest in opioid  
19 treatment and provide resources to their local  
20 jurisdictions. So we felt like that was  
21 reasonable, a reasonable way to define  
22 populations. So, again, folks are attributed to

1 geography based on their place of residence, not  
2 where they end up having opioid overdose.

3 And then, lastly, this question of is  
4 this a quality measure. So I will say this.

5 Opioid overdose is a complex phenomenon of health  
6 outcomes. I mean, you could say the same thing  
7 for an MI or for a hospitalization or for any  
8 kind of health outcome. These are complex events  
9 that do have to do with social structures and  
10 economics and all of the rest.

11 I will also add that there are clear  
12 evidence-based interventions that can reduce the  
13 risk of opioid overdose. The primary one is the  
14 provision of medication-assisted therapy, which  
15 we know can save lives from opioid overdose and  
16 reduce the risk of overdose or lethal overdose.  
17 On a broader level, we also know that reducing  
18 the availability of opioids in a community  
19 reduces the risk of opioid misuse. So there are  
20 kind of two primary ways in which healthcare  
21 entities and groups of healthcare providers can  
22 engage in reducing the risk of opioid overdose in

1 a community.

2 I think, so, yes, there are lots of  
3 other things that contribute to opioid overdose,  
4 but there are also specific things that we can do  
5 within the realm of healthcare that can reduce  
6 the risk of opioid overdose. We think, in that  
7 sense, it does reflect something about the body  
8 of care that is provided in a community. Yes,  
9 there are lots of other things, and we think that  
10 the way in which the measure is used to reflect  
11 those things, so, for example, we have tested the  
12 measure for use year over year in which an  
13 entity, a state or county, we'd compare it to  
14 itself and can try to show improvement over a  
15 previous year.

16 We acknowledge that it's a complex  
17 phenomenon, but we think there are things that  
18 folks can be doing on a local level. And we've  
19 also tested our measure to reflect that potential  
20 use.

21 CO-CHAIR CELLA: Okay. Thank you, Dr.  
22 Richman, for tracking and responding to, I think,

1 all of the issues raised. There are some  
2 continued comments or questions from the subgroup  
3 only, so we're still on the subgroup discussion.  
4 Gene, are you next? Okay.

5 MEMBER NUCCIO: Thank you for  
6 responding. I neglected to mention something  
7 else that concerned me about the measure. In  
8 your forms that you submitted, 2B3.2 regarding  
9 risk adjustment, you say that you are not risk  
10 adjusting this measure, and this gets back to how  
11 are you going to use the measure? In general, we  
12 typically look at measures being used to compare  
13 across entities, as opposed to simply improving  
14 within an entity. So a year-to-year contrast in  
15 a single county would be a within entity versus  
16 how county A in a state is doing with county B in  
17 that same state would be another way that we  
18 typically use these outcome measures.

19 You state in your risk adjustment  
20 rationale that "although the risk of opioid  
21 overdose varies according to patient demographic  
22 characteristics," and then you cite the Kaiser

1 Foundation study from 2018, "this variation  
2 reflects social rather than biological  
3 difference." I find it strange that you did not  
4 make any use of the sociodemographic variables in  
5 terms of risk adjustment, recognizing that  
6 there's already been evidence to show that  
7 sociodemographic variables make a difference.

8 So if you could respond to that issue.  
9 We're not asking, I think I made a comment that  
10 we're not looking at race, we're looking at  
11 sociodemographic variables.

12 CO-CHAIR CELLA: Go ahead, Dr.  
13 Richman.

14 MS. RICHMAN: Sure. So, yes, I think  
15 risk adjustment is a challenging and important  
16 question here because, on one hand, I think we  
17 all would agree that different, people in  
18 different communities have different rates of  
19 opioid overdose and opioid use, and that is a  
20 complex phenomenon that is absolutely  
21 attributable to the quality of healthcare in that  
22 community.



1           However, if we were to, say, adjust  
2           for poverty or some other marker of socioeconomic  
3           status or sociodemographics, really two things I  
4           think would happen. One is that we could obscure  
5           important difference of the very thing that we're  
6           trying to measure, and two, you know, as I think  
7           it's come up in another discussion of social  
8           risk, it's akin to saying that we are willing to  
9           accept a higher level of opioid overdose in the  
10          communities that are suffering the greatest.

11           So I think, rather than risk adjusting  
12          -- so we acknowledge that those factors are  
13          important, but I would say that, rather than risk  
14          adjusting, really thought should be given to how  
15          the measure is used. So we have tested the  
16          measure for use comparing one test entity to  
17          another within a year, and that's shown that we  
18          can identify meaningful difference.

19           And then how that information is used  
20          is important. So is it used to penalize  
21          communities? Is it used to identify  
22          opportunities for improvement? That, I think, is

1 the kind of key question is how that information  
2 is used, not necessarily whether or not it's risk  
3 adjusted.

4 And then an adjunct, yes, we do think  
5 there's a case to be made that, once differences  
6 are identified, could communities be encouraged  
7 to improve year over year, although I realize  
8 that's not kind of the primary way in which  
9 quality measures are often specified.

10 CO-CHAIR CELLA: Okay. Dave.

11 CO-CHAIR NERENZ: Okay. This is just  
12 a comment and basically a response to the  
13 response in the area of validity. If we are to  
14 consider this an outcome measure, my question  
15 then is outcome of what? And there is no  
16 specific conceptual model theory offered to us,  
17 nor is there any empirical data provided to us  
18 and materials to review either in the original or  
19 in the follow up linking this outcome to some  
20 defined prior something.

21 Now, you know, we've heard some  
22 worthwhile and probably valid speculation about,

1 well, the opioid rate could reflect this, could  
2 reflect that, but we have no data. So in terms  
3 of the rules of the game of how we judge  
4 validity, you know, we just heard that they're  
5 not resting on face validity. They consider that  
6 as kind of an adjunct, it's not the main support.  
7 But then we have no empirical information on  
8 validity that links this outcome to some act,  
9 some process, some something. So I still have a  
10 problem.

11 MS. BERNHEIM: This is Susannah from  
12 the Yale team. Can I just jump in with a quick  
13 question, actually, and a comment for the NQF  
14 staff? I just need a little bit of clarification  
15 that I think will help this discussion.

16 You know, when we present things to  
17 the scientific committee, there are certain  
18 pieces of information we're providing. There is  
19 a more comprehensive amount of information about  
20 the conceptual model for the measures that go  
21 then when it comes to the full committee, and so  
22 I want to understand what this committee needs

1 and weighs in on because, David, you're asking  
2 critical questions about something that is  
3 challenging which is a population health measure,  
4 right? We're not used to thinking about the way  
5 a community's actions, the health system and the  
6 community, relate to outcomes of a population.  
7 It's not the typical thing. As Ilana said,  
8 there's actually very good evidence that there  
9 are actions that communities can take and that  
10 healthcare providers then could take to reduce  
11 the likelihood, regardless of the rate of opioid  
12 use in the community, that reduce the likelihood  
13 that people are ending up with overdoses in the  
14 emergency room. But this measure is really  
15 intended to both incentivize and measure  
16 communities acting in ways that reduce those  
17 outcomes. They are clearly outcomes, and they're  
18 clearly outcomes that can be influenced by the  
19 quality of care provided in a community.

20 That piece of our work is less well  
21 represented when it comes to this committee. You  
22 know, we are mostly bringing, you know,

1 reliability testing and validity testing at this  
2 stage. And so I'm looking for the NQF staff to  
3 help us understand what this committee needs so  
4 we can make sure the right things are in front of  
5 this group and to bound the conversations to the  
6 NQF criteria related to this measure, which  
7 you're having an important, critical, challenging  
8 conversation on because it's a hard measure.

9 CO-CHAIR CELLA: Jeff, you wanted to  
10 add something.

11 MEMBER GEPPERT: So I made that exact  
12 same argument to NCQA yesterday, and their  
13 response was that their job was to create a valid  
14 sort of health status measure and they were  
15 completely agnostic as to how that health status  
16 was accomplished. And so we were okay with that  
17 response, and I don't know why the situation is  
18 different here. You know, the solution could be  
19 housing, it could be food security, it could be  
20 healthcare, it could be behavioral health.

21 MS. BERNHEIM: It's not agnostic, it's  
22 that there's evidence that there's a wide range

1 of activities that are better quality of care for  
2 a community that can influence outcome.

3 CO-CHAIR CELLA: Unless the subgroup  
4 objects, we have, de facto, moved into general  
5 discussion for all. So I think Larry and then  
6 Sherrie was up and then Karen. So Larry,  
7 Sherrie, and Karen, and then John.

8 MEMBER GLANCE: Great. So the first  
9 issue is one of risk adjustment and, most  
10 importantly, we're not accounting for the social  
11 factors that would drive the outcome in question,  
12 which is opioid overdose. And I would submit  
13 that, you know, if you're looking at the typical  
14 safe hospital quality measure, say for  
15 readmissions, so there are patient factors that  
16 the hospital has control over. So if you have  
17 surgery and you have fewer complications, you're  
18 less likely to be readmitted. So the hospitals  
19 can control that piece of it.

20 On the other hand, if you have a poor  
21 social support network when you go home and no  
22 one is there to take care of you, to some extent,

1 the hospital really, and you end up going home  
2 maybe to a poor neighborhood and et cetera, et  
3 cetera, the hospital has much less control over  
4 that. So you can make an argument, a fairly good  
5 argument, that, for hospital readmission  
6 measures, you ought to be controlling for social  
7 risk.

8 In the case of opioid overdose, it's  
9 a little different. So the driving factors are  
10 primarily social in nature. It's unemployment,  
11 it's poverty, it's, you know, food deserts. It's  
12 all those different things, right? So if you  
13 were to risk adjust for all those drivers,  
14 essentially you would be giving a free lunch, so  
15 to speak, to states that don't do a very good job  
16 controlling for those economic drivers of opioid  
17 overdose.

18 So I would argue that you would not  
19 want to risk adjust in any way because I would  
20 want to, you know, I think if you're going to  
21 look at how different communities do in terms of  
22 opioid overdose, you want to take into account

1       whether or not these communities successfully  
2       adjust the social drivers of opioid overdose.  
3       You don't want to risk adjust. So that's the  
4       first point I wanted to make. And I know this is  
5       a little atypical for me because I'm always  
6       arguing for risk adjustment. It was a little  
7       difficult for me to make this argument.

8                 And the second piece is in terms of  
9       David's point that there's not a lot of data out  
10      there that we can impact opioid overdose. And I  
11      don't know this literature, so I can't  
12      necessarily comment on this, but I would say  
13      that's okay, you know. So there's not a lot of  
14      data out there. That doesn't mean that we can't  
15      develop data, and, to me, it has a lot of face  
16      validity, the idea that, you know, this is one of  
17      the biggest challenges to our society is finding  
18      a way of cutting down on opioid overdoses. This  
19      is something that I think we ought to be looking  
20      at.

21                 And then, finally, the validity issue.  
22      I think if we, and I don't always follow the



1 rules, as Karen will, I freely admit to, but I  
2 think this is an example where they have  
3 addressed empirical validity by looking at  
4 construct validity, by comparing this measure to  
5 some other accepted measures. So I think that  
6 they've kind of crossed that threshold in that  
7 respect. Thanks.

8 CO-CHAIR CELLA: Jerry, thank you.  
9 Sherrie.

10 MEMBER KAPLAN: Susannah, this is  
11 Sherrie Kaplan. I was thinking to myself about  
12 why this is a quality measure, following up on  
13 David's point. And we do use things like ER  
14 visits for asthma, and the quality link is things  
15 like, well, for ER visits or hospitalizations for  
16 diabetes, you failed the primary care imperative.  
17 You know, you failed to treat those people  
18 adequately in primary care. So if that's the  
19 argument or even if it's not, if it's community-  
20 based stuff, you could actually sort of, if that  
21 was a model for looking at is this a failure of  
22 primary care or a failure to reach people to

1 services that actually could have mediated their  
2 opioid use or abuse, that's one argument you  
3 could make. I was trying to think out loud of  
4 why this would be a qualification.

5 But second thing is is that why  
6 wouldn't you then sort of link things with, the  
7 CDC lit in 2017, a bunch of states, I think it  
8 was 20 for naloxone use, for other kinds of  
9 opioid mediation stuff, could you not reach, as  
10 long as you have the CDC data, could you not then  
11 look at those communities that have benefitted  
12 from that and lots of new stuff compared with  
13 other counties or states that didn't?

14 CO-CHAIR CELLA: Karen?

15 MS. JOHNSON: Thank you. These are a  
16 little tricky. We do get, very rarely but we do  
17 get population-based measures, so we do have  
18 those. And we are going to tee up the discussion  
19 of, you know, quality measures and other things  
20 after we kind of finish this discussion.

21 But a couple of things that I did want  
22 to say, number one, I think Susannah is right.

1 One case that she asked about was I think part of  
2 what Dave would love to see, that linkage with  
3 the interventions. That is something that we  
4 asked for under the evidence subcriterion, which  
5 you guys aren't seeing that information yet. So  
6 I think there's probably more to come, it's just  
7 under a different criteria. So you're feeling  
8 the lack now, and that's just how the criteria  
9 are set up.

10 But I did go to look at our criteria.  
11 We do have somewhat, sometimes things are a tad  
12 bit different if you're talking about a  
13 population health measure versus the usual health  
14 outcome measure. So I was looking at what we  
15 have for validity testing, so let me read you  
16 what we have right now for validity testing. It  
17 demonstrates that the measure data elements are  
18 correct and/or that the measure score correctly  
19 reflects the effect of interventions to improve  
20 population health, adequately identifying  
21 difference in effectiveness.

22 So I don't know if that's helpful or

1 if that actually is less than helpful, but that's  
2 kind of how we are looking at the pop health  
3 validity testing.

4 CO-CHAIR NERENZ: Well, just to follow  
5 directly on that, the last phrase you mentioned I  
6 think sounds like the typical thing that we look  
7 at when we evaluate validity is that there's some  
8 statistical linkage between some defined  
9 interventions and the outcome and we are given  
10 statistical evidence on the percent of variance  
11 and the outcome that's explained by variation in  
12 the processes. And I just don't see that here,  
13 and I'm just looking for guidance about, if we  
14 don't have it, what do we do?

15 CO-CHAIR CELLA: Bijan and then John  
16 and then Jack.

17 MEMBER BORAH: Yes, I think this is a  
18 question for the measure developers. It's about  
19 correlation part. I think that the thing was  
20 it's right to do correlation between data is  
21 instead of focusing on the entire database, I  
22 think that both the database actually provide

1 insurance information, could they not have sort  
2 of enough correlation with Medicare population  
3 between those databases and then what they have?  
4 So that could have, again, if we are looking at  
5 population effects, that could have brought out  
6 that correlation. So focusing on the sub-cohort  
7 that is Medicare, we need those two databases,  
8 NEDS and NIS data.

9 And then another question, to bring  
10 back David's point about what's the intervention  
11 here? What is it that we are looking at? Again,  
12 I think that, essentially, we're looking at  
13 status quo, what is the effect of just the health  
14 services within the community, and so, therefore,  
15 we're looking at events in terms of what we get  
16 to see in all periods. So that's, you know, we  
17 don't have any, but we have the status quo, and  
18 that's what we are looking at. That's how I  
19 approach the argument for this particular  
20 measure.

21 CO-CHAIR CELLA: So there are two  
22 questions there for Yale. Dr. Richman, you want

1 to respond?

2 MS. RICHMAN: I'm sorry. I'm in  
3 clinic right now, so I got distracted. But  
4 somebody was asking me a question. Can you  
5 repeat the question for me?

6 MEMBER BORAH: Do you try to do the  
7 correlation with HCAHP and NIS data? I think you  
8 did cover it, and I asked NIS data and --

9 MS. RICHMAN: Yes.

10 MEMBER BORAH: -- they both have  
11 Medicare component into it. Like, did you try to  
12 do it? Are those subcohorts for Medicare data?

13 MS. RICHMAN: Yes. So, no, we used  
14 publicly-available aggregated NEDS and NIS data  
15 for our validation, yes, rather than look at  
16 specifically at Medicare, although, again, I  
17 think, you know, part of our rationale for using  
18 this broader population was to say that we could  
19 look within the Medicare population, but,  
20 actually, we felt like it was more powerful to  
21 look in a different population or a slightly  
22 different measure to say, like, okay, even in a

1 broader population, with a broader measure, we  
2 see that these two measures track together to a  
3 reasonable extent.

4 CO-CHAIR CELLA: And, Bijan, was your  
5 second question more rhetorical, or do you want a  
6 response for your --

7 MEMBER BORAH: No, the second one  
8 responds to David's point. I feel that it's more  
9 into looking at what's the effects of status quo  
10 health services within the community on opioids.  
11 And I feel that's how I look at this measure.

12 CO-CHAIR CELLA: Okay. I think we can  
13 leave that without a response. John and then  
14 Jack.

15 MEMBER BOTT: Yes. I mainly note the  
16 following in regard to, perhaps this is a bigger  
17 issue to talk about in the future but to use this  
18 example as an example of the issue of face  
19 validity. It seems like the measures I've  
20 reviewed, we've all reviewed, boy, when it comes  
21 to face validity, we just get soup to nuts for  
22 what we're seeing from when a measure developer

1 submits information on face validity. It seems  
2 that's likely suggesting that we could provide  
3 more guidance on face validity.

4 And as some folks noted, you know, as  
5 an example, I think we should provide some  
6 guidance for the team regarding the team members,  
7 the types of disciplines that should be involved.  
8 You should not be involving folks from your own  
9 institutions. That seems like a slam-dunk kind  
10 of rule. And if you would have articulated that,  
11 I'm sure Yale would have followed that.

12 And as Dave noted, perhaps some  
13 guidance on if you're going to go down the road  
14 of face validity, here's the types of validity  
15 issues you should address so we get the types of  
16 information that would be helpful to us in  
17 ascertaining validity. And maybe we could  
18 provide some guidance on the process by which  
19 that face validity occurs.

20 I didn't really see, and this is yet  
21 another example, how did they go about conducting  
22 that? We should ask for more specifics on the



1 results that we get that occur from face  
2 validity. I think their initial response, there  
3 was kind of a lack of response of what was the  
4 upshot of that face validity? They discussed it  
5 and what methods did you use, but when it came to  
6 what are the results it was silent.

7 But they did provide some initial  
8 information on page 84, and it was still a rather  
9 high level. The measure got a four on face  
10 validity, but really what was the question, what  
11 was voted on? I'm just really thinking we really  
12 need to firm up our guidance on face validity  
13 because we continue to get these kind of nebulous  
14 responses back from face validity, and the  
15 developer says, well, it's the initial round with  
16 the measure so we can do face validity, but  
17 oftentimes we're left kind of cold with the  
18 response we get, as here, I'm a bit disappointed  
19 with the lack of any understanding of true  
20 validity of the measure because of this use of  
21 face validity.

22 CO-CHAIR CELLA: Let's bring that back

1 for discussion after we go through the measure  
2 reviews because it's on the agenda for that sort  
3 of issue. So Jack and then Joe and then Patrick.

4 MEMBER NEEDLEMAN: So let me begin by  
5 saying I have some sympathy for, was it Susannah  
6 who said, you know, what are the terms here  
7 because I think some of the discussion has  
8 stretched into what the substantive committee  
9 would be deciding about the relative value of  
10 this measure against other measures that are  
11 doing the same thing, the usability of the  
12 measure. Those are not in our wheelhouse here,  
13 so I have some sympathy for the developers.

14 So I'm trying to figure out in my own  
15 head how I bring this back down to the issues  
16 that this committee should legitimately be  
17 discussing. And at the moment, I've got three,  
18 which is probably a lack of imagination on my  
19 part. One is it's presented as a population-  
20 based measure, as a measure of how effective the  
21 healthcare system and social service system and  
22 other systems in a state have been in dealing

1 with opioids, and the first question I would ask  
2 is, given the breadth of the interventions that  
3 are being assessed and that it's a population-  
4 based measure, is a Medicare-only measure valid  
5 on its face? Not is it good because, if I were  
6 on the standing committee, I'd probably say the  
7 population-based measures from the ED databases  
8 or the CDC measures are better measures and this  
9 is redundant, but that's not the question we're  
10 being asked. The question is is a Medicare-only  
11 measure in this space valid on its face? I'm  
12 inclined to give a pass on that, but I think  
13 that's one of the key questions that has sort of  
14 emerged from our discussions.

15 The second is the risk adjustment. If  
16 the goal is to figure out how well the systems  
17 are performing and compare performance across  
18 counties, across states, then the question is how  
19 hard is the job that they're facing there and how  
20 do you take that into account? So the counties  
21 in Southeastern Ohio have a much harder problem  
22 because the OxyContin folks dumped an awful lot

1 of product there. So the question is would you  
2 make any adjustments to the size of their problem  
3 in assessing how well the system is performing?

4 I don't think the answer is you have  
5 to have risk adjustment and if you don't -- I  
6 would like to see both a risk adjusted and  
7 unadjusted measure here to capture different  
8 dimensions of the product. So I'm not  
9 comfortable that there's no risk adjustment here.  
10 I'd like to see two versions of the measures.

11 The third question, and this one I'm  
12 going to throw at the developers, is about the  
13 reliability of the data. And we've got the  
14 standard language in the package here about  
15 Medicare data is used for billing, so we code for  
16 it. The main issues that Medicare is concerned  
17 about is over-billing.

18 And so the question I would ask is,  
19 given the social stigma associated with any  
20 inappropriate use of opioids, I believe that,  
21 where you've got something counted, it's there.  
22 So I believe the measure is specific. But I'm

1 not sure how sensitive it is, and I'd like to  
2 know what analysis has been done of the data  
3 that's the underlying data here. We have the  
4 coding data for the discharge abstracts that are  
5 in the AHRQ and other data which you say are  
6 correlated with this measure of undercoding, and  
7 has anybody looked at that and is that a concern  
8 we should have about the reliability of the data  
9 that undergirds this measure?

10 CO-CHAIR CELLA: Before you respond,  
11 this is just the timekeeper noting that this is  
12 really a very rich discussion, lots of people are  
13 very engaged and have a lot to say and ask about.  
14 We have still three more people that want to make  
15 comments, so let's try to make our points as  
16 succinctly as we can.

17 Please go ahead and answer that last  
18 question, if you can, Yale.

19 MS. RICHMAN: Sure. So there have  
20 been a number of studies that published  
21 literature that have compared diagnostic codes  
22 for opioid overdose to chart review using a

1 standard case definition, and we know that there  
2 is some undercoding. Claims-based measures, in  
3 general, are highly specific but not completely  
4 sensitive.

5 Now, whether or not complete  
6 sensitivity matters is dependent, I think, on the  
7 measure use. So you know, if we were a public  
8 health agency trying to count every opioid  
9 overdose in a jurisdiction, yes, we'd want  
10 complete sensitivity. But if the goal is to try  
11 to understand the comparative performance of  
12 entities or a change in entities over time, then  
13 I think complete sensitivity is less important.

14 And I will say that one of the things  
15 that emerged from our discussion with the expert  
16 panel is that, you know, obviously, in general,  
17 there's always a tradeoff between sensitive and  
18 specificity, but there's also some clinical  
19 uncertainty about what constitutes opioid  
20 overdose. So a patient could come into the  
21 emergency department unconscious and there could  
22 be a variety of reasons for that.

1                   So in the face of that kind of  
2                   tradeoff between sensitivity and specificity, as  
3                   well as the kind of underlying clinical  
4                   uncertainty, the general feeling, and I would  
5                   agree with this, too, is we prefer a measure that  
6                   is highly specific, even at the risk of some  
7                   tradeoff in sensitivity.

8                   So, yes, these issues have been looked  
9                   at. Yes, they're imperfectly sensitive. But we  
10                  believe they're specific and we believe they can  
11                  be used to compare entities over time,  
12                  particularly since the goal is not to do kind of  
13                  a census of all of the opioid overdoses in a  
14                  community but, rather, to have a signal that we  
15                  can use to compare in between entities.

16                  CO-CHAIR CELLA: Thank you. Joe, are  
17                  you still up? No? And, Patrick, you also --

18                  MEMBER ROMANO: It's covered.

19                  CO-CHAIR CELLA: Okay. Then Gene.

20                  MEMBER NUCCIO: Hi. Eugene Nuccio.

21                  Just to go back to the risk adjustment argument,  
22                  I did some quick surfing on the net and

1 discovered from the U.S. Census Bureau quick  
2 facts that the workforce weight in Mississippi is  
3 57.2 percent and in West Virginia 57.5 percent,  
4 so, looking at those, it would seem like, you  
5 know, there's maybe a slight difference. When  
6 you look at the deaths due to opioid from the  
7 National Institute of Drug Abuse, Mississippi's  
8 weight was 21.7 and West Virginia's was 49.6. So  
9 I would suggest that there are some ability to  
10 make use of at least some sociodemographic  
11 variables that then will allow you to more  
12 carefully tease out what makes a difference in  
13 terms of interventions, getting back to David's  
14 point about, if we have an outcome, we need to  
15 know how to change that outcome. And by  
16 controlling for at least some of the  
17 sociodemographics, I suspect that we could do  
18 that a little better than just using the raw  
19 rates, as is proposed.

20 MS. RICHMAN: I will say that we did  
21 some preliminary testing on a state level looking  
22 at the relationship between, for example, the



1 proportion of residents in poverty and opioid  
2 overdose rates, and the relationship is  
3 complicated. It's not perfectly linear. For  
4 example, Maryland has one of the highest rates of  
5 opioid overdose in the country, and it's also one  
6 of the richest states in the country. So, you  
7 know, part of that is sort of an ecological  
8 fallacy. There's a poor part of the state that  
9 it has a definitely concentrated population that  
10 uses and misuses opioids and also has a  
11 population of people who are wealthy, and those  
12 are two not necessarily the same population but  
13 just to illustrate the fact that, although you  
14 think about these things as tracking together, it  
15 is not actually perfectly sort of correlated.

16 CO-CHAIR CELLA: Okay. Trying to  
17 bring us to a close without foreclosing. Sean  
18 has a comment, and then I'm going to ask if  
19 anyone else has any comments or questions and  
20 then one last opportunity for Yale. Go ahead,  
21 Sean.

22 MEMBER O'BRIEN: This is about risk

1 adjustment. I didn't know if you had the idea of  
2 developing both adjusted and unadjusted versions.  
3 I think they address two different questions, but  
4 both questions are relevant and meaningful. But,  
5 fundamentally, I don't have a problem with the  
6 unadjusted version, just going back to what  
7 question had asked and answered, but most  
8 measures, what I think about risk adjustment  
9 attempting to do is trying to replicate a  
10 hypothetical randomized experiment where patients  
11 could be assigned to different providers. So  
12 when you don't do that, in the case of comparing  
13 two states, A and B, if state A had a better  
14 outcome for this measure, I wouldn't necessarily  
15 assume that if you switch their populations that  
16 state A would still have it better. It could be  
17 that state B was investing more resources and  
18 using their resources more effectively than state  
19 A, but it's still relevant to know that they have  
20 a worse problem and perhaps need to invest more  
21 resources. And that answers the questions that I  
22 think I'm more interested in from a public health

1 perspective. I think it's addressing something  
2 that's probably helpful.

3 CO-CHAIR CELLA: Okay. Thanks. Any  
4 other comments from anyone? Okay. So thank you,  
5 Dr. Richman. You represented the measure well,  
6 and I think that we're finished with the  
7 discussion. It's time for a vote. And Dr.  
8 Walters is not here, nor is Kurlansky, so there  
9 will be four subgroup voters and the rest of us  
10 on the shadow vote.

11 MS. OGUNBEMI: Okay. We are now  
12 voting on the reliability of Measure 3492. Your  
13 voting is open.

14 (Voting.)

15 MS. OGUNBEMI: Okay. Voting is  
16 closed. High is one vote at 25 percent, moderate  
17 is two votes at 50 percent, low is one vote at 25  
18 percent, and insufficient is zero votes and zero  
19 percent. So the measure passes reliability, and  
20 we'll go now next to validity.

21 Voting is now open for validity of  
22 Measure 3492. Your options are high, moderate,

1 low, and insufficient.

2 (Voting.)

3 MS. OGUNBEMI: Voting is closed for  
4 validity of Measure 3492. Results are zero votes  
5 high at zero percent; moderate, one vote with 25  
6 percent; low, two votes, 50 percent; and  
7 insufficient, one vote at 25 percent. Measure  
8 3492 fails validity.

9 CO-CHAIR CELLA: Okay. Thank you.  
10 Well, Subgroup 3, that concludes your job. We  
11 now move to Subgroup 4 and the members are Matt  
12 Austin, Bijan Borah, Lacy Fabian, Joe Kunisch,  
13 Sean O'Brien, Patrick Romano, Sam Simon. And the  
14 first measure to discuss is 3528, CDC and VON  
15 harmonized outcome measure for late onset sepsis  
16 and meningitis in very low birthweight neonates,  
17 CDC. And Michael again is going to lead us off.

18 MR. ABRAMS: Thank you. This --

19 CO-CHAIR CELLA: One second, Michael.  
20 One second.

21 MS. WILBON: Are the developers on the  
22 line? Is anyone from CDC there?

1 MR. POLLOCK: Yes, yes, we are.

2 MS. WILBON: Okay. Thank you. I just  
3 wanted to check before we got started. Thanks.

4 MR. ABRAMS: Good. So this measure is  
5 looking at sepsis and meningitis infections in  
6 very low birthweight neonates, and the status of  
7 it previously was consensus not reached on  
8 reliability. Let me make sure that that's the  
9 status. Actually a failing grade on reliability  
10 and a passing grade on validity, so we'll be  
11 focusing on reliability in this.

12 Our setup for you is one of the  
13 unusual situations where we're talking about  
14 element-level validity standing in or  
15 substituting for reliability, okay? That's going  
16 to be the main focus of our discussion.

17 But let me go through the details of  
18 the measure with you, and this appears on page 32  
19 of the discussion guide. This time, this is the  
20 little swapping error here. It's under the  
21 heading for the opioid measure, but it is at the  
22 bottom of page 32 for this particular sepsis

1 measure. And it's looking at late onset sepsis  
2 or meningitis infections in very low birthweight  
3 infants. And there's some preface in there about  
4 the prevalence that's in the introductory  
5 material there and the descriptive material on  
6 why this is an issue of importance. I won't  
7 review that explicitly. But the numerator of  
8 this measure is the number of sepsis infections  
9 or, separately, meningitis infection events. And  
10 this is a survival measure where there's a  
11 comparison of those without, who don't  
12 experience, infants who don't experience those  
13 events.

14           The denominator, the focused  
15 population, are neonates in a specific age range,  
16 days of life 4 to 121. Also, a certain  
17 birthweight range, in the very low birthweight  
18 range, 400 to 1500 grams, and a gestational age  
19 of 22 to 29 weeks. The other thing you should  
20 know about the denominator of this measure is  
21 that it's those in facilities that do not include  
22 level 2, 3, or 4 nurseries.

1                   So we're talking about very specific  
2                   intensive care, neonatal intensive care units is  
3                   the population of focus. It's described as an  
4                   outcome measure. The negative outcome in this  
5                   case being, of course, the infection. The data  
6                   comes from abstracted health records, level of  
7                   analysis at the facility level. And there is  
8                   risk adjustment that is conducted in order to  
9                   create this measure, to create a standardized  
10                  infection ratio, and this briefly summarizes a  
11                  ratio of observed to predicted infection rates  
12                  across a number of different stratified groups.  
13                  And it's not calculated when the prediction  
14                  infection rates are below 0.2 in a certain  
15                  facility, so when they're sort of exceeding the  
16                  rate in a certain facility there's an exclusion  
17                  applied.

18                         The specifications list something like  
19                         3,000 - 3,100 specific codes for a variety of  
20                         different infection types. Included in the  
21                         definition is something about qualified anti-  
22                         microbial days, although it's a little bit

1       unclear why that particular definition is  
2       proffered. It seemed a bit of a non sequitur in  
3       the specifications.

4               The observed versus expected rates are  
5       derived from a Bayesian statistical model, which  
6       is to say not purely proportional but more  
7       nuanced and based on other information that the  
8       developers brought to bear. And the data comes  
9       from 716 Vermont hospitals. Over 40,000 neonates  
10      were assessed between 2010 and 2016 to look at  
11      this analysis.

12              Now, with regard to the reliability,  
13      and, again, this is going to be the central focus  
14      of your re-voting, it previously did not pass,  
15      but, arguably, the reason it didn't pass is  
16      because it wasn't reliability that was actually  
17      conducted. Instead, there was a sort of validity  
18      assessment that was done where the measure rates  
19      were compared to what the developers referred to  
20      as an online calculator. And this online  
21      calculator was another way to get at the events  
22      of interest, the infection events of interest,



1 with sort of an automated approach, and the  
2 developers can correct me if I'm misrepresenting  
3 that. But that was compared then to the measure  
4 as their way to demonstrate reliability. Those  
5 of you on the subcommittee reviewed that and  
6 said, huh, this feels like validity, it feels  
7 like an external standard is being applied, and,  
8 thus, you did not pass it as a reliability  
9 marker.

10           Again, this is a situation where,  
11 because it was element level, it was done with  
12 specific neonate measures or neonate events that  
13 this is a situation where we're talking about  
14 element-level validity, perhaps supplanting the  
15 need for reliability.

16           The results from that, by the way, are  
17 presented at the bottom of page 33 in a simple  
18 two-by-two table giving precision at 100 percent,  
19 recall, and the formulas are there, of 96  
20 percent, and a Cohen's kappa at 96 percent.

21           So part of the question certainly is  
22 how these 320 cases were selected in order to do

1 this element-level validity. That, again, is  
2 part of what you will discuss is whether or not  
3 this can supplant the need for reliability.

4 The validity results were quite  
5 similar.

6 CO-CHAIR CELLA: Sorry. You mentioned  
7 bottom of page 33, but those are the previous,  
8 right? Am I wrong?

9 MR. ABRAMS: Bottom of page 33,  
10 there's a two-by-two table that has the  
11 comparisons of the --

12 CO-CHAIR CELLA: Oh, of their  
13 submission?

14 MR. ABRAMS: Yes --

15 CO-CHAIR CELLA: From the discussion  
16 guide?

17 MR. ABRAMS: No, no --

18 (Simultaneous speaking.)

19 CO-CHAIR CELLA: There's a table in  
20 the discussion guide, but I'm on page 33 from the  
21 previous measure. But I'm -- I would look at the  
22 discussion guide, so --

1 MR. ABRAMS: Okay, yes. On the bottom  
2 -- in the -- page 33 in the discussion guide. I  
3 pulled it out from the -- from the submission.  
4 You'll find this reliability table that I'm  
5 speaking of.

6 (Simultaneous speaking.)

7 MR. ABRAMS: Yes, the headers are  
8 wrong on the measure, so it is --

9 (Simultaneous speaking.)

10 MR. ABRAMS: It is from the bottom of  
11 page 33, but wrongly labeled. Maybe they got  
12 swapped on our item. Okay? Everybody clear on  
13 where those numbers are? Those reliability  
14 numbers.

15 CO-CHAIR CELLA: Yes, now I am.

16 MR. ABRAMS: Very good.

17 CO-CHAIR CELLA: Okay, thank you.

18 MR. ABRAMS: The validity analysis  
19 looked quite similar. But they said instead of  
20 using whatever this online calculator was, they  
21 used manually extracted data as a gold standard  
22 and they looked -- looked at similar numbers,

1 300. So they have separate validity. And then  
2 they have validity that we're asking you to think  
3 about in terms of reliability -- is it -- because  
4 element-level reliability. So you've already  
5 passed on validity element-level based on manual  
6 chart abstractions. The question before you is  
7 what do you think of this reliability  
8 presentation using the online calculator and a  
9 similar number of measures at the element level?  
10 Just to wrap up the other details of the measure  
11 related to validity -- risk adjustment was a  
12 maximum likelihood estimator deployed using what  
13 they said were both univariate and multivariate  
14 comparisons, ultimately including the effective  
15 birth weight, gestational age, gender and whether  
16 or not the baby was transferred to a new facility  
17 as a neonate, presumably that reflecting some  
18 urgency to get the -- the child to a more  
19 intensive setting.

20 Meaningful differences were somewhat  
21 evident. I've given you at the bottom of page 34  
22 of the discussion guide there a time plot which

1 gives on the y-axis hospital rates in terms of  
2 percents of infections that occurred with time.  
3 And you can see when you get to 2007 the gap  
4 between the tenth and the 90th percentile -- that  
5 widest interval is -- is actually, you know,  
6 somewhere in the neighborhood of five percent or  
7 something like that, in that fairly wide  
8 interval. So in any case, that's their  
9 demonstration of the gap. Missing data, they  
10 comment about, is quite rare and not a problem.  
11 So with that I will pause and open it up for --

12 CO-CHAIR CELLA: Sam?

13 MEMBER SIMON: Great. Thank you for  
14 the summary, Michael. So this year we have  
15 another case where because data element validity  
16 was evaluated, the measure gets passed, and I do  
17 look forward to kind of coming back and  
18 discussing those in general someday. Put that  
19 aside. There was a problem with feasibility, but  
20 I've -- one of the problems really was actually  
21 trying to discern the measures -- the  
22 specifications of the measures. They're -- and I

1 say measures, because from my reading, we're  
2 talking about four different measures here.  
3 There's accrued, cumulative, infection rate --  
4 the monthly accrued infection rate. There's an  
5 overall accrued survival rate. And then there is  
6 the standardized infection rate -- that ratio.  
7 So the specifications, you know, when you look at  
8 the hierarchy of things you are evaluating for a  
9 liability, is the measure precisely specified, I  
10 think. It really felt, to me that I -- I  
11 couldn't even, with the details given, make heads  
12 or tails of this measure appropriately. So that  
13 -- that was one very fundamental issue.

14 The second, though -- another issue I  
15 want to raise is sort of more of a process issue.  
16 It's not a measure-development issue. But from  
17 NQF's perspective, given that there are -- the  
18 analytic activity looked at the designation of  
19 sort of this late-onset sepsis and meningitis,  
20 and there -- there was a reasonable validity  
21 check of that comparing the -- these two  
22 approaches. But I guess the question is, these

1 -- the four different measures that are applied  
2 in this form seem to warrant separate  
3 applications. I don't know that it's appropriate  
4 that we sort of cobble them together into one --  
5 one evaluation. So that's more of a process  
6 issue.

7           The other -- one other issue, I think,  
8 that I wanted to raise with subcommittee and the  
9 -- and the larger group is just a general lack of  
10 information. And in addition to the  
11 specifications, you know, there is a standardized  
12 infection ratio, but we have no model-fit  
13 statistics. We don't know how -- how well a  
14 measure is calibrated, so I -- I question even  
15 the validity of this measure. I know we're being  
16 asked to just look at reliability, but those --  
17 those are some of the very -- at a very high  
18 level, some real concerns I have with this  
19 measure.

20           CO-CHAIR CELLA: Patrick?

21           MEMBER ROMANO: Yeah, this is Patrick  
22 Romano. Yeah, I just want to emphasize that the

1 -- the very first step of the guidance for  
2 evaluating reliability is, are submitted  
3 specifications precise, unambiguous and complete  
4 so that they can be consistently implemented?  
5 And if the answer to that question is no, it must  
6 be rated as low. And clearly, in this case, the  
7 answer to that question is no. There are four  
8 different denominators that are given here. It's  
9 really unclear which denominator is being  
10 proposed as the performance measure and how the  
11 -- how the fundamental construction of the  
12 indicator works is not explained. So it fails on  
13 the very first step. So the data that's being  
14 provided about data element validity is helpful,  
15 but it doesn't obviate the low score on  
16 reliability.

17 CO-CHAIR CELLA: I think -- well, go  
18 ahead, Joe, and then we'll give CDC a chance to  
19 respond.

20 MEMBER KUNISCH: Okay. So first let  
21 me start out by saying thank you to the measure  
22 developer for providing that supplemental



1 material that actually clarified quite a few  
2 things for me. And full disclaimer, I actually  
3 met with our infection prevention team at our  
4 organization to kind of, you know, talk about  
5 their process on, you know, IRR and -- and how  
6 they use that and if they actually use the  
7 calculator. And that -- you know, in my review,  
8 that was one of the things. There was no initial  
9 information on that calculator -- what were the  
10 data elements used? And it is -- to this date I  
11 still can't find that calculator and my infection  
12 prevention people were unfamiliar with it also.  
13 So one of the questions -- maybe speak to that.  
14 And is it an actual calculator, or is it one of  
15 the worksheets?

16           And then on the reliability testing,  
17 if I understand it correctly the way you did it  
18 is the abstractors -- probably your infection  
19 preventionists -- took the data elements on the  
20 worksheet, then the epidemiologists reviewed  
21 those before entering them into now this  
22 calculator, which is the gold standard, and then

1 you did that comparison between the -- basically  
2 the epidemiologists and the calculator.

3 I am always a person that likes to see  
4 what I call real-world testing. Meaning the  
5 abstractors are really going to be the ones doing  
6 this work if this becomes a measure. So I am  
7 wondering why you didn't even report the  
8 agreement between the abstractors and the  
9 epidemiologists. That would have maybe made a  
10 stronger case for reliability -- or actually, at  
11 our organization it's the infection  
12 preventionists doing reliability between each  
13 other in agreement. They don't even use the  
14 online calculator for that. And I'll leave it at  
15 that.

16 CO-CHAIR CELLA: Bijan, do you want to  
17 say something before --

18 (Simultaneous speaking.)

19 MEMBER BORAH: Yes, I think there is  
20 some of the questions that we had initially. And  
21 they did provide pretty detailed response. And I  
22 think some of the questions -- and I still agree

1 with Joe that -- I agree -- even last night I  
2 tried to find out this -- this calculator and I  
3 could not. And I have really appreciate the  
4 developer, if they -- they can tell us as to  
5 where -- or how it is being used. And that --  
6 and that part I completely agree. It's very much  
7 less in detail, but I think now that they  
8 provided like quite a lot of details, I think  
9 that question, at least to me, some of that  
10 concern is sort of mitigated.

11 CO-CHAIR CELLA: So could the folks  
12 from the CDC please introduce yourselves and  
13 respond to what's been raised so far?

14 MR. POLLOCK: Sure. And this is Dan  
15 Pollock. I am the Surveillance Branch Chief in  
16 CDC's Division of Healthcare Quality Promotion.  
17 And I am joined by several colleagues. I will  
18 let them introduce themselves.

19 MS. ALLEN-BRIDSON: This is Kathy  
20 Allen-Bridson. I am the team lead for the NHS  
21 and Protocol and Validation Team and an infection  
22 preventionist.

1 MS. BAGCHI: Hello, this is Suparna  
2 Bagchi the validation (telephonic interference).

3 CO-CHAIR CELLA: Okay. Anyone else?

4 MS. MILLSON: This is Tara Millson.  
5 I am a member of the Protocol and Validation Team  
6 and an infection preventionist.

7 CO-CHAIR CELLA: Say your name again?

8 MS. MILLSON: Tara Millson.

9 CO-CHAIR CELLA: Thank you.

10 MEASURE DEVELOPER: Good morning,  
11 (telephonic interference). I am also with the  
12 Protocol and Validation Team at NHS (telephonic  
13 interference).

14 MS. CALI: I am Susan Cali, and I am  
15 also an infection preventionist for the Protocol  
16 and Validation Team.

17 CO-CHAIR CELLA: Okay, Dr. Pollock,  
18 who is going to lead the response?

19 MR. POLLOCK: I will lead the  
20 response. Thank you very much for the  
21 opportunity. Let me preface by saying that we  
22 recognize that our original submission created

1 some confusion and we recognize that we needed to  
2 be clearer and we've attempted to clarify on the  
3 reliability issues that were brought to our  
4 attention. So let me preface the response to the  
5 specific issues that were raised with a  
6 description of our plans for implementing the  
7 whole data supply chain that will serve up data  
8 for this proposed measure. And our design is to  
9 have a purely electronic process whereby data at  
10 the reporting facilities would be extracted from  
11 electronic data sources that are in routine use  
12 throughout the United States. And these are the  
13 electronic health record system itself, the  
14 laboratory information system, the medication  
15 administration system and the admission,  
16 discharge, transfer system. So the measure is  
17 designed so that with those systems up and  
18 running, implementers can extract the requisite  
19 data to consider the infant as a candidate both  
20 for the numerator and the denominator of the  
21 measure. This will obviate the need for  
22 infection preventionists or others to abstract

1 data from charts. It helps us move in the  
2 direction of what we consider to be electronic  
3 measures. And in our definition this -- this is  
4 an electronic measure.

5 So the goal is to have a standard way  
6 to implement a set of rules applied against the  
7 available electronic data. And the calculator is  
8 that set of standard rules developed by CDC for  
9 purposes first of evaluating the measure itself,  
10 but then as we move forward, the calculator and  
11 the logic embedded in it will serve as a  
12 reference implementation -- a set of  
13 specifications where vendor implementers could  
14 build into their implementations so that the way  
15 in which the data are processed on the sending  
16 sites will mimic completely what the calculator  
17 does right now. It's not a -- a calculator that  
18 we have yet made publically available because we  
19 are going to be launching the whole process of  
20 capturing LOS meningitis data next year in NHS,  
21 and at that point, we're glad to make it public.  
22 And we're glad to share it right now with

1 interested parties. But because this will be a  
2 new event in NHSN, it doesn't replace anything  
3 that we're currently doing, it's going to be a --  
4 a new addition for us.

5 That said, do we recognize that there  
6 are always concerns about the reliability of  
7 using electronic data sources compared with the  
8 traditional or conventional approach of manual  
9 processing by experts of the data in records? So  
10 the way that we designed our reliability testing  
11 was to, in effect, look at two raters using the  
12 same data. The data that are available via an  
13 abstractor reviewing records was served up to an  
14 epidemiologist with expertise in neonatal late  
15 onset sepsis and meningitis. And those data were  
16 reviewed manually, cognitively by that individual  
17 with a case determination rendered.

18 The same data were processed through  
19 the calculator. And again, the calculator is  
20 designed both to test the reliability of the  
21 measure as well as eventually to become a  
22 technical linchpin to the actual implementation

1 of the measure. And when we evaluated those two  
2 sets of determinations, we summarized that in a  
3 variety of ways, including a kappa statistic,  
4 which is a test of inter-rater reliability, with  
5 a very high kappa value of 0.96. So that's the  
6 rationale for the approach that we took to  
7 evaluating reliability.

8 Now when we -- I can stop there and  
9 ask if there are any questions, or move into the  
10 specific issues. What would you prefer?

11 CO-CHAIR CELLA: Why don't -- why  
12 don't we see -- thank you. Why don't we see if  
13 there are any questions following up on that?  
14 All right, go ahead, Jack.

15 MEMBER NEEDLEMAN: Jack Needleman. I  
16 just want a -- a quick clarification. You've got  
17 an existing measure based upon chart abstraction.  
18 You'd like to move it to a more automated way of  
19 -- of capturing the numerator, and that's the  
20 calculator. So you're -- this is a test if  
21 whether the calculator does is -- so if you've  
22 done is try to test whether the calculator is



1 doing as well as the manual abstraction was doing  
2 under the old measure?

3 MR. POLLOCK: Yes, because --

4 (Simultaneous speaking.)

5 MR. NEEDLEMAN: I got what you were  
6 doing here.

7 MR. POLLOCK: Yes, you've got the gist  
8 of it.

9 MR. NEEDLEMAN: Okay.

10 CO-CHAIR CELLA: Okay, thanks. I  
11 don't see any other hands raised or cards raised  
12 here, Dr. Pollock, so maybe you can continue on  
13 with the more detailed response.

14 MR. POLLOCK: Sure. So issue number  
15 one that we addressed was a difficulty in  
16 assessing reliability because the measure specs  
17 cover three different measures. Well, as we said  
18 in the response, the specs for the proposed  
19 measure include numerator and denominator  
20 details. There are two types of neonatal  
21 infections, namely, late onset sepsis and  
22 meningitis, for which measure data will be

1 analyzed and summarized using several different  
2 outcome statistics and -- and these have been  
3 referenced already in the conversation this  
4 morning. Cumulative admission risk, crude  
5 monthly risk, survival probability and  
6 standardized infection ratio.

7 In our response, we go through each of  
8 what those measure statistics amounts to. And  
9 the cumulative admission risk will be the lead  
10 outcome that reflects the risk of acquiring LOS  
11 or meningitis for any eligible neonate during  
12 their admission to an eligible neonatal unit. So  
13 we see that as really being the prime outcome  
14 statistics with these others available to  
15 complement what the cumulative admission risk  
16 would summarize.

17 So we have used the standardized  
18 infection ratio in other of our  
19 healthcare-associated infection measures. And we  
20 anticipate with sufficient data we'll be  
21 reporting out for those facilities that have  
22 enough denominator exposure and SIR. But these

1 other measures can be calculated as well, even  
2 without the SIR. So we wanted to have an array  
3 of different ways in which the measure data  
4 submitted -- the numerator and denominator data  
5 -- can be summarized. And again, we've done that  
6 with our other HAI measures where, in some  
7 instances we use both rates in the measure as  
8 well as standardized infection ratios, which are  
9 risk adjusted on summary measures, as well as a  
10 third adjustment type of the SIR -- a Bayesian  
11 process that reliability adjusts, taking volume  
12 of exposure into account. So for us, you know,  
13 we -- we've had a pattern of submitting measure  
14 proposals to NQF that have numerator and  
15 denominator specs that are accompanied by  
16 different ways that those numerator and  
17 denominator data can be summarized and used for  
18 -- for measure purposes. So I will stop there  
19 with respect to issue one and -- want to see if  
20 you have any questions or comments? Or if you  
21 want me to proceed to the subsequent issues.

22 CO-CHAIR CELLA: Keep going, please.

1 Thank you.

2 MR. POLLOCK: Issue 2 was additional  
3 background as needed on the data source and data  
4 collection methods -- more details. Used on the  
5 online calculator. I guess I -- I addressed some  
6 of that in my prefatory comments. In the  
7 response that we provided we -- we summarize it  
8 by saying our method of reliability testing is  
9 designed to demonstrate that the measure data  
10 elements are repeatable, producing the same  
11 results a high proportion of time when assessed  
12 from the same population and the same time  
13 period. And that's a definition or a concept --  
14 a conceptual view of reliability that's drawn  
15 straight from the NQF Measure Information Form  
16 282.

17 We've outlined -- specified the  
18 particular data elements that are -- that figure  
19 into the whole process of identifying both  
20 numerator and denominator data. And these are  
21 placed in a table on page 2 of our response. I  
22 won't read each of them, but I would say across

1 the board that these are intentionally  
2 structured, machine-processable, readily  
3 available data with the goal, again, of having  
4 this measure be an electronic measure in which  
5 there will be a set of algorithms applied against  
6 the available data. And those algorithms are, by  
7 the way, reflected in the flow charts that are  
8 also a part of our response. And that was Issue  
9 number 3, LOS and NET are not operationally  
10 defined, so we provided these flow charts for the  
11 denominator and the NET determination as part of  
12 the package we returned.

13 Issue 4 is a clear explanation of the  
14 methods used for reliability testing. So again  
15 we used samples of records at three different  
16 facilities and had a trained record abstractor  
17 produce the -- the summary data that were then  
18 reviewed by a trained epidemiologist with  
19 expertise. And neonatal laid out the sepsis and  
20 meningitis and that same data was packaged and  
21 rendered in a way where it could be processed by  
22 the online calculator, producing the results that

1 we've summarized in -- in the table that lines up  
2 the manual abstraction data that were used by the  
3 trained epidemiologist against the calculator  
4 results. And here again, the precision is 100  
5 percent, recall 96 percent and the kappa  
6 statistic 0.96. So we think these are very  
7 strong indications of reliability in the process  
8 of identifying the cases that we've been  
9 discussing.

10 CO-CHAIR CELLA: Thank you --

11 (Simultaneous speaking.)

12 MR. POLLOCK: Issue 5 --

13 CO-CHAIR CELLA: Sorry.

14 MR. POLLOCK: Sorry?

15 CO-CHAIR CELLA: I am sorry, I thought  
16 you were done.

17 MR. POLLOCK: Issue 5 is reliability  
18 cutting across organizations. What organizations  
19 were -- we actually involved in testing and we've  
20 included a table, page 4 of our response, that  
21 describes the three hospitals and there are  
22 clearly some differences across the various

1 dimensions that we've reported, including the EHR  
2 systems in use in those hospitals. So we -- we  
3 have confidence given that we kept it -- this  
4 measure in -- in -- several different information  
5 environments, that it is going to be feasible to  
6 have a more wide use of the whole measure data  
7 submission process.

8           And Issue 6 is the extent to which --  
9 the rationale for using previous measure NQF 304  
10 to justify validity and reliability. And NQF 304  
11 was used only indirectly. The validity  
12 demonstrated for that measure, for the infection  
13 definitions, is relevant but not really the focus  
14 of the reliability conversation this morning.  
15 And the reliability testing that we've done is  
16 independent of that -- that testing that was done  
17 for 304. So that's -- that's an overview of the  
18 issues that were raised and our efforts to  
19 respond to them.

20           CO-CHAIR CELLA: Okay, thank you very  
21 much.

22           MR. POLLOCK: Questions?

1                   CO-CHAIR CELLA: Thank you very much.  
2                   Sean?

3                   MEMBER O'BRIEN: Yes, this is a  
4                   comment slash question for NQF as well --  
5                   potentially the measure developer. And just kind  
6                   of -- trying to figure out where I am going in  
7                   the re-voting. And I answered low based on the  
8                   NQF instructions to rate low if you believe this  
9                   specification is not precise, ambiguous and  
10                  incomplete. And just to give an example of that  
11                  -- and even combined with information provided by  
12                  their response -- just the concept of a survival  
13                  probability is mentioned in the measure  
14                  information form. But the amount of information  
15                  that's present about it basically says the  
16                  numerator, denominator statements. The numerator  
17                  is the number of eligible neonates without an LOS  
18                  or neonates within an eligible location, the  
19                  denominator is the total number of eligible  
20                  neonates. And that's -- that's all the  
21                  information about the survival probability. In  
22                  their response -- they mention that basically



1 their survival measure can be used to calculate  
2 Kaplan-Meier plots -- the -- staff can better  
3 understand patients length of stay -- so it -- I  
4 completely trust that they're able to do that,  
5 but I don't know what about it is that they're  
6 collecting and measuring and presenting that  
7 allows them to construct those type of plots. So  
8 it's just not completely there. I guess my  
9 question is, on some level I don't have a -- I  
10 assume that they have very detailed documentation  
11 in place for everything they're doing.

12 So on some level, I am not sure I have  
13 to know all the ins and outs as long as it's  
14 clear that they have the documentation and it's  
15 being implemented in a way that's repeatable and  
16 reproducible and -- and clear. Perhaps it's good  
17 enough. But if on some level -- on some literal  
18 level, I think I'm still stuck voting low unless  
19 either the developer or NQF staff can clarify or  
20 address my concern.

21 MR. POLLOCK: Appreciate that. You  
22 know, the -- these are all statistics that are

1 calculable with the data that we will have in  
2 hand. They're spelled out both in the table at  
3 the bottom of page 2 -- the data elements that  
4 are included in the algorithm, as well as  
5 indicated in -- in the flow charts that are -- at  
6 the -- at the end of the response. So these are  
7 calculable outcomes with the data that we have  
8 specified. And the statistics are statistics  
9 that are -- are -- are used in other types of  
10 quality measures and -- and our intent is to  
11 follow the statistical calculations accordingly  
12 in the way we produce these measure data.

13 CO-CHAIR CELLA: Joe and then Sam and  
14 then Matt.

15 MEMBER KUNISCH: So -- this is Joe  
16 Kunisch. I am going to push back a little more  
17 on that reliability because I guess it wasn't  
18 clear to me, the plan was to electronically  
19 extract this with no human review in between. So  
20 you know, one, does that make it an official  
21 e-measure because there's different testing  
22 criteria under the NQF? So I will kind of leave

1 that question over to them. But in the way that  
2 you did it, basically, you scrubbed the data  
3 before you entered it into the algorithm. And  
4 we've done numerous electronic clinical quality  
5 measure testing, and if we did that, we would  
6 probably get perfect results too because we're  
7 already taking out the dirty data, per se -- or  
8 the cases that wouldn't be because of some data  
9 element that was erroneously entered in. So I am  
10 wondering, you know, what that -- the way we  
11 typically do it is we extract all the data  
12 elements from the EHR database. Then you would  
13 use that data, run it through your algorithm,  
14 randomly select some cases for, say, the  
15 epidemiologist to review. Then you want to see  
16 if your epidemiologist and your calculator are  
17 then in agreement. And you're getting a better  
18 picture, again, of real world data, which you  
19 probably are aware, is a lot of the time it's not  
20 really good.

21 So, you know, I -- I'd rather see  
22 testing like that, being it's going to be

1 electronic, basically clinical quality measure.  
2 Because again, if I am scrubbing the data ahead  
3 of time before putting it in, I expect to get  
4 near-perfect results.

5 MR. POLLOCK: Right, so -- appreciate  
6 that. The -- you using the word scrub, we can  
7 use the word extraction because a date of birth  
8 -- a date of NICU admission, transfer, discharge  
9 -- whether the birth is in-born, the hospital or  
10 -- the baby arrives from elsewhere, these are  
11 structured data that can be manually extracted  
12 from a record, or electronically extracted from a  
13 record. We opted to have a process of manual  
14 extraction, but we are confident from other --  
15 other measures that we have in use, that the  
16 implementers are going to be able to execute that  
17 in an electronic way -- to extract those data.  
18 So the difference between what you're describing  
19 as scrubbing and what we would call an extraction  
20 step is one is being done manually and the other  
21 is being done electronically. We're -- we're  
22 confident, based on our prior experience, in the

1 capabilities of EHR vendors and infection  
2 surveillance vendors with whom we work, that  
3 there are -- their processes -- their extract,  
4 transform, load processes -- ETL processes are  
5 going to work. And we can, of course -- and  
6 will, with implementers -- validate that they  
7 have appropriately implemented the protocol  
8 steps, as we've done with our other measures that  
9 are electronic. We see that as a -- an  
10 operational implementation issue, not a measure  
11 reliability test.

12 CO-CHAIR CELLA: Okay, thank you. A  
13 couple of more -- we'll have time for efficient  
14 points. Go ahead, Sam and then Matt.

15 MEMBER SIMON: Yes, this will just be  
16 really quick. This is just a clarification to  
17 the subcommittee and the broader group as well.  
18 Just wanted to clarify something that Michael  
19 said. There is a chart in the submitted  
20 information that looks at meaningful differences.  
21 But I want to clarify that that is not this  
22 measure. It is actually NQF 304. It's an

1 analogous measure, but it's not actually -- we  
2 don't have any measure information. We have the  
3 validity information. We don't have any measure  
4 of the whole summaries for statistics of how we  
5 -- we measured those --

6 (Simultaneous speaking.)

7 MR. ABRAMS: That's right. Thank you  
8 for --

9 (Simultaneous speaking.)

10 CO-CHAIR CELLA: Matt?

11 MEMBER AUSTIN: Yes, thanks. So my  
12 comments earlier -- yesterday, I think, sort of  
13 reflected some of my challenges with this measure  
14 in terms of it sort of being multiple measures  
15 within one form. And -- when NQF makes the  
16 decision to sort of separate those out into  
17 individual measures versus keeping them all  
18 together. I think might be an example of where  
19 we want to have some further conversation about  
20 them. At least, from a reviewer's standpoint,  
21 where it might be easier to have things as  
22 individual measures.

1                   It sounds like -- or what I come away  
2 with is that really the measure developer is  
3 focusing on maybe data element validity testing  
4 as a way to demonstrate reliability. Which does  
5 require that all critical data elements be  
6 validated. I don't know if we have a clear  
7 definition of what is a critical data element.  
8 But what struck me was it seems like the focus  
9 was really on the numerator, and matching those.  
10 In the SIR, there would be an expected number of  
11 infections, of which there are some parameters  
12 that go into that as well. So -- just for future  
13 consideration, I don't know how we want those  
14 tested, or if those need to be tested. But if  
15 we're going to rely on data element validity  
16 testing, that might be something to consider.

17                   CO-CHAIR CELLA: Patrick?

18                   MEMBER ROMANO: And just to amplify on  
19 that, with an electronic extraction procedure,  
20 presumably both the numerator and the denominator  
21 are important. And so there wasn't any effort to  
22 assess the reliability, or the -- the validity of

1 the data-element level of the denominator, which  
2 I would think would be relevant here. And again,  
3 it -- it sort of gets back to the issue that it  
4 wasn't clear initially what the preferred outcome  
5 -- I should point out that in the submission  
6 form, they actually describe four different  
7 numerators. We presume that what's being tested  
8 is the composite of any or none of those four  
9 different numerators. But that's another element  
10 that added to the confusion here. So that could  
11 be clarified, but -- anyway, yes. So this --  
12 this question of -- of what are the key data  
13 elements? Is it enough just to validate the  
14 numerator when the measure is risk-adjusted and  
15 has a specified denominator?

16 CO-CHAIR CELLA: Well let's give the  
17 CDC a chance to respond briefly, please. And  
18 then Jack with final thoughts, if you're raising  
19 -- I see you raising your hand. Dr. Pollock?

20 MR. POLLOCK: Yes, so -- appreciate  
21 that. There are two conditions here the -- for  
22 which the outcome statistics are going to be



1 applied. One is late onset sepsis, the other is  
2 meningitis. Both of those are defined primarily  
3 on the basis of microbiology results. If there  
4 is a particular type of microbiology result -- a  
5 pathogen that it is sometimes described as the  
6 commensal organism, that's where the qualifying  
7 antimicrobial days, come in because we wanted an  
8 indication that the clinical team viewed that  
9 pathogen and has warranted treatment. We have  
10 denominators to find for both LOS -- and for both  
11 -- late onset sepsis and meningitis. They are  
12 the same. We've got numerators that differ on  
13 the basis of the type of specimen that's being  
14 obtained. That's the fundamental difference for  
15 us, from our perspective. The key issue in the  
16 reliability testing really has to do with the  
17 case determinations. It's absolutely correct; we  
18 did not test the reliability of the denominator  
19 determinations. But we are confident that that's  
20 going to be a straightaway process, again. That  
21 will certainly work as it's worked in -- in other  
22 types of denominators that are -- are captured

1 and reported electronically in NHSN.

2           So we focus on -- in our efforts, our  
3 -- our reliability efforts just to evaluate,  
4 again, the calculator because the -- the  
5 calculator and the algorithms embedded in it  
6 really afford case terminations, from our  
7 perspective, are the main methodologic issue with  
8 this measure. We recognize full well that the  
9 measure data -- the basic numerator and  
10 denominator data -- can and will be summarized in  
11 different ways. We see, again, that the  
12 cumulative admission risk will be the lead  
13 outcome measure that we'll -- we'll use as -- as  
14 a primary outcome measure for performance  
15 measurement purposes. So this is our -- this is  
16 what we've got.

17           CO-CHAIR CELLA: Yes, thank you.

18 Jack.

19           MEMBER NEEDLEMAN: I've got three  
20 quick questions. First of all, I just want to  
21 clarify your answer to Joe's question about data  
22 scrubbing. I understand that you pulled the data

1 manually rather than having it pulled  
2 electronically. But I just want to confirm that  
3 you did not do any exclusion of cases where data  
4 was clearly wrong, or edit any of the data that  
5 was pulled manually. It was pulled exactly the  
6 way you would expect it to be pulled in the --  
7 from the electronic data, the health record. Is  
8 that correct?

9 CO-CHAIR CELLA: Yes or no answer,  
10 please?

11 MR. POLLOCK: That is correct.

12 CO-CHAIR CELLA: Thank you.

13 MEMBER NEEDLEMAN: Okay. Because of  
14 the SIR, your risk adjuster is a critical  
15 component to this measure. It is what produces  
16 the denominator to the SIR. And the description  
17 of it is not clear. The statistics for it are  
18 not clear. The variables that were excluded by  
19 your process are not clear. So I have two  
20 questions about it. It looks almost as though  
21 you simply pulled the SIR from the earlier 304  
22 measure. Is that correct or not?

1 MR. POLLOCK: We used data from a  
2 blog, but it's not from, you know, the one -- 304  
3 measure proposal itself.

4 (Simultaneous speaking.)

5 MEMBER NEEDLEMAN: Okay. And the --  
6 okay. The second question is whether the risk  
7 adjuster is done only on Vermont data. And if  
8 so, how valid do you think these coefficients are  
9 as you bring the measure nationally?

10 MR. POLLOCK: Well, we -- we expect  
11 that they're valid as we bring the measure  
12 nationally. We haven't built the measure into  
13 our system at this point. But when we do, we'll  
14 of course have additional data with which to  
15 evaluate the risk adjustment and the coefficients  
16 -- as we've done with all of our risk-adjusted  
17 SIR measures. And if we find on the basis of  
18 additional data that our risk adjustment needs to  
19 be changed to reflect what we then have  
20 available, by all means we will update as we've  
21 done with other NQF-endorsed measures -- our  
22 predictive models used in the SIR calculation.

1 (Simultaneous speaking.)

2 CO-CHAIR CELLA: Okay, Dr. Pollock --  
3 Dr. Pollock?

4 MR. POLLOCK: We have implemented --

5 CO-CHAIR CELLA: Hello?

6 MR. POLLOCK: We -- we -- we needed a  
7 data source to include the data that we're --  
8 building into NHSN to produce models and include  
9 them in our measure proposal --

10 (Simultaneous speaking.)

11 CO-CHAIR CELLA: Dr. Pollock?

12 MR. POLLOCK: -- which is exactly what  
13 we --

14 CO-CHAIR CELLA: We're not -- we're  
15 not voting on validity, so I am sorry to cut you  
16 off. But we're not voting on this issue. We're  
17 only voting on reliability. So I apologize for  
18 cutting you off, but we're really running against  
19 the clock. Any other --

20 MR. POLLOCK: Got you. Thank you.

21 CO-CHAIR CELLA: Go ahead, Bijan.

22 MEMBER BORAH: So I -- sort of two

1 quick questions. So one is following up -- can  
2 you please confirm that the two flow chart that  
3 you provided as response, they are now going to  
4 be used as -- sort of in a defining numerator and  
5 the denominator? And if that is correct -- so I  
6 am just looking at the -- sort of second flow  
7 chart. And I think that both the bubbles in  
8 there sort of would be defining the critical data  
9 elements that-- that will be going into this  
10 algorithm. So I guess my question is, if I have  
11 a hospital with NICU, how easy for me to have  
12 this data elements in one place? I mean, for  
13 implementation?

14 MR. POLLOCK: How easy? Well --

15 MEMBER BORAH: I mean, can you -- can  
16 you -- can you get all these data elements in  
17 sort of in a -- in a form? I mean, how -- how  
18 easy or difficult to get it, you know? I mean, I  
19 don't think they will be coming from one data  
20 system alone. I guess the question is, you know,  
21 what -- what is your plan in implementing or  
22 executing this, you know, in the real world?

1 MR. POLLOCK: Sure. Good question.  
2 Clearly the data are not coming from a single  
3 system. There would be several systems from  
4 which data would be drawn electronically. But  
5 again, our experience with electronic measures --  
6 or as we would define electronic measure -- as  
7 substantiated that vendor implementers, or  
8 homegrown implementers, are able to tap into  
9 laboratory, antimicrobial administration, EHR,  
10 hospital systems, ADT systems -- and produce from  
11 both -- from all of those systems, files that  
12 incorporate the data and process those data  
13 against decision rules that are standardized.  
14 Very -- we're not -- we're not concerned about  
15 the feasibility here. We're confident that this  
16 is going to be readily implementable in multiple  
17 environments.

18 CO-CHAIR CELLA: Okay, and thank you.  
19 Any objections to moving to vote?

20 Go ahead, Yetunde.

21 MS. OGUNBEMI: We are now voting on  
22 Measure 3528, Reliability. Your options are --

1 CO-CHAIR CELLA: Hang on one second,  
2 sorry. Go ahead.

3 MS. JOHNSON: Yes, just wanted to  
4 clarify -- just a couple questions of you guys  
5 from NQF. First of all, multiple measures under  
6 one number -- we do allow that. So your  
7 questions -- and maybe it's good that we talked  
8 about this before we voted. So one of the things  
9 I heard was a question about specifications. So  
10 you have to ask yourself, do you understand this  
11 measure enough that you feel like that the  
12 different implementers would be able to implement  
13 it consistently? Okay, so that's one of the  
14 questions that you would answer. If you feel  
15 like that maybe there's enough for one of the  
16 four, or two of the four, or three of the four --  
17 but maybe not another, let's talk about that  
18 before we vote because we may be interested in  
19 passing some pieces of it, but not all of it.  
20 That's possible. Okay?

21 In terms of data element validity, as  
22 you know -- and we'll talk about this a little



1 bit later today -- if -- if you're satisfied with  
2 the validation of the data elements, you can use  
3 that as your rating. We talked about imputing  
4 your rating for validity -- so you can do that.  
5 You asked about a definition of critical data  
6 elements. If you'll bear with me. Let's see.  
7 It should include those elements that contribute  
8 most to the computed measure score -- that is,  
9 account for identifying greatest proportion of  
10 the target condition, event or outcome being  
11 measured -- the numerator, target population  
12 denominator, the population excluded -- or the  
13 exclusions -- and, when applicable, risk factors  
14 with largest contribution to variability and  
15 outcomes. So you have to ask yourself, do you  
16 feel like what was presented reflects the  
17 critical data elements? Now, sometimes people  
18 will say, this measure -- you know, A, B, C, D --  
19 what is really important is the numerator and if  
20 they tell me the numerator and I'm happy with  
21 that, then I'm happy. Other people will say, no,  
22 you know, I need to see -- you know, denominator,

1 exclusions. So that's, again, a judgment call  
2 for you. So did I hit Matt and -- did I hit all  
3 the questions?

4 MEMBER KUNISCH: I think -- just the  
5 -- the question about the e-measure. So, you  
6 know, to me this is extract -- pure electronic  
7 extraction. It doesn't fall under the -- you  
8 know, the typical HQMF QRDA format. If they're  
9 going to take the data directly, though, you know  
10 --I mean, should it be in QRDA format at that  
11 point, or some other accepted -- but what's --  
12 where do you cut off where this is an eCQM, and  
13 it requires this additional testing and this  
14 doesn't?

15 MS. JOHNSON: Right. So we would not  
16 see this as an eCQM because it's not in the HQMF  
17 format with the -- I am forgetting the letters.  
18 The quality data model -- all that kind of stuff  
19 that you have to do for eCQMs. And also, I  
20 didn't see anything about value sets. So we're  
21 pretty specific about what we would expect to be  
22 a formal eCQM.

1                   MEMBER KUNISCH: And -- and well, you  
2 know, just -- kind of a, I don't know -- say,  
3 word of caution, or -- when you talk about  
4 aligning programs and, you know -- CMS is doing  
5 this. CMS under the hybrid, I'll call it, free  
6 admissions is doing it under the QRDA format. So  
7 the 13 critical data elements have to be  
8 submitted in QRDA format. Not just directly  
9 submitted into their systems. So, you know, I  
10 would encourage CDC to align so when you're  
11 reporting these things, they're following their  
12 same standard, I guess.

13                   CO-CHAIR CELLA: Lacy?

14                   MR. POLLOCK: Oh, I couldn't -- this  
15 is Dan Pollock, just very quickly. QRDA is a  
16 format. And it's a format that is a  
17 representation of a standard called clinical  
18 document architecture -- CDA. And our intent or  
19 our design is that the data that would be  
20 submitted to CDC from participating facilities  
21 would be in the form of a CDA message. So it's  
22 essentially using the parent standard, and it's

1 given rise to QRDA. But we are constructed and  
2 built in a way that we can accept CDA messages.  
3 And so we've focused on CDA.

4 MEMBER FABIAN: Just a quick note on  
5 the standards. So CMS as of 2019 is moving  
6 forward to CQL, so different from PDM and the  
7 QRDA.

8 MR. POLLOCK: And those are -- those  
9 are relevant standards when facilities are  
10 reporting directly to CMS. What we do in our  
11 reporting on behalf of facilities to CMS is we  
12 receive the data from the facilities, and then on  
13 the CDC side, we do the calculations and provide  
14 facility-specific data to CMS. We are glad to  
15 provide that facility-specific data to CMS in  
16 whatever file format CMS wants, be it QRDA, be it  
17 the new format. That's -- that, if I may say so,  
18 is not that big of a deal. What's a big deal is  
19 the front-end stuff -- how the data are  
20 extracted, transformed and moved to CDC to begin  
21 with. That's the focus.

22 CO-CHAIR CELLA: Okay, are we back to

1 Yetunde?

2 MS. OGUNBEMI: Yes, let's do it.

3 CO-CHAIR CELLA: Okay.

4 (Simultaneous speaking.)

5 (Laughter.)

6 MS. JOHNSON: We have had -- from our  
7 audience -- a question about some of the work  
8 that Patrick's done on a -- another measure. So  
9 Patrick, do you want to describe what you've done  
10 and maybe when you've done it? We're trying to  
11 figure out if maybe we should ask Patrick not to  
12 vote on this one?

13 MEMBER ROMANO: Yes, in the interest  
14 of full disclosure -- so I serve on the Perinatal  
15 Core Measures Expert Panel for the Joint  
16 Commission. And one of those core Measures that  
17 is in the Joint Commission's portfolio is PC-04,  
18 which is called Healthcare-Associated Bloodstream  
19 Infections in Neonates. That's a measure that is  
20 harmonized -- partially harmonized with another  
21 measure that AHRQ developed that I was involved  
22 with over a decade ago, which is called NQI-03.

1 So it's not clear to me whether these are  
2 considered to be competing measures, because  
3 these measures don't include meningitis. And of  
4 course they're captured in completely different  
5 ways. But anyway, I just want to be transparent  
6 about my involvement --

7 (Simultaneous speaking.)

8 CO-CHAIR CELLA: Can I make a  
9 suggestion? I mean, I -- do you have a  
10 suggestion?

11 MS. MUNTHALI: So what we're going to  
12 do is find out if they are competing or related.  
13 Because if it is related as well, you'd have to  
14 recuse yourself. So what we're saying now is for  
15 Patrick to recuse himself from voting, and we'll  
16 find that out and then get his vote afterward.

17 (Simultaneous speaking.)

18 CO-CHAIR CELLA: So my suggestion --  
19 my suggestion is that you shadow vote -- can you  
20 shadow vote, Patrick? Can you find the  
21 SharePoint? And -- pardon?

22 MEMBER KUNISCH: I am also on that.

1 CO-CHAIR CELLA: Okay, so can both of  
2 you please shadow vote with your -- put your --

3 MS. MUNTHALI: You were not on -- you  
4 were not developing -- I think, Patrick, you had  
5 direct measure development -- you were directly  
6 developing measures for one of the measures in  
7 the core set, right? You developed one of those  
8 measures?

9 MEMBER ROMANO: Well, we both serve on  
10 the -- on the Technical Advisory Group for the  
11 Joint Commission --

12 (Simultaneous speaking.)

13 MEMBER ROMANO: -- the Joint  
14 Commission as your specification.

15 MS. MUNTHALI: And then your -- you  
16 had further involvement in one of those measures?

17 MEMBER ROMANO: With the -- with the  
18 architects, that's very remote.

19 MS. MUNTHALI: Okay.

20 CO-CHAIR CELLA: Okay, so are you  
21 asking only Patrick? Or both Patrick and Joe?

22 MS. MUNTHALI: I think both Patrick and

1 Joe --

2 CO-CHAIR CELLA: Okay.

3 MS. MUNTHALI: -- because it's the same  
4 scenario. And we will -- you can shadow vote.

5 CO-CHAIR CELLA: Can you shadow vote,  
6 please? And then put -- be sure to put your name  
7 in the name thing so that they can pull it out if  
8 it's needed. We'll see where the vote goes  
9 without you included. There are lots of people  
10 on this panel, so we'll be able to get a  
11 percentage. So -- I think now we're ready to go.

12 MS. OGUNBEMI: We're now voting on the  
13 reliability of Measure 35 --

14 CO-CHAIR CELLA: Jack?

15 (Laughter.)

16 MEMBER NEEDLEMAN: Sorry. I would  
17 like to -- Karen asked whether there were some of  
18 these four that we wouldn't want to see pulled  
19 out. I don't believe the Vermont-based risk  
20 adjuster coefficients are appropriate for a  
21 national measure. And I would like to see the --  
22 the vote on the SIR measure, anything that relies



1 upon the risk adjuster done separately.

2 MEMBER AUSTIN: Can I clarify real  
3 quick? It's the Vermont Oxford Network, which is  
4 a NICU neonatal register. So people who talk  
5 about Vermont -- it's actually hospitals across  
6 the nation. So it's not just Vermont. So just  
7 to clarify.

8 CO-CHAIR CELLA: Okay. Are you  
9 withdrawing your --

10 (Simultaneous speaking.)

11 MEMBER NEEDLEMAN: I withdraw the  
12 request.

13 CO-CHAIR CELLA: Okay. Back to you,  
14 Yetunde.

15 MS. OGUNBEMI: Okay. We are now  
16 voting on the reliability of Measure 3528. Your  
17 options are high, moderate, low and insufficient.  
18 And --

19 CO-CHAIR NERENZ: Please remind us for  
20 this measure, not a discussion, do they have to  
21 do either data element or measure score, or both?

22 MS. JOHNSON: This is an outcome

1 measure, so they can do score level of testing,  
2 or data element testing.

3 CO-CHAIR NERENZ: Or?

4 MS. JOHNSON: Yes, it doesn't have to  
5 be both.

6 CO-CHAIR NERENZ: Okay, okay. That's  
7 all I want to know.

8 MS. JOHNSON: I'm correct, right  
9 Michael? Yes.

10 MR. ABRAMS: And they only did data  
11 elements?

12 MS. JOHNSON: And they did data  
13 element.

14 MS. OGUNBEMI: Okay, so our in is  
15 five. Yes, perfect.

16 So we have zero votes high; moderate,  
17 one vote at 20 percent; low, four votes at 80  
18 percent; insufficient, zero votes, zero percent.  
19 So the measure fails.

20 CO-CHAIR CELLA: Let me just clarify  
21 the math. If -- if both Patrick and Joe were to  
22 vote high or moderate, it would still be 4-3,

1 which would fail -- is that right?

2 MS. OGUNBEMI: It would be consensus  
3 not reached --

4 (Simultaneous speaking.)

5 CO-CHAIR CELLA: So -- so you'll have  
6 to determine whether it's failed, or consensus  
7 not reached after -- after this. Okay. Okay,  
8 thank you. Larry, did you want to make a  
9 comment? We're going to take a break -- okay.

10 MEMBER GLANCE: A really quick  
11 comment. Just to the measure developers. I  
12 think we're -- our discussion here, if necessary,  
13 focused on what the materials that they presented  
14 us, which was on data element reliability and  
15 data element validity. I also think, having  
16 looked at the literature from this group, that  
17 this is a very strong group of -- this is a very  
18 strong measure developer. And I think that if  
19 they decide to come back and resubmit this  
20 measure at a later time, I think it would be  
21 extraordinarily helpful -- a couple things. One  
22 would be to provide more detailed specifications.

1 Two would be to break out the different measures  
2 separately. I think it was very difficult -- it  
3 sounds like, for the work you -- to evaluate each  
4 -- all four measures in one package. Three, give  
5 a -- some detailed technical specifications on  
6 the risk adjustment models that were used. And  
7 four, look -- focus on score level reliability  
8 and validity measures.

9 CO-CHAIR CELLA: I think what you're  
10 hearing, Dr. Pollock and company -- and there are  
11 other head nods in the room -- is don't take this  
12 as a rejection. Take it as an encouragement to  
13 -- to bring it back in -- in March. Is that  
14 fair?

15 MEMBER GLANCE: Yes.

16 CO-CHAIR CELLA: Okay. All right,  
17 we're going to take our break now, and we'll have  
18 to cut it to more like eight minutes -- seven or  
19 eight minutes. So just a quick break and come  
20 right back so we can get back on track.

21 (Whereupon, the above-entitled matter  
22 went off the record at 11:11 a.m. and resumed at

1 11:19 a.m.)

2 CO-CHAIR CELLA: These are two  
3 measures that have passed. But they were pulled  
4 up for discussion around a very specific question  
5 for clarification and that I wonder if -- and  
6 Dave is going to lead the discussion and I'm  
7 going to sign off.

8 But I wonder, Ashlie, if you could do  
9 an abbreviated summary. And then Matt will  
10 introduce the question why we put forward these  
11 measures. And they may not go back for a vote.  
12 So we'll decide that. We'll see that based upon  
13 the discussion if there's specific questions.  
14 But how about a brief summary, Ashlie?

15 MS. WILBON: Sure. I'd also wanted to  
16 welcome Mary, and I think she has some colleagues  
17 on the phone as well from NCQA. Thanks for  
18 joining us.

19 So we've merged these two next  
20 measures, 3483 and 3484, into the same kind of  
21 topic. They're very similar measures that I  
22 think share some of the same issues. So just

1 give me a second here for my notes.

2           So 3483 is an Adult Immunization  
3 Status measure. It's a composite. Both are  
4 composites. The Adult Immunization Status  
5 measure looks at the immunization status for five  
6 vaccines. So influenza, Td or Tdap, Zoster,  
7 pneumococcal. One, two, three, four. We're  
8 missing one. Pertussis, okay. Or Tdap, right?  
9 Okay.

10           And the other measure, 3484, is a  
11 prenatal immunization status. It looks at three  
12 different immunizations which includes flu,  
13 tetanus, and diphtheria, pertussis as well. And  
14 again, also a composite.

15           Both measures passed reliability and  
16 validity. The one issue -- the first issue that  
17 was raised and which pulled these measures up for  
18 discussion was around the level of analysis. The  
19 level of analysis was checked for health plan and  
20 integrated delivery system.

21           NQF states that when a measure  
22 developer submitted a measure, the level of

1 analysis must align with the testing that is  
2 submitted. So if you check a box for health  
3 plan, you need to also submit testing that aligns  
4 with health plan level of analysis.

5 And so for this measure, because there  
6 was two level analyses checked, we wanted to  
7 clarify with the developer whether or not that  
8 integrated delivery system checked box was  
9 intended to be checked.

10 And if so, how the testing  
11 demonstrates reliability for that level of  
12 analysis because it appeared that the testing  
13 only really focused on the health plan level of  
14 analysis. So that's the first issue.

15 The second issue that came up in the  
16 evaluations as well was around the reliability  
17 scores. And this wasn't necessarily an issue  
18 that Matt identified. But it came up in another  
19 subgroup member who suggested that it be brought  
20 forward for discussion in that the reliability  
21 scores essentially were close to perfect in some  
22 instances, kind of 0.99, 0.9 -- in the 0.9 range

1 all the way up to 0.99.

2 And I think there was some concern  
3 over how -- whether it's kind of mathematically  
4 possible to achieve a perfect reliability score  
5 and what some of the factors might have been that  
6 contribute to that score. Some of the subgroup  
7 members were wanting the developer to provide a  
8 little bit more color onto how they think that  
9 this score could be achieved and kind of what  
10 some of the factors that might be that  
11 contributed to that.

12 And I think those were the two main  
13 issues. And so I will hand it over to Matt to  
14 add any additional commentary. And then perhaps  
15 we'll open it up to the developer to provide any  
16 responses to that.

17 MEMBER AUSTIN: Yes. Just for sake of  
18 time, I'll actually just say what you captured,  
19 Ashlie. And so my concern, this is absolutely  
20 right on which is it was clicked off as being  
21 specified for both health plans and integrated  
22 delivery system. But at least from my review,



1 the only testing I saw was for health plans.

2 And so I didn't know I had missed  
3 something or if there was an unintentional  
4 inclusion of integrated delivery systems. So  
5 that's the issue I wanted to approach.

6 MS. BARTON: I'd actually like to  
7 introduce my colleague, Lindsey Roth, who's on  
8 the phone who has been the champion for these  
9 measures, both the immunization measures.  
10 Lindsey, can you hear us?

11 CO-CHAIR CELLA: We can't hear you.

12 MS. BARTON: No, we can't. Okay. So  
13 what I would say --

14 CO-CHAIR CELLA: Maybe she's mute.  
15 Let's give her a little bit of a chance to  
16 unmute. Or she's not mute on our end, right?

17 MS. OGHUNBEMI: No. But if you are,  
18 it's star 7 to unmute.

19 CO-CHAIR CELLA: Or maybe she'll keep  
20 trying.

21 MS. BARTON: Right.

22 CO-CHAIR CELLA: Go ahead.

1 MS. BARTON: So what --

2 CO-CHAIR CELLA: She's on the web?

3 But we can't hear her. She's probably trying to  
4 figure out how to --

5 MS. BARTON: It's possible. Well,  
6 it's a quick answer. So this is --

7 MS. ROTH: Okay. So can you hear me  
8 now?

9 CO-CHAIR CELLA: Yes.

10 MS. BARTON: Yes, we hear you,  
11 Lindsey.

12 MS. ROTH: Okay, great. I'm sorry  
13 about that. That did the trick. Okay. So, yes,  
14 I can address the two issues. I'll just start  
15 first with the integrated delivery system issue.

16 So I'll explain that we selected this  
17 category because in our field tests and in our  
18 first year pilot results of the measures, it  
19 included health plans that are considered  
20 integrated delivery systems. So health plan  
21 provider groups all are under one entity.

22 So that's how we were defining

1 integrated delivery systems in this case and we  
2 didn't see a need for a separate analysis for  
3 these plans because they're still looking at the  
4 health plan level. So that's the intent behind  
5 selecting that.

6 And then for reliability, so we  
7 institute a standard approach for calculating  
8 reliability in the health plan level. I can  
9 describe. It's different between our previous  
10 submission and this submission.

11 So in the previous submission, we  
12 heard the concerns about there only being a few  
13 health plans in our field tests. So in this  
14 submission now we recalculated reliability using  
15 the beta-binomial method on a much larger number  
16 of plans, over 135. And we also at this time  
17 provided the overall beta-binomial scores and  
18 then the distribution of the beta-binomial  
19 instead of only providing the median which we had  
20 done the first time.

21 I think I did also see a note  
22 somewhere about unequal sample sizes across the

1 plans and whether this could be contributing  
2 towards the reliability results. I did want to  
3 clarify that each plan includes all the members  
4 in their plan who meet the denominator criteria.  
5 So we're not looking at a sample of members  
6 within plans.

7 And then we do include the  
8 distribution of the measured denominator across  
9 the plan. I believe that was the exclusion  
10 section of the testing form.

11 So, and I think we've heard your  
12 concerns about our overall approach to  
13 calculating reliability for our measures. So  
14 it's requested we're looking to providing  
15 additional information on our approach as well.

16 MEMBER AUSTIN: So, Lindsey, this is  
17 Matt Austin. So it sounds like in the testing  
18 you provided, that included some integrated  
19 delivery systems in the results? Is that --

20 CO-CHAIR CELLA: In our health plans.  
21 So the health plans that are integrated delivery  
22 systems.

1                   MEMBER AUSTIN: Okay. So an example  
2 might be a Kaiser or something like that?

3                   CO-CHAIR CELLA: Yes.

4                   MS. ROTH: That's correct.

5                   CO-CHAIR NERENZ: Dave here. I know  
6 we're terribly pressed on time. My suggestion  
7 here is I think there's essentially semantic  
8 confusion and misunderstanding. Because what I  
9 think I hear going on is that this is  
10 fundamentally a health plan measure. It was  
11 tested in health plan.

12                   By the way, some of them may also be  
13 characterized as integrated delivery system. But  
14 there's a whole big universe of integrated  
15 delivery systems that are not health plans that  
16 this measure was not designed to work in nor was  
17 it tested in. And is that fair?

18                   MS. BARTON: I think that's fair.

19                   CO-CHAIR NERENZ: You have to have a  
20 defined population. If the integrated delivery  
21 system has no defined population, you have no  
22 denominator.

1 MS. BARTON: That's correct.

2 CO-CHAIR NERENZ: Okay. So I'm just  
3 -- I'm trying to jump to a potential conclusion.  
4 It would seem like this is really specified for  
5 and tested in health plans, period.

6 MS. BARTON: Yes.

7 CO-CHAIR NERENZ: If by accident some  
8 of them are integrated delivery systems, that's  
9 just, oh, well. That is -- okay? Is that --

10 CO-CHAIR CELLA: You can say health  
11 plans, including health plans that are integrated  
12 delivery systems.

13 CO-CHAIR NERENZ: But it's not  
14 important.

15 MS. BARTON: Right. I think that's  
16 fair.

17 CO-CHAIR NERENZ: Is that?

18 MS. BARTON: Yes.

19 MS. JOHNSON: So we would just ask you  
20 to uncheck integrated delivery systems in your  
21 specifications.

22 MS. BARTON: Right.

1 MS. JOHNSON: And --

2 MS. BARTON: Yes.

3 MS. JOHNSON: -- we would be done.  
4 You'd be going forward and endorsed as a health  
5 plan measure.

6 CO-CHAIR CELLA: The reason I said  
7 including is because I think there may be some  
8 reason you would want to be sure to include  
9 health plans that are integrated delivery systems  
10 that might not necessarily want to be required to  
11 report as a health plan, right? I would think  
12 you might want to specify health plans including  
13 those health plans that are integrated delivery  
14 systems or including integrated delivery systems  
15 that are health plans.

16 MS. BARTON: We'll work with NQF on  
17 how --

18 CO-CHAIR CELLA: To get the language  
19 so that --

20 MS. BARTON: -- those boxes have been  
21 defined --

22 CO-CHAIR CELLA: -- you can find your

1 universe of who's --

2 MS. BARTON: -- and what's included in  
3 which box to make sure that we're lined up.

4 CO-CHAIR CELLA: Okay. And the  
5 reliability issue?

6 MS. WILBON: So I don't know, Patrick.  
7 Did you have a question other than the integrated  
8 delivery system issue? Okay. Please go ahead.

9 MEMBER ROMANO: So it's an interesting  
10 question for those of us who are measurement  
11 geeks here, and I've had a little back and forth  
12 with John Adams over the last week or so to  
13 understand better. But the Adult Immunization  
14 Status composite measure here is not a  
15 traditional patient level all or none composite  
16 with the zero, one response.

17 In other words, the numerator -- the  
18 denominator is the number of immunization  
19 opportunities. The numerator is the number of  
20 immunization opportunities that were actually  
21 administered.

22 So there is a problem with assumption



1 violation in the traditional beta-binomial model  
2 because you have each enrollee could have  
3 anywhere from, as I recall, three to five  
4 opportunities. And those are obviously not  
5 independent of each other.

6 So I think the reliability estimate of  
7 1.000 may be a little bit inflated because  
8 essentially the denominator is inflated because  
9 you're counting all of these immunization  
10 opportunities as if they're independent of each  
11 other where it's actually some kind of complex  
12 multi-level data structure where the immunization  
13 opportunities are three to five times greater  
14 than the number of enrollees.

15 So it's probably a minor issue. Maybe  
16 it's not 1.000. Maybe it's 0.958. But anyway, I  
17 think we can accept that it's pretty close. But  
18 it may require a little bit of work.

19 MS. BARTON: But I appreciate that.  
20 That's a useful point for us to go back and talk  
21 to our analytics colleagues in terms of how to  
22 make sure that our reliability statistics are

1 matching the criteria of the measure. I was not  
2 aware that all composite measures had to be all  
3 or nothing.

4 MEMBER ROMANO: No, no, of course not.  
5 It's a perfect design. I think it's a lovely  
6 design for the measure. It's just that you might  
7 need to incorporate different assumptions into  
8 the reliability assessment.

9 MS. BARTON: Thank you.

10 MEMBER ROMANO: And one related --  
11 well, maybe not related. But one question for  
12 you to think about. I think that clearly the  
13 indirect criteria for validity were satisfied  
14 here. I think you reported a score level of  
15 validity.

16 But there does appear to be very  
17 severe ascertainment of influenza vaccinations in  
18 particular if you compare these numbers like with  
19 Medicare population with very solid numbers from  
20 the CDC. They run about four times lower. The  
21 CDC reports about 60 to 70 percent population  
22 penetration for influenza vaccination, and you're

1 reporting about 15 to 20 percent at the median.

2 So clearly there are a lot of  
3 immunizations for influenza in particular that  
4 are being given that aren't beyond the knowledge  
5 of the health plan. So that's just another.

6 MS. BARTON: Which is why we think  
7 that this is an excellent opportunity for health  
8 plans to learn how to track better the care that  
9 their members get so that they can close gaps  
10 where they're needed.

11 CO-CHAIR NERENZ: Okay. I'm detecting  
12 not a need for a revote on this with Patrick's  
13 comment, if it drops from 1 to 0.95. I'm just  
14 looking around the room for nods of confirmation.  
15 So I think perhaps we've taken care of this one.  
16 Matt, are you okay? You're the one that --

17 MEMBER AUSTIN: Yes. I mean, if my  
18 other subgroup committee members are comfortable  
19 with just specifying this as a health plan, I'm  
20 comfortable with that.

21 CO-CHAIR CELLA: Good. Okay, good.  
22 Thank you.

1                   MEMBER NEEDLEMAN: Just one quick  
2 question and a comment on the reliability  
3 estimate. I appreciate Patrick's concern that  
4 you get the calculation right. We think that's  
5 in there. But what's driving these numbers up to  
6 one is basically the large number of members of  
7 each of these health plans.

8                   Where we see lower reliability, we've  
9 got a big standard error around the estimate  
10 because the denominator is small. We've got --  
11 these are accurate estimates of the rate that  
12 you're seeing in these plans with the  
13 denominators of tens of thousands, hundreds of  
14 thousands.

15                   So, yes, the reliability numbers are  
16 fine. You're getting accurate measures of what's  
17 happening with the plan. Their reliability is  
18 not an issue.

19                   CO-CHAIR CELLA: Let's look to the --  
20 thank you, Mary. And then -- thank you. Go  
21 ahead and take on the slide. There's a slide  
22 that has some questions on it. We're moving

1 right into our discussion. Dave is going to take  
2 it.

3 CO-CHAIR NERENZ: No, let's just take  
4 a quick deep breath. First of all, again, thanks  
5 again. We've done the required substantive work  
6 reviewing these measures. We've had all kinds of  
7 interesting discussions. A tough issue sometimes  
8 of how do we think about this, how do we think  
9 about that. What are the rules? How do they  
10 apply to this strange situation?

11 And I thank you all for engaging in  
12 this, working it through until we have produced  
13 the product that we have been asked to produce.  
14 I want to just pause and acknowledge that.

15 Now it's a different mindset. You can  
16 sit back in your chairs now. Now we're  
17 reflecting on how we do our work and how we have  
18 done it well, how we can do it better. And I'm  
19 told there are some slides with questions for our  
20 consideration. I'm not seeing it.

21 CO-CHAIR CELLA: What is your opinion  
22 of our change to allow developers to provide

1 additional information after your preliminary  
2 analysis?

3 (Laughter.)

4 CO-CHAIR NERENZ: Clearly, there's no  
5 subgroup division relevant here. So everybody is  
6 free to do thumbs up or a card up to comment.  
7 But this is now a fully open discussion for  
8 everybody. I see a lot of thumbs up. Alex and  
9 Bijan have cards up.

10 MEMBER SOX-HARRIS: Having been  
11 through this before, I thought that was great. I  
12 think it would be good to have some kind of  
13 deadline for them so they're not sending them the  
14 morning of this meeting or Sunday afternoon. If  
15 we're traveling, there's really no chance to look  
16 at it.

17 MS. WILBON: There is a deadline.

18 (Laughter.)

19 MEMBER BORAH: I agree with that  
20 point. We need to have some time to explain or  
21 to go over those responses.

22 CO-CHAIR CELLA: John, you were --

1                   MEMBER BOTT: Yes. Well, similarly,  
2 while there is a deadline, correct me if I'm  
3 wrong, I think we first received it Thursday  
4 night. So there's minimal opportunity to review  
5 the additional material.

6                   CO-CHAIR CELLA: Gene?

7                   MEMBER NUCCIO: Just a quick comment  
8 about the measure compilation document which I  
9 thought was great. I really appreciate it. It  
10 needed Appendix B, okay, which says, developer  
11 late comments. Because there was no link to  
12 where the developer late comments were. And so  
13 trying to find that as you're reading what our  
14 compilation was and then their late responses  
15 would've been helpful.

16                   MS. WILBON: We think that's super  
17 helpful. We actually went in the actual  
18 discussion guide section for each vendor. But  
19 your point is valid.

20                   MEMBER TEIGLAND: And some of them  
21 were linked incorrectly.

22                   MEMBER NUCCIO: As you went through,

1 if you click on that. For example, the Group 3  
2 was in the 30s for our compilation. But the  
3 developer response was a page like 80-something.

4 MS. WILBON: Right.

5 MEMBER NUCCIO: And so trying to find  
6 that amongst everything, it's just one more link  
7 or one more set of links.

8 (Simultaneous speaking.)

9 MEMBER NUCCIO: And we appreciate  
10 that. I know it's really great and very helpful.

11 MEMBER GLANCE: I completely agree.  
12 But one corollary to that is I think that the  
13 need for developer response would be mitigated if  
14 they all send some very detailed technical  
15 specifications, especially if it's a risk  
16 adjustment measure.

17 I think oftentimes the problem that  
18 we're having as a group is when they sort of give  
19 us very sparse details on what they're doing.  
20 And so then we have to sort of second guess and  
21 ask a lot of questions. So I think at the very  
22 beginning of the process if we had detailed



1 specs, it would be really helpful.

2 MR. ABRAMS: So I have a question for  
3 you all. So what was done was this appendix was  
4 made at the bottom. We pasted the developer's  
5 response. Would you or would you not like it if  
6 staff tried to interweave the responses after the  
7 questions that you posed in the actual section  
8 that's relevant? Just asking how you would  
9 prefer to digest the information from.

10 MEMBER NEEDLEMAN: In an ideal world,  
11 yes. But frankly what would be more useful for  
12 me in terms of where the staff spent their time  
13 is a lot of the issues were over the reliability,  
14 testing some of the other data. And we get  
15 refined measures.

16 Frankly, I would rather have the staff  
17 get some of the stuff from the testing appendix  
18 into the discussion so I'm not running around  
19 looking for the testing appendix on the  
20 SharePoint site and then finding the right page  
21 in it to go look. That, to me, would be more  
22 valuable in terms of understanding what the

1 developers are responding to than having the  
2 staff spend time trying to interweave the data in  
3 to the comments.

4 The thing that a number of the  
5 developers did that was very useful which I would  
6 tell them if you're giving us response, do this,  
7 was to put the comment down and then the  
8 response. And that makes it very easy to go back  
9 and forth between the two documents.

10 MEMBER FABIAN: I'm just going to add  
11 on to Mary's comment. But I think that the -- I  
12 see that as the middle ground of being able to  
13 submit information after the fact and continuing  
14 to improve what's required in the form. So I  
15 think it's already ideal and best practice is  
16 what if the form is laid out in a way that's  
17 clear enough for us to get it the first time as  
18 well as clear enough instruction from the  
19 reviewers, the developers being able to supply  
20 the right information.

21 So I think we're always doing it in  
22 that way hopefully. And then we have this

1 secondary submission while we're still working  
2 through that catch up between what processes  
3 we're trying to add in and what expectations are  
4 reasonable for people hatching up the best  
5 process.

6 CO-CHAIR NERENZ: Joe?

7 MEMBER HYDER: I'll echo Jack's point.

8 I think the detailed and highly formatted  
9 specifications in the initial documents were very  
10 helpful. I think that there's some really  
11 specific technical things about reliability and  
12 validity that we'll want to see programmed in.

13 Having the developer response come in  
14 a little bit of a jumble frankly is fine by me  
15 because I'm going to read the whole thing anyway.  
16 And I may learn something along the way. But  
17 having it up front the way it was, was great and  
18 probably could be improved a little bit.

19 CO-CHAIR NERENZ: Sean?

20 MEMBER O'BRIEN: Yes, I thought the  
21 whole process was great and the material provided  
22 by the staff was very helpful. Just one thing

1 about, like, timelines from the developer's  
2 perspective, I think they had a week or less to  
3 prepare responses including new data analyses and  
4 a holiday in there. So I think if it's possible  
5 to extend the timeline, then you'd possibly get  
6 better data from the developers.

7 CO-CHAIR NERENZ: Terri?

8 MEMBER WARHOLAK: I thought that the  
9 process went really well. And as somebody who is  
10 new, I thought it was explained very well and  
11 that was very helpful. So I really appreciated  
12 the staff.

13 I got to tell you, though. I'm not  
14 really a fan of having multiple measures on one  
15 form just because, like, if I can't figure it  
16 out, then how can possibly calculated reliably?  
17 So I would like to see those separated. Not -- I  
18 mean, both for, like, so that it's not, like, an  
19 all or none, they all pass or none do. We'd have  
20 to pull them out. But also just for clarity  
21 sake. I think it really helps.

22 CO-CHAIR NERENZ: Just a quick

1 response to that. We got lucky actually the  
2 previous cycle with all the CAPs measures. Those  
3 of you involved in some of those subgroups you  
4 can do. Say, the hospital CAP survey, just kind  
5 of off the top of my head yesterday, said 5 or 6.  
6 It's, like, 10, 11. There are 11 measures and  
7 they're all under the same number.

8 And what it means, if you're in a  
9 subgroup or if this comes up in this setting,  
10 you're basically having a discussion -- well,  
11 either you have to say we're having a discussion  
12 about number three, period, and that's all that  
13 this is about. Or you're basically discussing  
14 and voting a package of 11.

15 And we got an image of how tough that  
16 was just a few minutes ago this morning with  
17 trying to figure out, is this one okay, but this  
18 one is not okay. I said we got lucky with CAP  
19 because they all went through and they all had  
20 some of the same properties and they were tested  
21 in the same way. Okay. That's all fine.

22 But myself would want to echo that

1 concern. If we could somehow have things come to  
2 us as 1223A and 1223B or something and then  
3 distinctly separate them for review and  
4 discussion. So if we're going to have something  
5 in front of us to sort out, at least we know it's  
6 that one we're worrying about and not that one  
7 that live under the same number.

8 Okay. Patrick, you're up, and then  
9 Jen next.

10 MEMBER ROMANO: Yes. I think that the  
11 challenge we had here today was to pinpoint what  
12 is the measure. I mean, because I think that the  
13 performance measure, the accountability measure  
14 that we were discussing this morning is the SIR.

15 And so everything else are just  
16 components needed to construct the SIR or else  
17 they're ancillary things that are reported, the  
18 registry programs like Sean's program. I mean,  
19 they report all kinds of things back to the  
20 participating organizations.

21 And it's wonderful. You get a whole  
22 dashboard of measures from STS. But you need to

1 be clear about bringing to this committee the  
2 measure that is intended for accountability, not  
3 all little pieces of it.

4 CO-CHAIR NERENZ: Okay. Jen and let's  
5 try to stay focused on the question. And then  
6 some of these things about how the measures are  
7 done may pop up again after lunch.

8 MEMBER PERLOFF: My quick corollary is  
9 that measures that are distinct also can be very  
10 related and have a pattern. So it's not just the  
11 half measures when they're 11 and 1. Even today  
12 with the measures we were just talking about,  
13 they were two closely related immunization  
14 measures. And looking at them together and  
15 thinking about those patterns also is very  
16 revealing. So it's both within a complex set,  
17 but they can be distinct and talking and looking  
18 at them together.

19 CO-CHAIR NERENZ: Yes. And I guess my  
20 point just to be clear is I don't mind as a  
21 subgroup member getting these ten together or  
22 three together. Having them together because of

1 their similar structure is a good thing. It's  
2 just clarity and discussion so that if we have a  
3 problem with one of them and it comes to this  
4 forum, at least we know we're talking about this  
5 one specifically. Okay? Good.

6 How about the second question, the  
7 pulling of measures? We did do that for, what,  
8 four or five measures total. I guess I'm sort of  
9 looking -- I have to look at Matt and Sherrie a  
10 little bit. But personally I thought it was  
11 good. Other comments?

12 MEMBER KAPLAN: I didn't even pull as  
13 many as I wanted to. The CAPS measures may be  
14 the same, but that's -- I put the brakes on that  
15 one.

16 CO-CHAIR NERENZ: Jeff?

17 MEMBER GEPPERT: I think if we pull a  
18 measure, we need to be more explicit about that's  
19 what we done and why we did it because sometimes  
20 it was -- it seemed like we were evaluating the  
21 measure in total, but we weren't, in fact. There  
22 was some specific issue that we were supposed to



1 be focused on.

2 CO-CHAIR NERENZ: Patrick?

3 MEMBER ROMANO: Right. And similarly,  
4 I think if the measure is pulled, it should be  
5 fair that the measure might require a revote  
6 because there might be some information that not  
7 everybody appreciated. So if a measure is  
8 pulled, I mean, a few times people said, well,  
9 the measure already passed, the measure already  
10 passed. Well, that's fine. But at least the  
11 idea of pulling, it should open up the  
12 possibility that there might need to be a revote.

13 CO-CHAIR NERENZ: Yes, just a quick  
14 response. I know, Sherrie, you got a card up.

15 MEMBER KAPLAN: I just wanted to -- so  
16 I get dinged and it's accurate for evaluating  
17 measures on what I think should be the standard  
18 versus what actually NQF gave out as the  
19 standards and where we are with adjusting the  
20 standard for the current evaluations.

21 So I think the pulling opportunity  
22 gives you the chance to say, well, here's the

1 things I was concerned about. And maybe the  
2 developer has a response to that that actually  
3 would reflect my concerns about it, enough to get  
4 through this issue until the standards move along  
5 and change. But I think the point of why are you  
6 objecting to this and what do you want to raise  
7 as an issue would help.

8 CO-CHAIR NERENZ: And I think as we  
9 come into this room, assuming we keep doing  
10 things this way, we can probably do a better job  
11 of targeting and streamlining the discussion. As  
12 I think to some extent we did.

13 But actually sort of in writing  
14 formally in advance and say, here's the issue  
15 upon which this was pulled. Say, here are the  
16 two or three outcomes plausible for discussion of  
17 that issue. Which of those may require a revote?

18 Just so everybody sort of knows in  
19 advance, are we debating something that if  
20 settled in a certain way will lead to a revote?  
21 If so, let's know that in advance. Or we just  
22 say something that we just need to clarify but we

1 probably don't need to revote.

2           It's like the thing that we just did  
3 about to specify for health plans. So I hope I  
4 didn't jam that through too far. But it just  
5 seemed like it had an easy solution. It's just  
6 kind of essentially an error in the check box.  
7 Fix the error, go on, move on.

8           So those that are pulled, I think we  
9 can frame them a little better in future cycles.  
10 But still I thought we did a pretty good job as  
11 it was with focusing, what's the key issue, what  
12 do we need to talk about, and then do we or do we  
13 not need to take action?

14           All right. In person versus webinar?

15           CO-CHAIR CELLA: I mean, travel is not  
16 fun for busy people. But I thought it was much  
17 better to do it in person. That's my opinion.

18           CO-CHAIR NERENZ: Terri and then John.

19           MEMBER WARHOLAK: I've come pretty  
20 far, but I think it was worth it, absolutely.  
21 It's so much easier to follow the conversation  
22 with a group this big in person than if we're on

1 the phone. I really appreciated meeting  
2 everybody face to face.

3 CO-CHAIR NERENZ: John, then Sam, then  
4 Matt.

5 MEMBER BOTT: Just maybe on the other  
6 side of the fence. I think with a constructive  
7 facilitation guidance, I think it could easily be  
8 just as well conducted by phone. I mean,  
9 traveling pretty far for essentially weighing in  
10 on two measure assigned to my team seems like an  
11 exorbitant use of my time.

12 CO-CHAIR NERENZ: Same order, Sam,  
13 Matt, then Gene.

14 MEMBER SIMON: Yes. I mean, having  
15 done it both different ways, I think the quality  
16 of the discourse is way higher having it in  
17 person. And really I think it was important to  
18 have it this way.

19 I think it also might -- I think it  
20 goes a ways towards promoting some consistency  
21 across the different subgroups. So I think  
22 that's something else to consider.

1 CO-CHAIR NERENZ: Matt?

2 MEMBER AUSTIN: Sam just made my point  
3 about I think hearing the conversations of the  
4 other subgroups is helpful in terms of promoting  
5 consistency and learning.

6 CO-CHAIR NERENZ: Gene?

7 MEMBER NUCCIO: I learned a lot on how  
8 the other groups reflected on what the problems  
9 were and seeing the information. And that's  
10 absolutely missing with the webinars in terms of  
11 you never hear what the other groups have done.

12 CO-CHAIR NERENZ: Jeff?

13 MEMBER GEPPERT: Is there a technical  
14 capability in this facility to more kind of video  
15 conferencing type participation? That would at  
16 least give some people the option to do this  
17 remotely.

18 MS. JOHNSON: I think yes. The answer  
19 is yes. Although I haven't learned how to do  
20 that. Let me just say I haven't learned how to  
21 use it yet.

22 MEMBER KAPLAN: Yes, we used it once

1 for another quality measurement meeting, but this  
2 was just last week and it was for the entire day  
3 and it worked. So we could use that in the  
4 future as well.

5 CO-CHAIR NERENZ: Elisa?

6 MS. MUNTHALI: I just wanted to  
7 clarify the process then. So we do the in person  
8 now for the measure reviews as well. We would do  
9 that twice a year plus the in person to discuss  
10 the -- or we would just do away with that and  
11 then just have these?

12 That's helpful because I see both  
13 sides. I agree. Like, in John's camp where  
14 traveled and was here two days to have two  
15 measures and we briefly discussed which is --  
16 it's a hard justification of time relative to all  
17 the practicalities that are happening.

18 But of course, like, the discussion  
19 was face to face. It's better. You're kind of  
20 forced to pay a bit more attention than if you  
21 were on the phone. You're able to get distracted  
22 with the other things that are happening.

1       However, we're still going to have to do all those  
2       things tomorrow now that we weren't doing today.  
3       So we should ask a question once we go back to  
4       all of it tomorrow.

5                   CO-CHAIR NERENZ:   Just a quick  
6       response, and this is looking forward so we don't  
7       know for sure.  It may turn out that if we get  
8       into a pattern of two meetings, one spring, one  
9       fall, largely like this.

10                   If we get more consistent in our own  
11       thought processes, if the measures --  
12       requirements of the measure developers are more  
13       clearly stated, we may find that in a day and a  
14       half or a two-day block of time we can spend less  
15       time with controversial measures and more time  
16       with deeper, broader issues.

17                   But we don't know.  We'll have to see.  
18       And it also depends on how many come in a given  
19       cycle.  If we get double set of measures in, we  
20       may have twice as many to talk about here.  So  
21       we'll just have to see how it goes.  Larry?

22                   MEMBER GLANCE:   Having done both, I

1 think that the in person hearing was vastly  
2 preferable. I also think this is going to segue  
3 way into the third question that you had or the  
4 third -- actually, the fourth, the one about the  
5 shadow voting.

6 And I think the reason it's really  
7 important is right now you can have a small group  
8 of five people who decide to pass the measure and  
9 then it doesn't go in front of the whole group.  
10 And it may mean that small group of people  
11 achieves consensus. But maybe the rest of the  
12 group would not have agreed with that decision.

13 And if that's the case, then you  
14 really do need to have an in-person meeting. And  
15 I think that's something that we have to discuss  
16 because, I mean, if you think about other types  
17 of review, like, one of the standing committees,  
18 for example. I've been on a standing committee  
19 for readmission measures for many years. And we  
20 all talk about and we all vote on every single  
21 measure, not just a small subgroup.

22 And I think that that gives a lot more



1       credibility when you have a large group of people  
2       as opposed to a small working group who weighs  
3       in. And there's no way you can do that through  
4       the small working groups talking over the phone  
5       obviously.

6                       On the other hand, I think it does  
7       demand a bit more of an investment on everybody's  
8       part to do some kind of review of every measure  
9       before they come to these meetings. And that's a  
10      big deal because we look at a lot of measures,  
11      and I think it's something that we have to talk  
12      about.

13                      But I don't think you can separate out  
14      those two issues. The one is do we have an  
15      in-person meeting? And two, do only the working  
16      group members vote on individual measures or  
17      should it be the entire group?

18                      I would favor, A, the in-person  
19      meetings. I think those are incredibly valuable.  
20      And two, I think we really should seriously  
21      consider having everyone vote, not just a small  
22      group because I think then it becomes a lot

1 easier for us to go to the standing committees  
2 and say, look, you had 30 people -- 30  
3 methodologists who voted on the scientific  
4 acceptability. This group did not think this  
5 measure was scientifically acceptable.

6 So honestly, you should really, really  
7 take that into account in your decision making  
8 versus if we go to the standing committee and say  
9 there were five people who voted and we don't  
10 think this is a good measure. Then they kind of  
11 look at us and say it's five people. Honestly,  
12 we have 30 people on our standing committee.  
13 We're not necessarily going to take your thinking  
14 into consideration as much.

15 CO-CHAIR NERENZ: Good. Thank you.

16 Lacy then Jack.

17 MEMBER FABIAN: I just had a quick  
18 question. I may have missed your point. So if  
19 we all voted, though, on this, we would only be  
20 doing that for specified measures that got pulled  
21 then, not the ones that automatically -- or had  
22 consensus reached. So that would only be the

1 challenge. You would still only have the  
2 committee members voting on those measures that  
3 got all or nothing. But then they wouldn't have  
4 the opportunity to have the whole panel at 30.

5 But I agree that if -- I would find  
6 that more valuable in this meeting if we were  
7 able to all go. But I'm not sure how it syncs up  
8 with the measures that don't get pulled.

9 CO-CHAIR NERENZ: Yes. That's a good  
10 question. Just a quick response where we're  
11 headed. You could almost imagine some kind of  
12 reverse triage process where if the subgroup all  
13 thought it was wonderful, then we don't spend  
14 time on it. Kind of flip, look at the other side  
15 of the spectrum. Or maybe it's only the ones in  
16 the middle.

17 If the subgroup all thought it was  
18 awful, we don't talk about it. If the subgroup  
19 all thought it was wonderful, we don't talk about  
20 it with the exception anybody can pull anything  
21 for discussion. That overrides. And then we  
22 talk about what's in the middle.

1           So there would be some ways to do it.  
2           But the result of what I just said would still be  
3           that only a subgroup would do the really goods or  
4           the really bads. There would not be a full group  
5           vote. Larry, your point was, if possible, it'd  
6           be nice to have a full group vote on everything  
7           theoretically.

8           MEMBER GLANCE: No, I agree with this  
9           and with the approach that you're suggesting. I  
10          think it's very similar to what an NIH study  
11          section does during triage. The ones that are  
12          absolutely awful, there's no point in really  
13          bringing them up for discussion.

14          It's a little bit different from an  
15          NIH study, the ones that are absolutely terrific  
16          where everybody agrees. We don't discuss those  
17          as well. But it's that gray zone. And I think  
18          we have to sort of fine tune that gray zone so  
19          that we can make it practical and so we can make  
20          it work, right? I mean, obviously, we got  
21          through I don't know how many measures here. But  
22          we can't do 40 measures in two days.

1                   CO-CHAIR NERENZ: Absolutely. Okay.  
2 Jack, Patrick, and Dave.

3                   MEMBER NEEDLEMAN: Yes, I don't think  
4 it's feasible to do 55 measures with all of us  
5 reviewing them nor have I seen any measures where  
6 everybody was in agreement. The really bad ones  
7 the staff is doing a terrific job never let it  
8 get to us.

9                   So I do think -- I think the subgroups  
10 work. I think the subgroups have worked very  
11 well. I suspect when we actually see the shadow  
12 voting stuff, the shadow votes are for the most  
13 part going to closely match the final  
14 subcommittee votes, not perfectly but pretty  
15 close.

16                   So I like the consensus not reached.  
17 Perhaps some consensus not reached coming up to  
18 the full committee. I like the ability of any  
19 member of the committee to pull a measure up.  
20 And I would extend that beyond the individual  
21 subgroups. So that requires having everybody  
22 seeing the results of all the subgroups to be

1 able to say, gee, I'm not sure the subgroup voted  
2 the way I would have here and I'd like some more  
3 discussion with this.

4 Those are two feasible things. But  
5 everybody voting on everything and we don't have  
6 the weeks that would be required to be able to do  
7 that.

8 CO-CHAIR NERENZ: Okay. Let's do  
9 Patrick and Dave. And then just a time check. I  
10 noticed that straight up noon there's a schedule  
11 for public comment. Just because members of the  
12 public may have arranged their own schedules, we  
13 may need to do that essentially on time. So  
14 let's take a couple minutes and then we'll see  
15 where we are, how many public comments there are.

16 MEMBER ROMANO: Yes. So I think  
17 overall the process will move fairly quickly. I  
18 share John's frustration a little bit at  
19 essentially having two days out of my schedule  
20 for effectively one vote.

21 And so the question is, is there a way  
22 where members here can feel like their time is

1 being utilized more effectively when there's  
2 shadow voting and so forth? How would the shadow  
3 voting potentially be fed back to inform the real  
4 voting?

5 So I worry about the reliability of  
6 the subgroup folks, especially five people in a  
7 subgroup. If you get three, moderate or high,  
8 you're at 60 percent which is not greater than 60  
9 percent. And so you're in consensus not reached.

10 So we end up with a fair number of  
11 CNRs that I think could be avoided if there are a  
12 way of marshaling more votes. So somehow there  
13 has to be a mechanism to marshal more votes,  
14 whether it's through making the subgroups larger  
15 or whether it's through in selective cases  
16 allowing everyone to vote on particular points  
17 based on the discussion that's happened here.

18 I love the idea of the sort of NIH  
19 reverse triage. If there were specific criteria  
20 for bringing those measures back to vote on the  
21 entire version.

22 CO-CHAIR NERENZ: All right. Dave and

1 then Zhenqiu. And after Zhenqiu, we're going to  
2 do public comments. So if anybody is teed up on  
3 the phone for public comment, we're going to get  
4 to you in just a couple minutes.

5 CO-CHAIR CELLA: So I got a sneak peek  
6 at yesterday's results in the shadow voting, and  
7 eight out of ten times there was agreement and  
8 twice there was no agreement. My hypothesis was  
9 not confirmed by the two that didn't agree. I  
10 thought that the reviewers, the subgroup members,  
11 would be tougher than the listeners and the  
12 shadow voters.

13 Turned out it was the other way around  
14 on the two where there wasn't agreement. And I  
15 have a different new hypothesis about why. My  
16 first hypothesis was the reviewers -- remember  
17 these discussions, we were kind of tough, right?  
18 I mean, there was a lot of -- most of it was  
19 asking questions about things that involved a  
20 critical view or concern.

21 And I'm thinking that the reviewers  
22 who were more immersed in the material were



1 actually bringing out their concerns but on  
2 balance wrote in those two examples a little more  
3 positive. But those of us listening and not as  
4 immersed in the review might have been more  
5 influenced by that discussion.

6 So one way to fix that, I agree with  
7 Larry. My personal view is I hope we'll move  
8 away from shadow voting and have whatever comes  
9 out of this committee come from the committee as  
10 opposed from a subgroup. I agree with that  
11 argument.

12 But one way to get around that  
13 phenomenon, if it's true, that by listening and  
14 not being as immersed in the detail, listening to  
15 the discussion that actually in a couple cases  
16 tipped the people on the shadow vote more  
17 negatively is to review with the subgroup at the  
18 end of the discussion. So where are you now in  
19 your vote?

20 Now that does mean it's a public  
21 statement of your vote, so it's maybe something  
22 to consider. But that's one way to actually get

1 kind of a recheck on where the reviewers are with  
2 the vote.

3 CO-CHAIR NERENZ: Okay. Zhenqiu, your  
4 card is down.

5 MEMBER LIN: No. So Patrick already  
6 touch on that. I thought it's a good idea to  
7 enlarge the subgroup a little bit more. They  
8 also solve various concerns, right? I mean, you  
9 have more members vote on it and carry more  
10 weight. And it may be hard for whole committee  
11 to review everything. But at least you have more  
12 people involved.

13 And also I saw another problem. I say  
14 for a subgroup if you have six people and then  
15 two or three couldn't make it, now you're down to  
16 three, right? Based on three votes, right? I  
17 think it's a good idea to acknowledge the  
18 subgroup.

19 CO-CHAIR NERENZ: I'm seeing nods. I  
20 think that's a process issue we have to deal  
21 with. That gets pretty tough from a developer,  
22 particularly if it goes south. But three or four

1 votes.

2 Tell you what. We may have some time.  
3 We may not get much public time. But let's --  
4 since it's on the schedule and we have people  
5 waiting either in the room or on the phone, I'll  
6 let staff here manage public comment.

7 MS. OGHUNBEMI: If there's anyone on  
8 the phone that would like to provide a public  
9 comment, you can do so now. If you're muted, you  
10 can press star 7 or you can submit a comment via  
11 the chatbox.

12 CO-CHAIR NERENZ: Just give it a  
13 couple more seconds. I'm not hearing anything so  
14 far.

15 MS. OGHUNBEMI: And we're getting  
16 ready to bring up the shadow voting for all  
17 measures.

18 CO-CHAIR NERENZ: All right. I am not  
19 hearing any public comment.

20 MS. OGHUNBEMI: Yes.

21 CO-CHAIR NERENZ: All right. So let  
22 us -- we're about to see some shadow voting

1 results. But let's go Matt and Bijan, and then  
2 we'll see if we have shadow voting to look at.

3 MEMBER AUSTIN: Yes. Real quickly.

4 So sort of tagging on to the previous comments  
5 about how to expand the number of votes. I mean,  
6 one possible idea is to -- if Subgroup 1 had  
7 originally reviewed the measure, asked Subgroup 3  
8 to review the measure if that measure did not  
9 pass or did not have consensus, right?

10 So it's not necessarily opening it up  
11 maybe to the entire group, but maybe it's  
12 assigning it to another subgroup who combines  
13 with the original subgroup. So there might be a  
14 way to sort of even out workload too because we  
15 could have actually a lot of measures in this  
16 meeting. So if you had to review every single  
17 measure, that could be a lot of work. So that  
18 might be a way to sort of balance.

19 CO-CHAIR NERENZ: Yes, nice idea.

20 Thanks. Bijan?

21 MEMBER BORAH: So I think it's going  
22 back to that workgroup issue. So if we were to

1 enlarge the subgroups, that does not mean that  
2 with the number of measures that we would have to  
3 evaluate would increase. So how do you kind of  
4 reconcile or how do you actually deal with that  
5 data?

6 MEMBER PERLOFF: I'm going to lead  
7 into the next question on the list that was there  
8 before. I will confess publically to everyone  
9 here. I was bad on the documentation side of  
10 this round. In some sense, I've evolved past the  
11 form. I'm going to put this in a positive spin.

12 I've done the form so many times now,  
13 I write down sort of critiques and then I have to  
14 go fit them into the form. And I find myself  
15 spending so much time just navigating. But I'm  
16 learning the criteria. I'm getting really good  
17 at critiquing measures.

18 So if we have more measures, larger  
19 committees, more measures, we have to be more  
20 streamlined in how we're able to provide some  
21 feedback, I think. So there is this sort of  
22 interconnectedness between what we're looking at

1 and what we need to get back to do.

2 And to Larry's point, I think there's  
3 an -- we need an intermediate set of information.  
4 If we were to skim all of these measures more  
5 quickly, the documentation takes a long time to  
6 go through. So there needs to be sort of an  
7 upper level abstract that gives you a lot of the  
8 texture that we need but in a snapshot.

9 So that's a hard ask. But I think  
10 that these two sort of issues will help kind of  
11 address some of the other things that we're  
12 talking about.

13 CO-CHAIR NERENZ: All right. Shadow  
14 votes, do we have something to look at? We're  
15 going to need some motivation.

16 MS. WILBON: This is a little bit  
17 small. We tried to fit everything on one slide.  
18 So largely, there was agreement. We didn't have  
19 time to calculate the number of people who were  
20 not comfortable submitting ratings for the  
21 measures we read this morning. We'll work on  
22 that.

1                   But you can see -- and actually, I  
2                   don't know if Karen will want to review some of  
3                   this. But essentially, on all but two measures,  
4                   the shadow vote corresponded with the subgroup  
5                   vote. The exception was the med rec and the  
6                   0018.

7                   So I think for those us that were a  
8                   part of this 2456 Measure discussion, that might  
9                   not have been such a surprise that there was some  
10                  discordance there. And 0018, I'm not as sure. I  
11                  don't know if others might have --

12                 CO-CHAIR CELLA: It was very close.  
13                 If it was a one column to one column comparison  
14                 and it was very close, then it probably would've  
15                 passed overall.

16                 MS. JOHNSON: That one, just FYI, the  
17                 numbers from the shadow vote was right at 60  
18                 percent. And remember we need 60.0-something or  
19                 other.

20                 CO-CHAIR CELLA: Yes. But if you  
21                 combine that with the subgroup vote, it would've  
22                 passed.

1 MS. JOHNSON: Yes.

2 CO-CHAIR CELLA: So there's really  
3 only one where the vote would've been different  
4 had you used the whole group.

5 MS. JOHNSON: Yes, Yes. So it was  
6 pretty good. One of the things that I thought  
7 was really interesting -- and again an idea  
8 hasn't been that we want all of you to look at  
9 all the measures, certainly not in glorious  
10 detail, right? So that's too much.

11 So we were really interested in  
12 whether or not you felt comfortable submitting a  
13 rating after looking at whatever you felt like  
14 looking at and after hearing whatever.

15 So to me, a little bit what's  
16 interesting but I haven't had time to think about  
17 it very much is did people feel -- lots of people  
18 felt pretty comfortable on several measures and  
19 quite a few felt pretty uncomfortable on several.  
20 I'm not quite sure what the difference between  
21 the measures were. So there is a pretty wide  
22 variation there.



1                   MEMBER NEEDLEMAN: Karen, can you ask  
2 the group how many felt comfortable when it was a  
3 shadow and sort of an advisory vote versus how  
4 many would've felt less comfortable if the vote  
5 had been for purposes of endorsement or not -- or  
6 moving the measure forward or not as opposed to  
7 shadowing this?

8                   I voted on some things because I'm an  
9 aggressive person. I voted on some things that  
10 I'm not sure I would've. Had all the background  
11 and had not fully absorbed the documentation, I'm  
12 not sure I would've been prepared to vote if it  
13 was a vote that counted.

14                  MS. JOHNSON: Okay. So you were  
15 comfortable shadow voting but not necessarily  
16 comfortable real voting. Okay, okay. Yes, and I  
17 didn't think to ask it in that way, yes, yes. I  
18 don't know if anybody has any thoughts on what  
19 you're seeing here.

20                  MEMBER AUSTIN: So for me, I was sort  
21 of a mixed bag. Sometimes I didn't feel  
22 comfortable and sometimes I did. Some of it was,

1 at least for me, sort of the complexity of the  
2 measure and how much I sort of could follow in  
3 terms of the conversation and quickly sort of  
4 absorb from the documentation. And for other  
5 ones, sometimes I could do that and sometimes I  
6 couldn't. And where I couldn't, I felt less  
7 comfortable.

8 MS. WILBON: Do you think that we  
9 could work on maybe the way that we're  
10 structuring the introduction? So at this time,  
11 we had, like, staff do kind of a higher level  
12 overview and then, like, the lead discussant do  
13 more in depth maybe overview of what the issues  
14 were.

15 I'm wondering if that maybe that intro  
16 was structured in a way that even if you didn't  
17 review the measure, if you had all -- I mean, we  
18 thought we were trying to sort of do that. But  
19 maybe in some cases it wasn't as clear or  
20 consistent about how the measure was structured  
21 or about the specifications or something like  
22 that.

1 I'm just wondering if maybe that would  
2 help or if it was maybe more the nuance of the  
3 things that at a high level you really can't get  
4 to that level.

5 MEMBER AUSTIN: For me personally,  
6 it's I'm better with visual than audio, right?  
7 So to have someone sort of verbally describe the  
8 measure, it doesn't quite sink in the same way as  
9 literally as you see in the numerator and  
10 denominator.

11 CO-CHAIR NERENZ: Okay. Something  
12 struck a chord. We've got Christie, John,  
13 Sherrie, bang, bang, bang. Just like that.

14 MEMBER TEIGLAND: Okay. I'll start.  
15 I think the discussion guide is the key here and  
16 I relied on it heavily. I did have to sometimes  
17 go back to the measure specs. But I think we  
18 need that measure spec. I do, because that's how  
19 I look at them. I want to see the detailed  
20 definition. I don't want to see the description  
21 that you provided usually wasn't very useful for  
22 me, right? It was not that accurate. It was

1       ambiguous and overbearing.

2                       So I had to really -- but we had the  
3 documents. But they're hard to find and  
4 sometimes the internet would stop on me. So I  
5 think that if we had a good discussion guide  
6 really and we can quickly find the -- we have the  
7 specs, I feel confident in the subgroup's  
8 committees to, Yes, analyze these measures and  
9 tell me what the issues are and then look at the  
10 information, hear the feedback and most made a  
11 decision.

12                      There were a couple where they were  
13 really complicated. And I said, no, I'm not  
14 comfortable. But I think if we really think hard  
15 about how we do those discussion guides and  
16 really actually spent a lot of time on them. So  
17 I won't say spend more time, but maybe there was  
18 some stuff there that wasn't all that relevant.  
19 And I don't know how to do that.

20                      MR. STOLPE: But having easy access to  
21 the specs would be useful for you.

22                      MEMBER TEIGLAND: Absolutely, yes.

1           MR. STOLPE: Let me ask you this then.  
2           So this isn't something that's hard for staff.  
3           So we could easily put in, say, an appendix, for  
4           example, with a link --

5           MEMBER TEIGLAND: Yes.

6           MEMBER O'BRIEN: -- at the front of  
7           the discussion of the individual measure. So if  
8           you want to click on that, it will lead you  
9           directly into a link to the appendix. Is that  
10          something --

11          MEMBER TEIGLAND: Yes, that would've  
12          helped because I had to go search for it in my  
13          own files, right? I had it somewhere.

14          MS. JOHNSON: Really funny thing is  
15          that we didn't even think of doing that. It  
16          would've been easy to do.

17          MEMBER TEIGLAND: Yes, yes.

18          MR. STOLPE: Well, I tried to  
19          summarize some of the specs and some of the  
20          discussions which was an effort for me. But if  
21          it would just be easier to --

22                           (Simultaneous speaking.)

1                   MEMBER TEIGLAND: It'd be better for  
2 me to look at the specs.

3                   MR. STOLPE: For example, just put  
4 them in a link.

5                   MEMBER TEIGLAND: I can read that spec  
6 quicker than I can try to figure out what you're  
7 trying to tell me.

8                   MS. WILBON: That's helpful.

9                   MEMBER BOTT: Yeah. My comment is a  
10 hybrid of Christie and Matt. Like Matt, I often  
11 -- if I get lost in the verbal conversation, I  
12 like to fall back and look at a document. And I  
13 resisted going to SharePoint because I figured I  
14 fart around so much on SharePoint and miss more  
15 of the conversation.

16                   So if there was a humongous document  
17 like what I saw on the map coordinating  
18 committee, perhaps in the discussion guide if I  
19 can click on the testing form and then there's  
20 the full testing form for that measure or that  
21 MIF, that would've been golden. I would've had  
22 the information I possibly would have needed.

1 CO-CHAIR NERENZ: Sherrie?

2 MEMBER KAPLAN: So having sat on a  
3 bunch of NIH committees, the prior reviewer  
4 really gives you that snapshot. And the staff  
5 actually does that for you. So the primary  
6 reviewer's role in this case is being served by  
7 staff, of course. And the synthetic kind of  
8 comments of everybody who actually did review it  
9 and summarized those in a single place is great  
10 with the links would've helped a lot back to the  
11 original proposal.

12 Because honestly when those proposals  
13 -- they come in, in two parts. And the testing  
14 part is the one you really want. And that's  
15 often -- when you read the first part and then  
16 it's referring you back to the second part and  
17 then that's got an appendix to some third part.  
18 If you could streamline that, I think the whole  
19 process would go down a whole lot easier. And  
20 for me, that staff summary is critical because I  
21 don't want to have to do that.

22 (Simultaneous speaking.)

1 CO-CHAIR NERENZ: Just quickly. We  
2 just have our scheduled lunch for you. People  
3 are probably ready to pass out from hunger.

4 (Laughter.)

5 CO-CHAIR NERENZ: We'll do Patrick,  
6 Daniel, Lacy, and maybe we can set this to rest  
7 until we come back after lunch.

8 MEMBER ROMANO: I just wanted to  
9 comment on that one clear instruction set because  
10 maybe that could be viewed as a process failure  
11 or a process improvement opportunity.

12 So this was a case where perhaps there  
13 needs to be a higher level committee discussion  
14 about what constitutes appropriate evidence for  
15 validity testing. Because basically the  
16 developers were saying the measures stay valid  
17 because nobody has ever shown a better way to do  
18 what we're doing. That is using pharmacists to  
19 measure med rec.

20 And second, that the score is valid  
21 because we can improve it. Well, yes, they  
22 demonstrate that they can improve the score. But



1 is that a strong enough construct? It's not  
2 really a quality construct because it's not  
3 linked to outcomes in any way.

4 So I have a feeling that this is an  
5 example where this could come back to the large  
6 group and say, is this is really construct  
7 validity if the construct is simply that we can  
8 improve? I can improve lots of things. That  
9 doesn't mean that it's meaningful. It doesn't  
10 measure -- it doesn't mean that it's a quality  
11 concept just because I can improve it.

12 So that's -- I mean, I'm not trying to  
13 revisit us in history here. But just to sort of  
14 explore how when we find these discrepancies,  
15 there might be a process to bring them back and  
16 say, well, what issues are raised?

17 CO-CHAIR NERENZ: Okay. Daniel, Lacy.

18 MEMBER DEUTSCHER: Just a very brief  
19 comment. I think I would have not felt  
20 comfortable actually voting on the measures I  
21 haven't really reviewed in depth. And thinking  
22 of what you said that on this cycle we didn't

1 have that many measures. So we could possibly  
2 have many more which means less discussion time  
3 on each one of them.

4 And during that small amount of time  
5 getting into the documents I haven't really spent  
6 time looking at and digesting that and giving a  
7 valid vote, I would have not felt comfortable.

8 I think maybe a compromise, I would  
9 probably prefer to have, like, a minimum number  
10 of members on the subgroups, maybe a little bit  
11 higher than what we had today by one or two,  
12 maybe seven members or as a minimum which would  
13 mean maybe probably to our review a little bit  
14 more measures than we have but not too much of  
15 that. Maybe that's a compromise I would have  
16 preferred.

17 MEMBER FABIAN: I also wouldn't have  
18 felt comfortable having the vote count. I felt  
19 okay being harsher on the measure because I knew  
20 it wasn't counting. But it was a way to say --

21 PARTICIPANT: Speak louder, please.

22 MEMBER FABIAN: I really think that

1       there's opportunity to make the improvement. But  
2       to the point of the visual, so more details and  
3       access to the details is great. But the reality  
4       is being able to review like all of the measures  
5       against ahead of getting those details or even  
6       during is not going to happen.

7               So to the point that I think Matt made  
8       about being visual, it is really nice to have the  
9       slide that overviews, like, where the consensus  
10      wasn't reach and then what numbers were there. I  
11      wonder if there's opportunity to take that, like,  
12      with an extra couple of bullet points.

13             And these are the particular issues  
14      that are being discussed around consensus not  
15      reached because that was the other challenge.  
16      Like, some of the measures, we departed away from  
17      the part we were voting on. Not to say the  
18      discussion wasn't valuable for other things. But  
19      as a person who didn't review the measures, it  
20      made it that much more difficult to be confident  
21      on what I was actually voting on.

22             So if I had that cue as a part of the

1 slide to remind me, oh, we're just voting on this  
2 piece, I would've felt more comfortable paying  
3 attention to that and then having my vote  
4 potentially count.

5 CO-CHAIR NERENZ: Yeah. And just a  
6 quick reply and I'll get out of the way and  
7 watch. One thing conceivably we could think of  
8 is trying to even bring out in sharper detail  
9 what's the reason for, say, the consensus not  
10 reached. We had the distribution in the books.  
11 But if three people said low and two people said  
12 moderate, why?

13 In the discussion, it kind of comes  
14 out. But if we could set that up in advance  
15 somehow and say, okay, here's the key issue.  
16 These people felt this number was okay. These  
17 other two people looked at the same number. They  
18 interpreted it the same way. They thought it was  
19 not okay. It's simply a matter of where the  
20 low-moderate line gets drawn. And now let's see  
21 what we can do with that.

22 And that's different from saying these

1 people looked at this number and then led to the  
2 rating. And these people looked at this whole  
3 different number and went to the rating. And now  
4 let's see if we can sort that out.

5 So I was sort of looking at that  
6 during our two days. Can we figure out as  
7 tightly as possible why something is in front of  
8 us? And then can we help the group and all of us  
9 resolve that? But we'll see if we can do that.

10 MEMBER TEIGLAND: Wouldn't that be in  
11 the comments? I mean, whenever I rate something  
12 low, I carefully say why the heck I rated it low.

13 CO-CHAIR NERENZ: Yeah. But some of  
14 that didn't flow through --

15 MEMBER TEIGLAND: So maybe that needs  
16 to be --

17 CO-CHAIR NERENZ: -- the computer,  
18 yeah.

19 MEMBER TEIGLAND: -- in the  
20 discussion, yeah.

21 CO-CHAIR NERENZ: Or even some  
22 selection of that sort of to highlight the

1 disagreement. Not all comments, but just to say  
2 --

3 MEMBER NEEDLEMAN: Why doesn't it in  
4 the discussion guide?

5 MEMBER TEIGLAND: Sometimes.

6 MEMBER NEEDLEMAN: Sometimes.

7 MEMBER TEIGLAND: Sometimes.

8 (Simultaneous speaking.)

9 MEMBER TEIGLAND: And I don't know if  
10 everybody ranks them, if they just say low.

11 (Simultaneous speaking.)

12 MS. JOHNSON: I think sometimes it was  
13 pretty clear that there were two or three things  
14 that were problematic across the board. And  
15 other times, there were lots of different things.  
16 It was Wednesday, Tuesday. So I think in  
17 general, we've gone a little bit more for  
18 comprehensiveness rather than synthesis.

19 So maybe we'll get you guys to help us  
20 on that a little bit. We don't want to hide any  
21 concern. Of course, you can still bring that up  
22 even if it's not in the discussion guide. So

1 maybe we do need to synthesize more.

2 MEMBER KAPLAN: Karen, could you add  
3 to this afternoon revisiting your story? Because  
4 high-moderate don't mean anything.

5 MS. STONE: We put it on the list.

6 MEMBER KAPLAN: Is that on the list?

7 CO-CHAIR NERENZ: Yeah. Okay. We  
8 have -- what do you want to do about return time?  
9 We're five minutes over. Do you want to take the  
10 full half hour? Do you want to come back in 42  
11 and eat fast? What's the pleasure of the group?

12 PARTICIPANT: Forty-two.

13 CO-CHAIR NERENZ: Okay, 42. So let's  
14 go.

15 (Whereupon, the above-entitled matter  
16 went off the record at 12:23 p.m. and resumed at  
17 12:49 p.m.)

18 CO-CHAIR NERENZ: These are a little  
19 more finite methodological issues, and they have  
20 a couple of flavors. And then eventually I'm  
21 going to turn to Karen to kind of walk us  
22 through.

1           One of the things we want to do -- now  
2     reflecting back on how we've spent the last  
3     day-and-a-half -- is identify methodological  
4     issues that we should try to settle over a period  
5     of time, like in a December webinar call or  
6     something, where we've had some time to think  
7     about it.

8           Not likely to settle it in five  
9     minutes, but we've seen now -- particularly in  
10    this set of measures -- that this is an important  
11    issue in order for us to do our work. To  
12    communicate with developers, to be consistent, we  
13    need some thought and some resolution. So  
14    there's that kind of thing.

15           There may be a couple of things that  
16    we can settle quickly, meaning right now. And  
17    we'll see if that can happen. So for at least  
18    this block of time, it's not so much about the  
19    mechanics and workflow of our process. It's  
20    about: how do we think about this approach to  
21    validity, or how do we think about this  
22    particular problem with risk adjustment?



1           So it's moved a little more into  
2 substance. And with that, I will let Karen take  
3 us. Because there's all kinds of things we could  
4 talk about.

5           MS. JOHNSON: We have an ongoing list.  
6 Let me tell you a couple of things that we know  
7 we'd like to tackle and that we'll tackle  
8 eventually, and I'm not sure where we'll get.  
9 But we've often talked about we should identify  
10 thresholds for certain things. We agree, but  
11 that's not an easy conversation. So let's just  
12 know that we're not going to do that today.  
13 Okay? We'll come back to some of those things in  
14 the future. And if those of you on the phone  
15 wouldn't mind muting your phone, we'd appreciate  
16 it.

17           So one of the things that might be  
18 really fast to chat about today is kind of some  
19 faces that were made when we said, oh yeah,  
20 remember, NQF allows data element validation to  
21 kind of stand in place additional reliability. So  
22 this was something that has been an NQF thing

1 since before I came. I've been here nine years.  
2 It's been here before I came, and probably before  
3 you came, Elisa.

4 And so we don't really know what the  
5 thinking was behind it. I suspect that some the  
6 thinking was a way to make things a little bit  
7 easier on developers. And also many years ago, a  
8 lot of our measures were more basic process  
9 measures that were paper-based, so people often  
10 were working with fairly small testing samples.

11 I don't know, Marybeth, maybe you  
12 remember. Do you? Marybeth used to work at NQF.  
13 Maybe you have some history that would give us  
14 just a flavor of why that is.

15 MEMBER FARQUHAR: I think you're  
16 right. I think it had to do with measure  
17 developers and how much information that we were  
18 asking at the time. They did have a spreadsheet  
19 or a worksheet, but it was kind of not like what  
20 you have now. It was very abbreviated, and a lot  
21 of questions were asked and a lot of information  
22 was passed to the steering committee. They

1 didn't have this panel at that point.

2 MS. JOHNSON: Right.

3 MEMBER FARQUHAR: So some of -- you had  
4 maybe one or two methodologists on the steering  
5 panel to do some of that work, and it just felt  
6 like they needed to do some more.

7 And remember too, it was evolving as  
8 we were going along. So this was an experiment -  
9 -- NQF's experiment. So they came along and they  
10 started listening and started with a consensus,  
11 and then they started to get folks more involved  
12 in that. But I believe you're correct with  
13 regard to the measure developer, and the burden  
14 that they felt that they had to submit all this  
15 information.

16 MS. JOHNSON: Okay. So Michael, I'll  
17 come to you in a second. So I think my feeling  
18 is that you guys would like to formally recommend  
19 that we recommend to our CSAC that we change  
20 that.

21 So maybe the way to have this  
22 discussion is does anybody think that we should

1 not move in that direction? So should the status  
2 quo -- you know what I'm saying? And Michael, do  
3 you --

4 MR. ABRAMS: Well, let me offer this  
5 connection to our meeting today to try and seek  
6 clarification from you about why data element  
7 validity might stand as a substitute for  
8 reliability.

9 And so if you recall the measure that  
10 came up today where we talked about this was the  
11 sepsis meningitis measure. Okay? And they, in  
12 proffering to us the reliability experiment that  
13 they did, they took their measure as it was run  
14 from their normal kind of chart review, and then  
15 they compared it to this online -- what they call  
16 this online calculator. Right?

17 And they did this in 320 cases and  
18 showed the positive predictive value and since  
19 then discussed with you those kind of statistics.  
20 And so they were high, so this is reliable. And  
21 they didn't do a very good job explaining this,  
22 but I'm intuiting that what they were trying to

1 convey and why they thought it was reliability,  
2 is because they viewed it as a kind of  
3 test/retest. Right? They used the same 320  
4 observations.

5 And the test/retest -- or maybe I'll  
6 modify it. They did a test and a retest with a  
7 different test. Right? And they used that as a  
8 way to say that they could reproduce the measure.  
9 And the fact that they did that they felt  
10 suggested the reproducibility overall could be  
11 accepted. And that was kind of the case they  
12 made.

13 I'm wondering if that might  
14 characterize -- and you all tell us -- if that  
15 might characterize why somebody would take data  
16 element validity like that and say that it tells  
17 you something about the reproducibility of the  
18 measure.

19 CO-CHAIR NERENZ: Patrick, and then  
20 Jack.

21 MEMBER ROMANO: I wonder --- and  
22 again, this may be part of the history that you

1 folks may be more familiar with. But would it  
2 make sense for this to be permissible one time  
3 for a new measure because of the fact that if the  
4 measure is not yet in use, then the developer  
5 will not have access to data with which to  
6 measure score-level reliability. And then they  
7 would be defaulting anyway to the reliability  
8 testing of patient-level data elements.

9           And validity testing of those data  
10 elements could be at least as good as reliability  
11 testing of those data elements under certain  
12 circumstances, depending on how the measure is  
13 collected in practice. And I think that the  
14 argument was made today, for example, that what  
15 they are calling reliability testing is really a  
16 validity testing of their mechanism for capturing  
17 the data.

18           But anyway, my point is that if we  
19 don't have score-level reliability, which we  
20 don't require, and it wouldn't be available  
21 initially, so in this particular case would it  
22 still make sense to allow validity testing with

1 the idea that if there's a very high level of  
2 validity, and if the method for validity testing  
3 is similar to what is being done in the field  
4 anyway, then it's effectively a reliability test  
5 at the same time.

6 CO-CHAIR NERENZ: And let me just  
7 comment. We'll get to Larry. What you said  
8 right at the end was getting to where I thought  
9 this needed to go. And I've been looking at the  
10 high-level math folks in the room who are more  
11 adept at this than I am.

12 Is it simply mathematically true that  
13 valid data elements must be reliable? That seems  
14 to be the logic upon which this is based, and I'm  
15 seeing at least two negatives shakes of heads.

16 So Larry?

17 MEMBER GLANCE: So reliability and  
18 validity are two different things. You can show  
19 that administrative data is reliable without it  
20 being valid.

21 So in order to show that  
22 administrative data is reliable, you would take

1 the medical record and you'd have two different  
2 abstractors abstract the same medical record and  
3 show that their reproducibly getting the same ICD  
4 codes.

5 But those ICD codes may not validly  
6 capture the data concepts. So for example, we  
7 know that ICD coding for myocardial infarction is  
8 not very sensitive. It may be very reliable.  
9 You get the same ICD codes for MIs from the same  
10 bunch of medical records, but it may still not be  
11 valid.

12 CO-CHAIR NERENZ: But it's the other  
13 one.

14 MEMBER GLANCE: So having said that --

15 CO-CHAIR NERENZ: It's the other one.

16 MEMBER GLANCE: You know, having said  
17 that, is the data -- if it's valid, is it  
18 necessarily going to be reliable? Well, the way  
19 you get at validity is you basically compare what  
20 you get using the data elements that you have,  
21 and then you compare them to the authoritative  
22 medical record and see if they agree. And that's



1 validity.

2 So, you know, I guess that would make  
3 an argument that if you have validity, you have  
4 reliability. But --

5 CO-CHAIR NERENZ: That seems to be the  
6 core question.

7 MEMBER GLANCE: Yeah.

8 (Simultaneous speaking.)

9 CO-CHAIR NERENZ: Could I -- no, keep  
10 going.

11 MEMBER GLANCE: But to me -- and maybe  
12 I'm going to be out of turn here, and maybe Karen  
13 is going to hit me for this. But I think really  
14 the bigger question is not about whether it's  
15 okay to have data validity without looking at  
16 data reliability.

17 I think really the bigger question is,  
18 under current NQF guidelines right now, if you  
19 pass the data reliability and pass the data  
20 validities, then you can get a pass on scientific  
21 acceptabilities.

22 And to me, I don't think that should

1 be acceptable. I don't think it's enough for the  
2 data quality to be high, for us to be able to  
3 endorse a measure as being scientifically  
4 acceptable. I don't think under any circumstances  
5 a measure should be endorsed in terms of  
6 scientific acceptability, unless you can  
7 determine that score -- at the score level, it's  
8 both reliable and valid.

9 I think we need to throw out base  
10 validity, even for a first-time measure. And I  
11 think we should throw out data quality as being  
12 the only requisite for endorsement for scientific  
13 acceptability. I think that should be -- to my  
14 way of thinking, that is like the core issue for  
15 our group.

16 CO-CHAIR NERENZ: Just before we get  
17 into that -- if we do get into that -- let's just  
18 -- I'm curious about the negative head shake  
19 simply on the more narrow issue of: does data  
20 validity imply or guarantee data reliability? I  
21 have a lot of negative head shakes down here.

22 Can we just sort of --- but then I

1       promise we'll come back to that one.  So I had  
2       Sherrie -- well, Sherrie was a very visible,  
3       negative shaker.  And let's just move down the --

4                       (Simultaneous speaking.)

5                       CO-CHAIR NERENZ:  Yes, this is the --  
6       the California group doesn't like this one.

7                       MEMBER KAPLAN:  So some of this is  
8       absolutely disciplinary training.  And that's who  
9       I am, so that's kind of how I was trained.

10       Measures are only valid and reliable for the  
11       purpose they were put to and the context they  
12       were tested in.

13                       And so are you going to re-validate a  
14       thermometer?  No, because it's been tested so  
15       frequently, and we know what the intervals mean.  
16       We know which are probably reproducible, in whose  
17       hands they're reproducible, blah blah blah.

18                       And one of the measures of glycemic  
19       control, for example, has gone through those  
20       kinds of transformations really.  You can ask the  
21       question, is it valid?  Is it reliable?  For what  
22       purposes and what circumstances?

1                   But that's why it gets me -- it grinds  
2 my back teeth when people say I'm using a valid  
3 tool. Because we don't know the circumstances --  
4 you use the measure of functional status that  
5 requires literacy of adults and now you're using  
6 a four-year-old. No. So can you have a valid  
7 measure that's not also reliable? It depends on  
8 the circumstances. And can you be accurate  
9 without being reliable? Can you -- yes. You can  
10 be accurate, and then not be able to reproduce  
11 that accuracy because you change the  
12 circumstances of testing.

13                   So for me, it's goofball to ask the  
14 question can you have a valid measure that you  
15 can't reproduce? Why would you want to do that?

16                   CO-CHAIR NERENZ: And again, let's  
17 just do the foreign language translation. In  
18 your context, in your life, a measure is what we  
19 are calling around here a data element, like a  
20 survey score for a patient.

21                   MEMBER KAPLAN: Yeah, close to the  
22 IPO.

1 CO-CHAIR NERENZ: Okay. No, I  
2 understand. It's just --

3 MEMBER KAPLAN: Can you have an  
4 accurate data source without it being  
5 reproducible? Yeah.

6 CO-CHAIR NERENZ: Yeah, got it. Okay,  
7 sure. Jack.

8 MEMBER NEEDLEMAN: Okay. So we're  
9 dealing with lots of language, and sometimes  
10 we're very precise and technical, and sometimes  
11 we're very colloquial. So for me, the validity  
12 question colloquially is: are they measuring what  
13 they think they're measuring? That's the  
14 validity issue.

15 How well it's measured, how accurately  
16 it's measured, how representative this measure is  
17 of the unit on which we want to analyze it, is a  
18 reliability question.

19 MEMBER KAPLAN: How accurate it is.  
20 (Simultaneous speaking.)

21 MEMBER NEEDLEMAN: Well, let me -- I'm  
22 going to be much more specific about that.

1           So we measure -- the reliability issue  
2 comes up at two very different levels. It comes  
3 up at the individual measurement point for  
4 one-by-one-by-one, where the measures wait. So  
5 if I'm measuring blood pressure, I know there's  
6 going to be variability there. So the question  
7 is: is the measure I got reliable? Is it a  
8 reflection of what I think the blood pressure is  
9 going to be?

10           In the case of the issue today it was:  
11 if I go through the medical records, if I go  
12 through the electronic health record and I use  
13 this algorithm, am I always going to come up with  
14 the answer, this patient had sepsis, or this  
15 patient didn't have sepsis, or meningitis?

16           And one of the issues of reliability  
17 is at the measurement level. Right at the  
18 measure -- where the measure is first applied.  
19 The second question that we have about the  
20 reliability: is the aggregation up? So when  
21 we're asking: does this clinician, does this  
22 hospital have a good score or a bad score? How

1 do they compare to others? Is that a reliable  
2 measure given the inherent variability in what  
3 we're measuring across patients?

4 And that's a separate issue from the  
5 question of: is the measure accurate enough to be  
6 called reliable at the measure level? What we  
7 were discussing today and what we were talking  
8 about was that the algorithm was being tested for  
9 accuracy at the individual patient measurement  
10 level. And the question was: is that reliable?  
11 And they were saying: do we get the same answer  
12 out of the HR that we get when we have a formal  
13 abstractor doing it?

14 But that doesn't answer the question  
15 -- the second reliability question -- which is,  
16 when we begin applying these measures of what  
17 proportion kids got sepsis, whether or not -- and  
18 we say, this place is doing better than this  
19 place, whether that's a reliable comparison given  
20 the inherent variability of the phenomenon at  
21 both places.

22 And so we've got two different levels

1 at which we're analyzing reliability. And this  
2 look at the score level says, we're ignoring, at  
3 least in the first round of the testing, the  
4 second issue.

5 CO-CHAIR NERENZ: Yes. Sean?

6 MEMBER O'BRIEN: To me, this is an  
7 issue of, can score-level -- can the item-level  
8 properties be replacing the score-level  
9 properties assessment, to meet some  
10 recommendation, or there's something.

11 But just to come back to this issue of  
12 reliability versus validity, I would say those  
13 are fundamental constructs and useful and helpful  
14 for organizing thinking in a lot of contexts --  
15 but we're sitting around talking about the same  
16 issue, debating, is this reliability or validity,  
17 then those terms are not as helpful as they could  
18 be.

19 So in the case of item-level  
20 reliability, if you randomly sample, say 10  
21 abstractors, from some population and get  
22 different results for the assessment of whether



1 an infection occurred based on chart review.

2           You could say that's --- and if  
3 there's discrepancies, say, describe that as a  
4 reliability issue. But if those 10 abstractors  
5 are associated with 10 different providers, and  
6 now those 10 abstractors are going to pool charts  
7 off to infinity for, now, one of the measures we  
8 used to compare across those providers, then  
9 you're now going to say, well, that's a  
10 permanent, fixed kind of systematic difference.  
11 And now in systematics, so let's call that  
12 validity. So I think it's context-dependent, and  
13 I'm not sure those distinctions are always that  
14 helpful.

15           (Off mic comments.)

16           MEMBER GLANCE: I guess the  
17 terminology does get really confusing. And  
18 Sherrie and I always have this back-and-forth.  
19 But if I could make it really concrete in terms  
20 of risk-adjusted outcome measures. So how to  
21 separate out the score from the data elements.

22           So if you look at readmissions, okay,

1 the data elements are whether or not you were  
2 readmitted -- yes or no -- and what the risk  
3 factors are for readmission. Those are the data  
4 elements. So when you're looking at reliability  
5 and validity at the data element level, okay,  
6 that's very different from looking at reliability  
7 and validity at the score level.

8 So when you're looking at reliability  
9 and validity at the score level, you're using  
10 something like the signal-and-noise ratio for  
11 reliability. For validity, we're looking at the  
12 risk-adjustment model. If it's a  
13 logistic-regression model, you're looking at  
14 discrimination and calibration.

15 And so the point that I was trying to  
16 make earlier is that currently under NQF rules,  
17 okay, you can pass a measure as being  
18 scientifically acceptable --

19 (Music plays in the background.)

20 (Off mic comments.)

21 MEMBER GLANCE: So under current NQF  
22 rules, a measure that the entire package can be

1 endorsed as being scientifically acceptable by  
2 only passing it in terms of reliability and  
3 validity of the data elements as I've defined  
4 them. And that, to me, should be one of the key  
5 discussion points for our group -- whether data  
6 quality, as measured using the reliability and  
7 validity of the data elements as I've defined it,  
8 should be enough for a measure to be called  
9 scientifically acceptable. And I think that  
10 should be a core discussion for our group.

11 CO-CHAIR NERENZ: Got it. Daniel?  
12 And then we'll see where we go from there.

13 MEMBER DEUTSCHER: I agree with Larry  
14 about the need to always look at the score level,  
15 since this is kind of the purpose of this group  
16 is to get to that level.

17 But going back to the reliability or  
18 validity question, I think that trying to  
19 determine or to state that a measure is reliable  
20 just because it's valid is kind of a non-valid  
21 statement, if I could say. Because --

22 CO-CHAIR NERENZ: Okay, if I could just

1 fine point. It's not that the measure is  
2 reliable, because it's the data element. Does  
3 that make any difference?

4 MEMBER DEUTSCHER: Right. Well, I was  
5 thinking of data elements. Yeah.

6 CO-CHAIR NERENZ: Okay.

7 MEMBER DEUTSCHER: And why is that  
8 maybe not a valid statement, because reliability  
9 and validity are not dichotomous. So you could  
10 have a measure that's valid under certain  
11 circumstances, but it's valid with a certain  
12 level of validity, and it might be also reliable  
13 with a certain level of reliability. So there's  
14 a certain level here and a certain level here.  
15 And one does not determine the level of the  
16 other, which is why they always need to be looked  
17 at. Both of them.

18 CO-CHAIR NERENZ: If I could try to  
19 weave a couple of things together and maybe just  
20 put out a straw person sort of proposal, and I'm  
21 intentionally sort of parking Sherrie's comment  
22 about reliability and validity being not

1 fundamentally -- just simply properties of  
2 measures, that's a big issue here that I agree  
3 with absolutely.

4 But that's -- our whole structure is  
5 we assign those labels or those pass-fail  
6 characteristics to measures. So we're going to  
7 have to get back to that.

8 What I think I'm hearing and saw in  
9 the head shakes, is that we are not happy as a  
10 group, because I heard nobody with this current  
11 rule that says, if you pass validity for data  
12 elements, you therefore get a pass on -- or you  
13 can use that to pass reliability.

14 I saw head shakes again, so I haven't  
15 heard anybody speak in favor. So I think --

16 MEMBER KAPLAN: Can you repeat that?

17 CO-CHAIR NERENZ: Well, I'm trying to  
18 figure out -- you can impute -- I'm not sure  
19 quite what the verb is. You can bring forward to  
20 us right now evidence of data element validity.  
21 And if that is acceptable, you do not have to  
22 separately bring forward evidence of data element

1 reliability.

2 And our scoring instruction is to take  
3 the validity pass and bring it over to the  
4 reliability category and give that a pass. That  
5 is the current rule.

6 And I have not heard anybody argue  
7 that that is a good rule. I have heard people  
8 shake their heads or say that is a bad rule,  
9 because validity does not guarantee reliability.  
10 And if that's the sense of the room -- and now  
11 I'm seeing nods -- we should convey that back to  
12 CSAC or whoever.

13 PARTICIPANT: You want to vote?

14 CO-CHAIR NERENZ: Okay, then -- well,  
15 okay. I mean, do we have a show of hands on  
16 that?

17 PARTICIPANT: We're agreeing that it's  
18 a bad rule.

19 CO-CHAIR NERENZ: It's agreeing it's  
20 a bad rule. Okay. Then there's the second thing  
21 that Larry has been speaking about is that -- and  
22 again, I didn't see any -- I'm watching the

1 non-verbals here. We currently have a state  
2 where particularly for new measures, if you pass  
3 the data element test, you do not have to pass  
4 measure score test, meaning if your data elements  
5 are reliable and valid, you're good to go.

6 That's what the current rule is.

7 Larry objects to that. I personally  
8 share that objection. I'm watching the  
9 non-verbals. I see other people. And the  
10 proposal then presumably would be essentially  
11 there are four boxes, and you have to check them  
12 all.

13 You have data element reliability and  
14 validity; you have measure score reliability and  
15 validity. The sense of the room that I think I'm  
16 seeing is that you must do all of them.

17 MEMBER NEEDLEMAN: So I want to  
18 revisit that sense of the room.

19 CO-CHAIR NERENZ: Okay. No, that's  
20 good. I just wanted to lay it out there to talk  
21 about it.

22 MEMBER NEEDLEMAN: Because -- and I

1 was not present at the creation. But the sense I  
2 had was when that bifurcation -- do we have data  
3 good enough to use as a measure if the data  
4 reliability issue was sufficient?

5 And I think the model was, if we're  
6 comfortable that the data is reliable, now let's  
7 go out to the field with this measure, get some  
8 more data from the field and decide whether at  
9 the score level, at the comparison level it's  
10 being used at, there's enough reliability to  
11 continue the measure. And that required -- but  
12 people were not going out into the field until  
13 they had an endorsement of the basic measurement  
14 concept.

15 And times have changed. And the  
16 question is whether we can expect the measure  
17 developers to go out in the field at this point  
18 and collect data from more and different groups  
19 based upon -- before they've been told at the  
20 measure level the data is reliable.

21 And that seems to me -- that was the  
22 split that seemed to be implicit in the data.



1 We're going to make sure the data is reliable, go  
2 out into the field, go collect data from a large  
3 number of providers, units, whatever your unit of  
4 analysis is.

5 And then come back with data on  
6 whether or not the scores are stable enough,  
7 consistent enough that we are comfortable that  
8 it's a reliable measure applied in those  
9 cross-comparisons among whatever the units are  
10 that are being compared.

11 To say let's not go there -- let's say  
12 we want to see both the data reliability and the  
13 score reliability, is to say to developers, go  
14 start collecting data from multiple units before  
15 you come to us with the specific measure in hand  
16 to ask us whether we think it's an inherently  
17 reliable enough measure at the data collection  
18 point. That's the question that you're asking.

19 CO-CHAIR NERENZ: Yes, thank you. And  
20 that's a good framing. I'm not an authority on  
21 the creation of this either. That sounds like a  
22 fair summary. And that would be the implication.

1           We would be telling developers, if you  
2           have to touch all four boxes first time in, you  
3           have to do that multi-provider, multi-unit data  
4           collection before you come in the first time.

5           Okay, so let's go Joe, Sean, Patrick,  
6           and then back to Larry.

7           MEMBER NEEDLEMAN: So my question  
8           would be what would be the consequence? Because  
9           I think we'd all love these bulletproof measures  
10          where they touch all four boxes, to use that  
11          phrase. What would be the consequence for the  
12          measure development pipeline if we tell  
13          developers that?

14          CO-CHAIR NERENZ: I'm implying in  
15          Jack's comment, it might be negative. But  
16          developers would have to speak to that. Sean?

17          MEMBER O'BRIEN: Yeah, so your  
18          proposal, or a specific direction which is  
19          requiring the developers to check four boxes, I  
20          think my proposal is scaled back a little bit  
21          from that, because I think the question of, what  
22          should developers be required to demonstrate

1 empirically, is a different topic. And I have  
2 some different thoughts about when validity  
3 testing makes sense and what types of analyses I  
4 want to see as a reviewer.

5           So a possible alternative or version  
6 of recommendation would be to revise the NQF  
7 evaluation criteria so that you don't have a box  
8 that says reliability, and those two  
9 fundamentally different things are stuck inside  
10 that box -- the item-level reliability and the  
11 score-level reliability.

12           They have the same word in common, and  
13 so because of some historical accident they were  
14 together. But they don't belong together. So  
15 split them apart, and at least I can get behind  
16 that very well, in terms of what -- and then I'd  
17 say, what do we require for first time  
18 submissions, things like that, for a different  
19 topic.

20           CO-CHAIR NERENZ: Okay. Andrew.

21           MEMBER ROMANO: I'm sorry, but I just  
22 want to go back --

1 CO-CHAIR NERENZ: Oh, and I'm sorry.  
2 I missed -- I'll get back to Jeff then. Sorry I  
3 didn't see your sign up. But Patrick first, then  
4 Jeff.

5 MEMBER ROMANO: I just want to go back  
6 to the previous question just for a second. So  
7 you asked basically if there was any  
8 justification for the rule whereby data element  
9 validity testing could substitute for data  
10 element reliability testing.

11 CO-CHAIR NERENZ: Right.

12 MEMBER ROMANO: And I do want to put  
13 forth one scenario. Okay? So a lot of the  
14 measures are based on administrative data.  
15 Essentially we could call it claims data or coded  
16 data. Right?

17 So when we're looking at the data  
18 element then, reliability testing means we have  
19 two different coders, given the exact same  
20 medical record in the same circumstances,  
21 independently reviewing and coding the medical  
22 record.

1           Data element validity means that we  
2           have a gold standard -- a criterion standard, if  
3           you will -- with maybe physicians or nurses, or a  
4           group of people coming to some kind of consensus  
5           decision about what the true value of that data  
6           element is.

7           Now, it could be argued that if the  
8           validity is very high -- close to 100 percent --  
9           and if the sample is representative of the  
10          population, then do we need to do another study  
11          -- a separate study, an extra study -- in which  
12          we test reliability by having two different  
13          coders reviewing the same record?

14          In other words, if we know the data  
15          element is true and valid and it's measuring what  
16          we want, and that's based on a sample that's  
17          representative of the population, then what is  
18          the additional value of doing a separate study  
19          with two different coders reviewing the same  
20          record?

21                   CO-CHAIR NERENZ: Well -- yes, and  
22           that's a wonderful way of framing it. And that's

1 -- again, it sort of draws the question, is the  
2 scenario that you described possible?

3 Meaning does that validity that you  
4 have tested guarantee the reliability that you  
5 have not tested? And I keep seeing negative  
6 shakes every time we frame it that way.

7 MEMBER ROMANO: My point is to you --

8 PARTICIPANT: Because it doesn't add  
9 any value.

10 MEMBER ROMANO: It doesn't guarantee  
11 it. But the question is: does it add value to  
12 know that the reliability is high? In other  
13 words, if you know that the data element is  
14 valid, do you also need to know that two coders  
15 would get exactly the same results? Because  
16 presumably if the reliability was below the bar,  
17 then that would show up on the validity test.

18 CO-CHAIR NERENZ: No, I think --

19 PARTICIPANT: No, no, no, no. No, no.

20 MR. ABRAMS: It would be helpful to  
21 clarify --

22 MEMBER ROMANO: Yes.

1                   MR. ABRAMS:  -- what we're talking  
2                   about in terms of the data element.

3                   MEMBER ROMANO:  We're talking about a  
4                   very specific situation, where reliability is  
5                   based on two coders independently reviewing the  
6                   same record.  Validity is based on the coder  
7                   being criterion-checked with a gold standard.  So  
8                   how could it be that you get 100 validity?

9                   MEMBER NEEDLEMAN:  You're shifting  
10                  things that are in the reliability category into  
11                  the validity category measure.

12                  MS. JOHNSON:  Now, I would say that  
13                  Patrick's scenario is probably the thinking that  
14                  happened back in NQF back in the day.  Right?  
15                  That somebody has done a test and they said, hey,  
16                  we've looked at the gold standard, it's accurate,  
17                  so why do we need to have somebody go back and  
18                  show that two people agree on the thing that you  
19                  know is accurate, right?

20                  MEMBER NEEDLEMAN:  Let me take  
21                  Patrick's example and make it a little bit  
22                  concrete and why I think there's a difference

1 between reliability and validity. There's a lab  
2 test somewhere in the -- from a culture somewhere  
3 in the medical record that says you either had an  
4 infection or you didn't. Right?

5 That's a gold standard. We know  
6 exactly what to look for there. That's the  
7 measure we're looking for to say: did this  
8 patient have an infection? That's the validity  
9 check.

10 The reliability check is somebody  
11 going through the records, do they find that test  
12 and get it accurately recorded? Do they record  
13 things positive where the test was negative? Do  
14 they miss tests entirely and report no test, no  
15 infection? That's a reliability check, not a  
16 validity check.

17 MEMBER ROMANO: Right. I understand.  
18 I'm not saying that they're not different. What  
19 I'm saying is that the reliability check doesn't  
20 add useful information to the validity check.

21 MEMBER NEEDLEMAN: If you can't --

22 MEMBER ROMANO: If the validity is



1 very high and the sample is represented --

2 MEMBER NEEDLEMAN: If I know exactly  
3 what I'm looking for in the medical record, but  
4 whoever is abstracting it routinely fails to find  
5 it, that measure is not reliable and shouldn't be  
6 used.

7 MEMBER ROMANO: But it wouldn't be  
8 valid either.

9 CO-CHAIR NERENZ: The data element  
10 isn't. Okay. Jeff, you looked like you were  
11 going to follow right on Patrick. So let's get  
12 --

13 (Laughter.)

14 MEMBER GEPPERT: I think part of the  
15 challenge with sort of -- it's really hard to  
16 think of an actual example of where a measure is  
17 valid but reliability adds value.

18 So that's probably like the key thing,  
19 right? We need to think like an actual concrete  
20 case where a data element is valid but a data  
21 element is not reliable. That'll help clarify  
22 our thinking. And there's some confusion about

1 whether what Jack just said is actually a true  
2 example.

3 CO-CHAIR NERENZ: So to my ear, for  
4 what it's worth, Jack just gave us one. But I --

5 MEMBER GEPPERT: I agree with Patrick  
6 that what he described is actually not a valid  
7 data collection process. That actually wasn't  
8 the point I was going to raise.

9 CO-CHAIR NERENZ: Okay, go ahead.

10 MEMBER GEPPERT: It was more to the  
11 point of the pipeline question. So isn't it not  
12 true that eQMs have sort of a different process  
13 where they don't have to demonstrate score level  
14 reliability and validity? That's not --

15 MS. JOHNSON: No, that's not quite  
16 right.

17 MEMBER GEPPERT: Okay. What's the  
18 criteria for eQMs?

19 MS. JOHNSON: For eMeasures we  
20 actually require data element validation --

21 MEMBER GEPPERT: Right.

22 MS. JOHNSON: -- for eMeasures. And

1 we say that if you have enough data, we would  
2 love to see score level. So it's pretty much the  
3 same as any other measure. There's really no  
4 difference other than we are actually requiring  
5 data element validity.

6 We also say that for an eMeasure, you  
7 don't have to show us reliability right now,  
8 right, because by definition if the eMeasures  
9 work the way that we thought they would work,  
10 you're doing it the exact same way every time.  
11 And therefore by definition it'll be  
12 reproducible.

13 MEMBER GEPPERT: Which is kind of the  
14 example that Patrick gave about the CDC with  
15 their automated process. So if we were to change  
16 the rules where now we require both data element  
17 reliability and validity, and measure score  
18 reliability and validity, that would be a change  
19 for eCQMs.

20 MS. JOHNSON: It would be a change for  
21 eCQMs. And what I would say is let's not worry  
22 about eCQMs right now because we might have to

1 say we need to do something a little different  
2 maybe for eCQMs. Or maybe at some point -- what  
3 I'd love to get to is the ideal. And then we can  
4 play around at the edges with: are there  
5 circumstances where we'd be willing to accept  
6 something a little bit less? Okay?

7 So I'd really like to go back to  
8 Patrick's. Because if you get all four, I think  
9 -- does anybody disagree that you would love to  
10 see NQF require score-level reliability? Does  
11 anybody disagree with that?

12 (Off mic comment.)

13 MS. JOHNSON: Okay. So that's one of  
14 the four boxes -- right -- that we would love to  
15 see.

16 MEMBER GEPPERT: The only question I  
17 think for me on the table is whether it's  
18 required at the first endorsement opportunity.

19 MS. JOHNSON: Right. So we'll come  
20 back to that.

21 MEMBER GEPPERT: Okay.

22 MS. JOHNSON: Yeah, we'll come back to

1 that. So we would love to see score-level  
2 reliability. Nobody's fussing at that. Okay.  
3 How about score-level validations? So some kind  
4 of either criterion or construct, or something  
5 like that?

6 MEMBER AUSTIN: Face validity?

7 MS. JOHNSON: Let's just talk about if  
8 -- that would in sections, so let's put that on  
9 the table --

10 MEMBER SIMON: Yeah, that's one of my  
11 questions.

12 MS. JOHNSON: -- for a few minutes.  
13 Yeah, let's not fight about face validity right  
14 now.

15 MEMBER SIMON: Yeah. The concern I  
16 have there is that if you're developing a measure  
17 that doesn't necessarily correlate with  
18 something, something that's fairly novel, and  
19 you're trying to do a cutting-edge measure --  
20 you're looking at care coordination, and you  
21 cannot validate the score -- you might be able to  
22 do a very nice analysis of face validity, but you

1 may not be able to get score-level validation.  
2 And that's something we've bumped up against with  
3 some measures. Looking at preventative care, for  
4 example, can be very tricky.

5 MS. JOHNSON: So what you're saying is  
6 it sounds great, but we know that sometimes  
7 there's a problem finding a reasonable, good  
8 enough comparator. Because we all fuss about the  
9 comparators that people come in and bring in.  
10 Right? And a lot of them do it because we say,  
11 hey, this is an X-Y-Z kind of measure. You have  
12 to do it. So here you are. I kind of know it's  
13 not great. But I'm willing -- this is what I can  
14 give you.

15 MS. WILBON: So my question would be:  
16 is construct validity the only kind of validity?  
17 I mean, I think known groups or some other types  
18 of validity came up as -- I mean, is --

19 MS. JOHNSON: We're using the term  
20 construct validity as an umbrella term.

21 MS. WILBON: Oh, as an umbrella. Oh,  
22 okay.

1 MS. JOHNSON: So don't worry about  
2 it's actually construct versus concurrent versus  
3 discriminate, versus known groups. It's all kind  
4 of validity. You're coming up --

5 PARTICIPANT: Non-face validity.

6 MS. JOHNSON: -- with some kind of  
7 relationship on --- okay. Yeah.

8 (Simultaneous speaking.)

9 MS. JOHNSON: Non-face. Other body  
10 part.

11 MS. JOHNSON: Non-face. Yeah.

12 MEMBER GLANCE: So I would challenge  
13 the idea of construct validity as being what we  
14 should be looking at. Because by definition,  
15 when you're doing construct validity, you're  
16 assuming that whatever score you come up at the  
17 score level, that it's valid if it demonstrates a  
18 reasonable level of agreement with some other  
19 measure that's capturing the same concept.  
20 Right?

21 So for example, if you were  
22 introducing a new mortality measure, one way to

1 demonstrate construct validity would be  
2 potentially to show that it agrees with some  
3 other mortality measure, or some other  
4 readmission measure, some other outcome measure.

5           And one could argue that you may not  
6 get very good agreement, but it doesn't mean that  
7 the measure is not valid. It just means that  
8 you're capturing a slightly different domain. So  
9 I would argue -- and I've argued -- you and I  
10 have had this discussion many, many times -- but  
11 for risk-adjusted outcome measures, really the  
12 way we should be looking at validity should be  
13 predictive validity.

14           And by predictive validity, I mean  
15 does the risk adjustment model work well.  
16 Because if you had -- in a perfect world with  
17 perfect risk-adjusted models, you could predict  
18 exactly what should be happening to a patient,  
19 what their predictive probability of death is,  
20 what the predictive probability of readmission  
21 is.

22           And then you'd know for a provider's



1 cohort, what is the level of agreement between  
2 the observed and the expected? So I would argue  
3 that predictive validity is what we should be  
4 talking about, not construct validity.

5 MS. JOHNSON: So can I stop you there  
6 just for a second?

7 MEMBER GLANCE: Sure.

8 MS. JOHNSON: And ask: can we shelf  
9 that one for a few minutes?

10 MEMBER GLANCE: Okay.

11 MS. JOHNSON: The reason I'd like to  
12 shelve it is half of our measures coming through  
13 right now are not risk-adjusted measures. All  
14 right?

15 MEMBER GLANCE: The complex measures  
16 though? The ones that we're looking --

17 MS. JOHNSON: The ones that you guys  
18 are seeing, but I'm talking about all of our  
19 measures. So we need something that we can say  
20 kind of across the board, not necessarily for  
21 just the complex measures that are coming here.  
22 So that's --

1 MEMBER GLANCE: Okay.

2 MS. JOHNSON: Yeah.

3 MEMBER GLANCE: Okay, got it.

4 CO-CHAIR NERENZ: Okay, we have a few  
5 other cards up and we probably have two or three  
6 different things on the table. It's so hard to  
7 keep it tight, and I know you're trying to work  
8 through a little grid. But let's go Sherrie and  
9 then Sean.

10 MEMBER KAPLAN: Well, for me, when you  
11 do psychometric testing, you're only validating  
12 the score. You're not -- the data sources you  
13 can check out, et cetera. But measures don't  
14 exist in the abstract. They exist in the  
15 application. So when you're testing them, it's  
16 how they're applied. So they're applied to  
17 someone and you get a score back. And then you  
18 do the psychometric testing on the score you get  
19 back.

20 And so those circumstances can change.  
21 The validation exercise there is really pretty  
22 simple one and it depends on the measure.

1 Because construct validity may be all you have.  
2 What I was going to ask you, Karen, to address on  
3 the NQF side is data collection costs money. And  
4 so if you can't get the money to do the empirical  
5 assessment of the score that you're trying to get  
6 the approval for, what processes does NQF have  
7 for different phases of development, which is  
8 what Sean was addressing?

9 If there is a tiering opportunity, and  
10 you absolutely can't get money to do the data  
11 collection without NQF endorsement, does that  
12 ever happen? And then can you consider kind of  
13 an opportunity in phased development, like the  
14 FDA has -- your Phase 1 measures have this kind  
15 of process?

16 CO-CHAIR NERENZ: Yeah, I was going to  
17 just think of that when Jack made the comment  
18 about the history of -- you know, first time  
19 through versus later time through -- that part of  
20 the trouble I think a lot of us have -- and I'm  
21 looking at Larry a little bit -- there's only one  
22 endorsement. It's either endorsed or not

1 endorsed.

2           And the first time through it gets  
3 endorsed and it goes out in the -- released in  
4 the wild has been our phrase. And all kind of  
5 crazy things happen. Who knows? This might be a  
6 more comfortable, low-key discussion if there was  
7 a provisional endorsement the first time, labeled  
8 explicitly that -- and then a second full  
9 endorsement, second or third or fourth time  
10 through, based on, I would say, touching all the  
11 four boxes. But there may a historical reason  
12 why that doesn't happen.

13           MS. JOHNSON: Yeah. Well, there's two  
14 things. I want to hand over to Lisa for  
15 something that we're hoping to institute. I will  
16 tell you that back in the day when we first had  
17 this first thing that we were talking about and  
18 how we would rate, the rating used to work like  
19 this.

20           If you did one level of testing -- it  
21 didn't matter which one -- then you were eligible  
22 for moderate. And then the idea was, as Jack

1 suggested, go out, get some more data, get some  
2 more money, do whatever it is you got to do.  
3 When you bring it back for maintenance, we would  
4 expect more testing at that point and hopefully  
5 at a different level, in which case you were  
6 eligible for a high. Okay?

7 So that was kind of the thinking 10  
8 years ago. Right? And at some point maybe five  
9 years ago, we started saying, wait a minute, we  
10 do a lot of accountability things. Score becomes  
11 very important. So score-level testing, we  
12 changed the way the algorithm works.

13 (Telephonic interference.)

14 MS. JOHNSON: So the algorithm now  
15 works that you're eligible for a high if you  
16 didn't score, and only moderate if you did data  
17 element. Right? So it's trying to get the field  
18 to go in one direction or the other, possibly in  
19 the wrong direction because both of them tell you  
20 something different, and we'd actually like to  
21 know them all I think.

22 But it still -- is one more important

1 than the other? Do we need to expect some kind  
2 of different testing as we go along? I think  
3 that's one way we could think about it.

4 Historically, we haven't been able to  
5 do that. Developers will say, I had a contract  
6 to do this, this is what I was able to do, and  
7 that's -- I don't have another contract so I  
8 can't add to that. Right? We would have loved  
9 to have new testing every time they come back.  
10 Right? Maybe a different population and  
11 different something or other, to your point, but  
12 we very seldom get that. And it's a resource  
13 requirement usually. So then that takes us to  
14 another thought that we've had.

15 MS. MUNTHALI: Yeah, it -- this  
16 conversation is -- this is what we struggle with  
17 almost on a daily basis. It's really challenging  
18 because we want to make sure the field knows that  
19 our measures have stood the test of time, they've  
20 gone through a rigorous scientific review.

21 But we also are concerned about the  
22 measure development pipeline. And if we are

1 causing undue angst and obstacles to measure  
2 developers who may have resource constraints,  
3 that may not have the money to do the testing,  
4 and so our first thinking on this, we introduced  
5 for eQCMs, in particular, what we call a trial  
6 approval process, in which short of the testing,  
7 if they could meet our evidence standards, our  
8 feasibility standards, our use and usability  
9 standards, we would give them NQF approval to go  
10 out for three years to go out there and test.

11 The thinking was that that would  
12 promote uptake of use of the measure, and perhaps  
13 they would also then get the opportunity to have  
14 access to the data that they needed to test.

15 This was about three or four years ago. I can  
16 tell you we probably have had one or two measures  
17 get fully endorsed. It's challenging still with  
18 the NQF approval.

19 So we realize that we probably need to  
20 provide developers access to multi-stakeholder  
21 committees, to some sort of NQF staff technical  
22 assistance, as we do for fully-specified measures

1 throughout the development pipeline. And so we're  
2 in the process now of trying to see if we can  
3 secure funding for this. It's a process in which  
4 we would give approval for developers at the  
5 ideation stage, so even at the evidence stage.

6 So we would bring together  
7 multi-stakeholder groups to see if this idea is  
8 strong in terms of its evidence. We would also  
9 do it for testing. And anything more than that  
10 would have to go through our full approval  
11 process. So I can't say more about it, but we've  
12 actually spec'd out this idea and developed it  
13 because we see the tension as these measures come  
14 forward to us, and the tension and challenges  
15 that developers have coming to us as well.

16 CO-CHAIR NERENZ: Sean, your tag has  
17 been up for quite a while. And then I've got  
18 Joe.

19 MEMBER O'BRIEN: Yeah. So definitely  
20 a lot of different perspectives and backgrounds.  
21 And I'm looking to change my mind on this, but  
22 Karen raised a good question of: do we all agree



1 that it's important to always require score-level  
2 validity testing?

3 In my case, I would say no. As a  
4 reviewer, the things I want to see are analyses  
5 that address the concerns that come to mind when  
6 I review the measure. And I'm really thinking  
7 about specific things. So in an outcome measure,  
8 it's almost always of interest to be sure of the  
9 differences you might observe not explained by  
10 case mix.

11 There's a measure yesterday looking at  
12 prostate cancer where they're measuring the  
13 intensity of symptoms, or presumably they're  
14 trying get at some type of underlying assessment  
15 of the intensity of symptoms by using three  
16 number claim days that had a diagnosis code, a  
17 particular diagnosis code, and you could say  
18 that's another example where your reporting the  
19 measure could vary from what you're actually  
20 measuring. And there probably is 10 other  
21 examples.

22 So when I want to see empirical

1 analyses, or when specific issues have come to  
2 mind -- and there's some data from the data at  
3 hand that could address that issue -- sometimes  
4 there's issues that come to mind, but the  
5 relevant data are not the data that the measure  
6 developer is collecting and analyzing; they come  
7 from other literature and other sources.

8           So I would just try to prioritize and  
9 make a plug for careful, critical thinking about  
10 where could this measure go astray from the  
11 difference between what it's measuring and wants  
12 to measure, and focusing on those issues.

13           As a developer, I would say when it  
14 comes to filling out the analyses to address that  
15 requirement for score-level validity testing, I'm  
16 often in the position of saying, what will get  
17 the job done and get the box checked here? I've  
18 done all the analyses that I think are important  
19 and are relevant. But now there's still some box  
20 to check off. And I think the box gets checked  
21 off by developers in different ways that don't  
22 always really get at anything too important.

1           So when you're measuring something,  
2           you cannot say, well, here's what we're literally  
3           measuring. But there's one step away from that,  
4           we're trying to get at something else. But even  
5           that is still trying to get at something else.  
6           So for example, if you're measuring something  
7           with claims, claims number, admissions for  
8           such-and-such diagnosis, or we're going to use  
9           claims data, then what about how did that measure  
10          if we had actual clinical data, and say, well,  
11          that's the thing we wanted to measure.

12                 And even that, there could be related  
13          some other underlying measure of quality. So as  
14          a developer, all you can do is pick one step  
15          along the way and provide some analysis showing  
16          that step one is associated with step two.  
17          Check. You're done. But we don't know  
18          necessarily about how you get from step three to  
19          step four, in terms of more and more underlying  
20          extrapolations of more fundamental constructs of  
21          quality.

22                 And then another example where you can

1 get the box checked is if you have a measure  
2 that's not directly measuring anything in  
3 particular, you can demonstrate that it's  
4 associated with some gold standard, then you can  
5 provide that analysis, demonstrate high  
6 correlation, and everyone -- all their review  
7 panels -- is happy.

8 But if your measure that you're  
9 putting forth is that particular gold standard,  
10 and you don't have anything else to compare it  
11 to, now you're stuck. So it seems to me a  
12 contradiction that you could use one measure and  
13 say it's the gold standard and serves to validate  
14 some other measure, but that alone is not going  
15 to stand by itself.

16 So I think there are a lot of  
17 paradoxes and just this requirement to always  
18 require -- it's tough for developers, and I'm not  
19 sure it always provides useful information. And  
20 so I would think about requiring less rather than  
21 more.

22 CO-CHAIR NERENZ: All right. Thank

1 you. Joe and Jack.

2 MEMBER KUNISCH: So speaking to the  
3 eQMs specifically -- but this may apply to all  
4 quality measures -- when you're developing a new  
5 one and you put it out there, or put it up for  
6 endorsement, you did your testing and everything,  
7 so you have limited data. And so you want to  
8 make it kind of provisional and let them go out  
9 and collect more.

10 The challenge with that is healthcare  
11 organizations are inundated in the quality  
12 metrics that they collect and report under  
13 registry, joint commissions, CMS, and so forth.  
14 So there is a reluctance to say, hey, look at  
15 this new measure. Let's adopt it and put it in  
16 our environment and start actually reporting out.  
17 But we're only going to use it internally,  
18 because right now it's not required.

19 The other challenges were dependent on  
20 EHR vendors, especially on the eQMs, to build  
21 these out for us. Now, if they don't do it and  
22 we decide to do it on our own, do we go by the

1 eCQM specifications, or kind of follow it because  
2 we now have to write our own custom queries to  
3 extract this data?

4 So if it does get adopted in CMS, now  
5 we have to go back and use this eCQM, official  
6 NQF version. So there's going to be a lot of  
7 challenges to say, okay, you've got three years  
8 to come back, go out and actually test this,  
9 because you've got to get people to actually  
10 adopt it.

11 And I think even manually abstracting  
12 measures or whatever, now you might get lucky and  
13 it's opioid crisis and we want to measure some of  
14 these things, so we adopt it because it has some  
15 value to us. But in general, I would just say  
16 it's going to be a significant barrier.

17 CO-CHAIR NERENZ: Jack?

18 MEMBER NEEDLEMAN: Yeah. I think as  
19 I process the conversation, I think all of the  
20 requests for the way we score puts a very sharp  
21 line between validation, is it valid, and is it  
22 reliable. And that climbs there. But I think a

1 lot of us have internal definitions of either the  
2 validity or reliability, to begin shading one  
3 into the other. And sometimes it matters, and  
4 sometimes it doesn't. I thinking of some of the  
5 measures we talked about today. So we had, for  
6 example, the CMS and Yale folks coming in with  
7 their opioid --

8 (Off mic comments.)

9 MEMBER NEEDLEMAN: Thank you. ED --  
10 thank you -- overdose. Thank you. So the first  
11 question about validity is do they have the right  
12 codes? Have they captured all the codes? It's a  
13 code-based measure. Have they captured all the  
14 codes? They would capture an overdose. Have  
15 they got any codes in there that aren't overdose?

16 Well, that's a validity issue. It has  
17 nothing to do with the quality of whether the  
18 coding's right. That's a group -- but are the  
19 codes right? That's a validity measure.

20 And then you've got the issue of,  
21 okay, so now we've aggregated this up and we're  
22 calculating it by state or by county or whatever.

1 And if you told me that the question here is,  
2 what's the overdose experience of Medicare  
3 patients, on its face it's a valid measure  
4 because that's exactly what the codes -- the  
5 codes are collected from that population, and  
6 that's who it's being applied to.

7 If you then ask me is it valid as a  
8 population measure and as a whole, then you get  
9 the issue of, can this stand if you had CMS data  
10 only -- the Medicare Part A and B data only --  
11 would you use it as a substitute for a measure of  
12 population rates of overdose, or is it surrogate?  
13 Or is it a proxy for that?

14 And that's a different validity  
15 question. Still about validity questions. And  
16 it gets answered by construct validity. In the  
17 case of the prostate stuff, we're being asked to  
18 assess as a matter of validity, does the number  
19 of claims days you had, is that really a measure  
20 of how dysfunctional you are? As either erectile  
21 dysfunction or incontinence, is that a measure of  
22 dysfunction? And I didn't see a lot of data to



1 discuss that. But that's the validity question.

2           When you get to the reliability  
3 question, now you get to the question, does the  
4 code -- the way the codes are implemented, the  
5 way people code into those codes -- do they  
6 overestimate? Do they underestimate? Is there  
7 systematic difference in that? And that's the  
8 reliability question. Somewhere in there the  
9 risk adjustment question comes. If you're making  
10 comparisons across different groups, is the  
11 comparison accurate? And that is sort of --  
12 sometimes I think of that as validity, and  
13 sometimes I think of that as reliability.

14           But we see things shading one into the  
15 other between is it inherently -- are they  
16 measuring what they think they're measuring if  
17 the measurement is good? And is the data good,  
18 which is the reliability question.

19           CO-CHAIR NERENZ: Yeah. And we're  
20 going to go to Larry and Christie. And I'm just  
21 trying to think how we can respond to that or  
22 resolve that because it sort of starts back with

1 Sean's comment.

2 I mean, somehow as long as these words  
3 are going to be in the common vocabulary between  
4 us and the developers, I think we need to have  
5 definitions and boundaries in saying, when we say  
6 this word, that we mean this and that.

7 I'm not sure -- although somebody can  
8 suggest it -- how to proceed without that kind of  
9 labeling and categorization. I mean I appreciate  
10 the difficulty, particularly when we come from  
11 different disciplinary backgrounds, and we tend  
12 to use words in somewhat different ways.

13 I don't know how to end up in a  
14 workable fashion without just declaring, for  
15 purposes of the work we do and the developers we  
16 do, here's what it is. But I'm open to -- I just  
17 don't know where to take this line.

18 MEMBER NEEDLEMAN: One of the issues,  
19 for me, is whether -- and I find myself looking  
20 at the validity section before I look at the  
21 reliability section, because I understand what --  
22 because the validity is about what the intent of

1 the measure is and how it's going to be -- how  
2 that intent is going to be realized in theory.

3 And the reliability is how good is it  
4 realized in practice, if I agree that they're  
5 measuring what they think they're measuring.

6 CO-CHAIR NERENZ: Okay, good. Larry,  
7 then Christie.

8 MEMBER GLANCE: Yeah. So just for a  
9 minute, I just wanted to bring back the  
10 discussion to the point where it started. And I  
11 think initially we were talking about whether or  
12 not it was enough for a data element to be valid.  
13 And I think we all kind of more or less agreed  
14 that we'd like to see both data element  
15 reliability and data element validity.

16 And then we kind of leapfrogged into  
17 saying, well -- and I sort of pushed this  
18 discussion -- I said I really think that we ought  
19 not to pass or endorse a measure based only on  
20 data reliability and data validity. And I think  
21 we all sort of agreed that we need to have  
22 score-level reliability and score-level validity.

1                   And then I think -- then we  
2                   leapfrogged to saying, okay, so then we should  
3                   basically check all four boxes. So data  
4                   reliability, data validity, score-level  
5                   reliability, and score-level validity. And I'd  
6                   like to respectfully push back on that. Okay? I  
7                   think that -- and this goes back to the issue of  
8                   pipeline in terms of how much we can expect from  
9                   measure developers. I think that we should  
10                  expect from measure developers to see information  
11                  on score-level reliability and score-level  
12                  validity. And the reality is, for the majority  
13                  of the measures that we look at, that's what we  
14                  see.

15                  I think that when you're talking at  
16                  looking at data quality, data reliability, data  
17                  validity, that can be a pretty big ask. If  
18                  you're telling a measure developer, a CMS  
19                  contractor, that you've got to go out there and  
20                  show that the administrative data used to  
21                  construct that model, both for the risk factors  
22                  and the outcome piece, that that -- if you want

1 to go out and show reproducibility, data  
2 reliability, that that may be kind of hard, not  
3 so much for the outcome in question -- although  
4 it may be hard for the outcome if it's a rare  
5 outcome -- but for a lot of the risk factors,  
6 they're pretty uncommon. So to be able to show  
7 reproducibility is hard.

8           Validity becomes even more complicated  
9 because for most of these measures -- the ones  
10 that are claim-based -- what you're doing is you  
11 have these mapping algorithms that take lots and  
12 lots of ICD codes and map them into diagnostic  
13 categories as risk adjusters. So my point being,  
14 without going into spending a lot of time on  
15 this, is that it is fairly resource-intensive, I  
16 think, for measure developers, to look at data  
17 quality, to look at data reliability and data  
18 validity.

19           So I don't know that that should be  
20 part of our -- and it's certainly not part of our  
21 initial ask. But I think that, again, going back  
22 to my initial point, is that for a measure

1 developer just to simply show that the data  
2 quality is high, and then that ought to be enough  
3 for that measure to be endorsed as being  
4 scientifically acceptable, that should not be  
5 acceptable.

6 And I guess if there was one outcome  
7 that I would like to see come out of this group  
8 today, is that we all agree that as a minimum, if  
9 we are going to look at scientific acceptability,  
10 we need to have a pass on both score-level  
11 reliability and score-level validity. And I was  
12 wondering if we could have a vote on that.

13 CO-CHAIR NERENZ: I think that's clear  
14 enough. Now, I just need to do a quick check.  
15 Christie, Sean, and Jen all had boards up. Are  
16 you seeking to speak to this point, or -- okay,  
17 let's go Christie -- I mean, that is a tangible  
18 proposal. It is not where I thought you were  
19 going to go with this, and it's going to take  
20 some discussion probably. But it's a tangible  
21 proposal. So Christie, why don't you say what  
22 you had, and then --

1                   MEMBER TEIGLAND: Yeah. I'm basically  
2 agreeing with that. And I keep coming back to  
3 this measure yesterday that Jack just mentioned,  
4 which was the measure of claims days that had a  
5 visit for incontinence or erectile dysfunction.  
6 And then I totally believe that those claims,  
7 they probably had a visit. I mean, I don't  
8 really need to see data element reliability  
9 there. We could probably do that. But it's  
10 claims data. It is what it is.

11                   I have a huge issue with the fact that  
12 that measure score could mean either thing.  
13 Right? It could mean that this person was too  
14 embarrassed to go to the doctor before the person  
15 got prostate cancer, had no claims for  
16 incontinence of erectile dysfunction. Then when  
17 they had prostate cancer, they had these  
18 conversations with their doctor. The doctor  
19 said, no, we can treat this. This is okay. It's  
20 okay. And then they have like 20 claims. And  
21 you're saying that's a bad thing? That's always  
22 a bad thing?

1           See, if you don't validate that score  
2           as measuring what it's supposed to measure, which  
3           is this person got this bad stuff happened after  
4           this prostate surgery, that is not a valid  
5           measure. We should not be judging people based  
6           on that measure. So -- and I wouldn't  
7           necessarily have to see testing, but I need to  
8           see some theory, I need to see some  
9           justification. I need to see something to tell  
10          me why. They didn't convince me that was a good  
11          measure.

12                   MEMBER TEIGLAND: Right.

13                   MEMBER PERLOFF: I would say on the  
14          flip side, I live and breathe claims data. And I  
15          can tell you every reliability call, it never is  
16          reliable in my book, because I know way, way too  
17          much. The arguments people make are either a  
18          waste of my time because they're wrong and I  
19          don't believe them, or they've gone to extreme  
20          lengths to prove what's already very well known.  
21          So that's not a good investment in my mind.

22                   So I'm concurring from the opposite



1 side of the coin that the item-level reliability  
2 is nothing to me compared to the score level.

3 CO-CHAIR NERENZ: All right, so that  
4 sounds to me a little bit like Larry's, and we're  
5 running out of time in this time block anyway.  
6 But since Larry put a proposal out, let me just  
7 try to restate it and make sure the essence is  
8 correct.

9 MEMBER NUCCIO: I just want to --

10 CO-CHAIR NERENZ: Okay, Gene, go  
11 ahead.

12 MEMBER NUCCIO: Some counter -- point.  
13 I agree that we should look for score level  
14 reliability and validity. I disagree that we  
15 should ignore a data element level reliability  
16 and validity. And I'll give you an example.

17 CMS is the owner, ultimately, of many  
18 of our measures. In its instrument-based  
19 measures, like MDS and OASIS for post-acute care,  
20 they have a great reluctance to ever do any data  
21 element-based testing at the reliability or the  
22 validity level, to the point where they go

1 through multiple generations of these  
2 instruments.

3           And then as we had in our group, we  
4 had reliability data from the late '90s, okay, on  
5 an MDS instrument that has since gone through a  
6 couple generations. And so to make believe that  
7 the score from the most recent data are based on  
8 reliable and valid items is a little bit --  
9 tense. And if CMS understands that they must pay  
10 for data element reliability and validity  
11 information, then, hey, add it to the pot of  
12 money, so.

13           CO-CHAIR NERENZ: All right, so that  
14 seems like there's a kind of a point,  
15 counterpoint here. Dave, you'll sort this out,  
16 right?

17           CO-CHAIR CELLA: Well, I might make it  
18 worse, because, you know, Jen, I don't live and  
19 breathe claims data; I'm more of an observer of  
20 claims data work. But I have begun talking to  
21 more -- more providers. And I hear often about  
22 how bad the current quality measures are. And,

1 you know, I, and they have all kinds of reasons.

2 But I actually think a lot of times it  
3 comes down to the fact that the garbage that goes  
4 in is -- what I'm hearing here from a few is we  
5 have to kind of ignore it. Because we all know  
6 it's bad, and if we pay too much attention to it,  
7 nothing will pass. And there'll be a revolution,  
8 and everything will go away, and NQF will  
9 dissolve, and we don't want that.

10 So I guess, you know, what I'm looking  
11 for is like what's the 20-year plan. I know  
12 we're not the Board of Directors here, but is  
13 there a 20-year plan for getting rid of bad  
14 measures and replacing with good measures?

15 And if so, I would be on the side of  
16 advocating for the quality of the data elements.  
17 Because I think a lot of times what people object  
18 to, and I'm talking more about the, you know, the  
19 clinicians that are judged by it, is that they  
20 know the data quality is not -- you know, you  
21 gave an example, Christie. But there are so many  
22 examples like that.

1                   MEMBER TEIGLAND: Yeah, there are so  
2 many.

3                   CO-CHAIR CELLA: It's not really  
4 measuring what it's trying to measure. And what  
5 I'm hearing here is that some of us are saying we  
6 really should ignore that because if we don't, if  
7 we pay too much attention to it, we're not going  
8 to like anything. So what's the 20-year plan?

9                   MEMBER PERLOFF: First a quick,  
10 friendly amendment. It's not that I want to  
11 ignore it, but there's no one developer that can  
12 solve that problem alone. It is a large,  
13 systemic problem, and we need to take on these  
14 issues of quality in claims data.

15                   But it shouldn't be put on any one  
16 development team alone. And that's why I want to  
17 take it off of them. Not because I want to give  
18 them a pass, that problem has to be resolved  
19 somewhere else.

20                   CO-CHAIR CELLA: So can we fix the  
21 20-year plan with small, with small improvements  
22 here and there? Or does it need a --

1                   MEMBER PERLOFF: But they can't make  
2 small --

3                   CO-CHAIR CELLA: -- wiping off of the  
4 table.

5                   MEMBER PERLOFF: -- improvements in  
6 the whole CMS data processing system, and that's  
7 our challenge.

8                   MEMBER ROMANO: So the one-year plan  
9 --

10                  CO-CHAIR CELLA: I want to hear the  
11 20-year plan first.

12                  CO-CHAIR NERENZ: Okay, let's do that,  
13 and then we'll go to Patrick.

14                  MS. MUNTHALI: So you're not going to  
15 hear the 20-year plan, but you're going to hear  
16 why the Scientific Methods Panel is so important.

17                               And it was important for us to  
18 establish and bring methodologists together,  
19 because we recognize too, our measures, the  
20 measures that come through, you know, sometimes  
21 they're not where we'd like them to be. They're  
22 sometimes not in a place where policy has gone

1 ahead of the science. That's a challenge we  
2 often have sometimes. So we are looking to the  
3 Scientific Methods Panel to help inform what that  
4 plan is.

5 We're already starting to think about  
6 the value of measures that are out there, to  
7 think about measure burden. Trying to learn  
8 about measures. There are so many things outside  
9 of the methodology that we still don't know about  
10 with these measures. And part of it is trying to  
11 get the feedback from the field that we don't get  
12 in the rest of the evaluation of measures.

13 And so we do have an initiative that  
14 was spearheaded by the Board to start to look at  
15 that. So this is part of that, you know,  
16 progressive, why we don't have an answer right  
17 now. We're hoping that we can do this in  
18 collaboration with the Scientific Methods Panel  
19 and the CSAC.

20 CO-CHAIR NERENZ: All right, let's, we  
21 can probably spend a few more minutes, but we do  
22 have to watch our time, especially with people

1 having flights scheduled and whatnot. There are  
2 some update things we have to do.

3 Let's go Patrick, Sean, Sherrie, and  
4 then may just have to nip this off at that point  
5 with a -- because I -- with respect to Larry, I  
6 don't think your proposal is just going to sail  
7 through unopposed, so that means that we'll still  
8 have to keep talking about it.

9 MEMBER GLANCE: Why don't we have a  
10 straw vote?

11 CO-CHAIR NERENZ: No, we can do that;  
12 we can do that. Let's end with that, but I heard  
13 a couple of -- let's just see how it shakes out,  
14 let's see where it goes. Okay.

15 MEMBER ROMANO: I just want to be, I  
16 just want to agree very strongly with what  
17 Christie said, that -- but I also want to observe  
18 that we're collectively interpreting the idea of  
19 a score in two different ways. And so if we're  
20 going to say that we're requiring score level  
21 validity, we need to be clear about what's a  
22 score.

1           Because what Christie described is a  
2           score at the patient level, whereas others talk  
3           about a score at the level of the accountable  
4           entity.

5           CO-CHAIR NERENZ: Yes.

6           MEMBER ROMANO: Now I agree completely  
7           with Christie that the problem with that measure  
8           was that it wasn't clear that it was valid at the  
9           patient level. In other words, the patients that  
10          had this stepped increase in the number of claims  
11          actually had worse erectile dysfunction. So  
12          that's the fundamental validation question there.

13          But when we talk about reliability of  
14          score level, we're talking about reliability of  
15          the accountable entity score. In the case of  
16          validity, I don't care so much about that.

17          Because if this is a valid measure of  
18          a relevant patient-reported outcome or an outcome  
19          that matters to patients, and we have other  
20          evidence that this is an outcome that is  
21          partially preventable or can be improved, then  
22          why do we need to show that it has some construct



1 validity with something else? Because that  
2 becomes a trivial exercise that people show two  
3 variables are correlated with each other, but it  
4 doesn't tell us that either one is valid. They  
5 could both be invalid, and they're both  
6 correlated.

7 (Laughter.)

8 MEMBER ROMANO: So in this case, what  
9 I care about is what Christie said, that's  
10 validity. Now at some point down the line we'd  
11 like to see that provider organizations can  
12 improve these scores, known groups validity,  
13 other kinds of things. But I think I just worry  
14 about applying a single definition of score and  
15 saying that all the measures have to meet score  
16 level validity, when there's really different  
17 ideas of a score.

18 CO-CHAIR NERENZ: Well, let's just not  
19 try to set policy on one word that has two  
20 different meanings. When we say measure score  
21 level in this room, it means, as you just said,  
22 Patrick, it's at the level of the accountable

1       entity. I know Sherrie, all of us who come from  
2       psychometrics struggle with that, because if you  
3       give one patient a survey, that patient gets a  
4       score. But that is not the meaning of the word  
5       that is relevant in this discussion.

6                   And you, Patrick, you said it. When  
7       we say measure score, we're talking about at the  
8       accountable entity. It's 50 patients, it's 100  
9       patients, it's 10,000 plan members, it's whatever  
10      it is. It's an average typically. Okay, so  
11      let's just be careful about the word. Sean and  
12      then Sherrie.

13                   MEMBER O'BRIEN: So ultimately it's  
14      the score level in the sense of measuring the  
15      entity of interest, but it's the score level  
16      reliability and validity you ultimately care  
17      about. And so I think that item level properties  
18      can be subsumed into the score level aspects.

19                   And I think we just heard examples  
20      where item level issues could be an issue for  
21      score level properties. And if those issues for  
22      a specific measure were of interest and were

1 concerns, those should and could be addressed  
2 empirically.

3           And I could give examples of where,  
4 other examples of item level validity issues or  
5 reliability issues impacting score level validity  
6 or reliability. But I'll skip that and say I'm  
7 definitely ready to vote yes on Larry's proposal.  
8 Ultimately, I'd like to maybe make a placeholder  
9 for a possible further proposal.

10           In terms of what is the checklist that  
11 we look at when we're assessing measures, and  
12 right now it's we look at validity, possibly at  
13 two levels, and reliability at two levels. And  
14 is that the most useful for helping us to get  
15 information from us in terms of what's important  
16 to pay attention to and to provide feedback to  
17 measure developers?

18           From my standpoint as it's currently  
19 formed, validity and reliability, it's all kind  
20 of mushy and we might as well just get one big  
21 acceptable. And teasing them out, I don't know  
22 what to make of one versus the other that much.

1       Ultimately, and when I review journal submissions  
2       for -- in the peer review, I'm not categorizing  
3       my thinking -- between reliability and validity.  
4       But there are other types of checklists.

5               So some things that I think could be  
6       a different way of organizing criteria, and this  
7       is something I sent to NQF ten years ago. At the  
8       end of a meeting, we're really too late to bring  
9       it up. But I'll just say here was my list, I  
10      might not have time to go through it all, but  
11      here is my list of checklist.

12             Measure topic, does the measure topic  
13      have a direct and unambiguous relationship with  
14      quality? Two, inclusion/exclusion criteria, the  
15      proposed inclusion/exclusion criteria justify an  
16      appropriate data quality. Are the required data  
17      elements captured consistently, accurately, and  
18      reliably?

19             Did the data -- did clinicians  
20      faithfully capture that and rely on clinical  
21      variables? Case mix suggests -- applicable --  
22      when applicable -- are they risk -- sufficient

1 variables measured with adequate detail or were  
2 there any important risk factors excluded. Were  
3 variables under the provider's influence  
4 appropriately excluded? Has the fit of the model  
5 been demonstrated empirically?

6 Sample size considerations, getting at  
7 reliability, analytic considerations, getting at  
8 missing data and other issues. Reporting issues  
9 in terms of whether uncertainty measures are  
10 presented in technical documentation in terms of  
11 whether it's been specified precisely and  
12 unambiguously.

13 So to me a more concrete, paying  
14 attention to specific concrete issues that could  
15 vary from measure to measure is more helpful for  
16 me. I think that reliability and validity  
17 fundamentally useful constructs, but they're just  
18 too broad to be useful for what we're trying to  
19 do.

20 CO-CHAIR NERENZ: Okay, thanks. I  
21 just at first glance hearing, I sort of like  
22 that, although it's kind of a radical overhaul of

1 what the developers get. But I -- maybe that  
2 could be sent around for further discussion.

3 All right, to close out, Larry, why  
4 don't you clearly state a -- oh, I'm sorry,  
5 Sherrie.

6 MEMBER KAPLAN: Just I wanted to react  
7 to Larry's proposal --

8 CO-CHAIR NERENZ: Okay.

9 MEMBER KAPLAN: Because I think one  
10 size fits none. I think there are circumstances  
11 in which it makes sense to have the data element  
12 and, the way you call it, and score reliability  
13 together, and you have to both. And you've been  
14 in, you know, around for a long time so you have  
15 empirical data, and you should put it out there  
16 for us to look at.

17 And there are circumstances in which  
18 it makes no sense at all. And by the way,  
19 Patrick, you don't get to be stupid about which  
20 construct allocation variable that you use.  
21 Yeah, you could correlate, you know, quality of  
22 life with the number of Kias on the street, you

1 know, but.

2 So the idea that you've got to have  
3 some kind of conceptual basis for doing what  
4 you're doing. And that rationale should be  
5 shared. If you left one of these out, you should  
6 have to tell this group why.

7 And then make a case for, you know,  
8 you got a certain -- certain kinds of measures  
9 need it. You can't just kind of do this  
10 checklist, tick-box thing. There have got to be  
11 categories of measures that should have certain  
12 requirements of them. And I think NQF is going  
13 to have to now be more nuanced about and more --  
14 less kind of all measures have to have this.

15 So, Larry, I think I would vote  
16 against your proposition, only because I think  
17 there are circumstances in which you'd want both,  
18 and there are circumstances in which the  
19 evolution of the measure is so new, and we need  
20 measures in this area, but we'd be willing to  
21 accept less than the score level.

22 CO-CHAIR NERENZ: So, Larry, just so

1 we can do the straw vote, if you can just clearly  
2 state --

3 MEMBER GLANCE: Sure.

4 CO-CHAIR NERENZ: -- that you proposed  
5 we would require X and Y; we would not require P  
6 and Q and so --

7 MEMBER GLANCE: Sure. So currently,  
8 a measure developer can have a measure endorsed  
9 for scientific acceptability if they pass only  
10 the data reliability and data validity piece,  
11 okay. But hold on. So what I would -- I would  
12 put two parts to this, though.

13 The first one is that that is not  
14 enough, okay. Yes, or no, is it -- the question  
15 is is it enough for a measure to be endorsed as  
16 scientifically acceptable if it only passes on  
17 data reliability and data validity. That'd be  
18 the first vote.

19 The second vote, two separate votes,  
20 the second vote would be to replace that, but  
21 they're two votes, would be with the requirement  
22 that a measure can be deemed to be scientifically



1 acceptable if at the score level, as I have  
2 defined it, not as you've defined it, as I have  
3 defined it. If at the score level --

4 CO-CHAIR NERENZ: The group is asked  
5 to work with.

6 MEMBER GLANCE: Exactly.

7 CO-CHAIR NERENZ: The measure score at  
8 the accountable entity.

9 MEMBER GLANCE: Yes, exactly. It is  
10 both reliable and valid, okay. So those are the  
11 two questions on the table.

12 CO-CHAIR NERENZ: All right, I think  
13 we might have done the first one already, but why  
14 don't you -- so the first one is would people  
15 agree that passing data element reliability and  
16 validity only is not acceptable?

17 There's a funny void down at that end  
18 of the table. I take that to be -- okay, people  
19 don't disagree. We've got maybe three-quarters  
20 of the hands up, three-quarters, 80 percent. But  
21 not all.

22 All right, so the second, it seems to

1 essentially flip it. Is says now if you have  
2 measure score reliability and validity, you can  
3 pass. Who would support that? This is more  
4 looking like half, a little under. Okay, so as  
5 usual we --

6 (Laughter.)

7 PARTICIPANT: Consensus not.

8 (Laughter.)

9 CO-CHAIR NERENZ: No, but I -- we do  
10 need to close this out. I think that this has  
11 been useful discussion because we just need to  
12 keep to plugging away at this because we have  
13 concerns and objections about what goes on. We  
14 don't want to make the measure development  
15 pipeline so tough and so impossible that nothing  
16 comes through, but also I like this term release  
17 into the wild. You've got CMS particularly  
18 moving millions and millions of dollars around  
19 into here and away from there based on measures  
20 that may have some pretty weak properties. So  
21 it's balancing that that's the issue. We don't  
22 have the whole full view of the balancing, but we

1 play a role. So maybe to be continued. But I --

2 MEMBER O'BRIEN: Can I say something  
3 real quick: You mentioned something about the  
4 burden to developers. When I voted yes -- and I  
5 was listening to the wording that Larry put forth  
6 and I thought about asking this. I think  
7 measures should and could qualify for endorsement  
8 if they were deemed to be valid at the score  
9 level and reliable score level. I didn't say if  
10 they had empirical analyses demonstrating those.  
11 I think that a review assesses it and then  
12 convince a group of people to think about it  
13 carefully, that's good enough. And it might  
14 require the empirical analyses, but I don't think  
15 that's always going to be necessary for me.

16 MS. JOHNSON: Can I get one more just  
17 straw vote? What if we modified Larry's thing  
18 and said do you guys believe we should ask our  
19 CSAC to bless our changing requirements so that  
20 we require score-level reliability? I'm not  
21 saying anything about anything else, but right  
22 now we don't always require score-level

1 reliability. I just want to know if that -- if  
2 you -- right now I've got a thing and I've got a  
3 check mark there that I thought that's what I  
4 heard you say, but I don't know that -- I don't  
5 know --

6 (Simultaneous speaking.)

7 MEMBER ROMANO: Can I ask a question  
8 to clarify?

9 MS. JOHNSON: Yes.

10 MEMBER ROMANO: So in the first  
11 submission under this proposal --

12 MS. JOHNSON: Right.

13 MEMBER ROMANO: -- would it be  
14 adequate to simulate score-level reliability? In  
15 other words, knowing the distribution of how many  
16 patients would be eligible across accountable  
17 entities and how many accountable entities there  
18 are, developers could simulate what they would  
19 think that the score-level reliability would be  
20 before they've actually collected multi-site  
21 data.

22 MEMBER KAPLAN: What if you added

1 unless you can find a compelling reason for not  
2 --

3 MS. JOHNSON: We could add that.

4 CO-CHAIR NERENZ: So it's kind of  
5 where we have now with the social risk-adjustment  
6 that we essentially ask for it except if you can  
7 convince us you don't need to do it. Then you  
8 can go through. So it could be structured  
9 similar to that.

10 MEMBER NEEDLEMAN: I'm going to  
11 suggest that when this gets to the next committee  
12 which actually will set the policy, there will be  
13 a lot of pushback, some of which we've already  
14 heard in this room. So I think it's perfectly  
15 reasonable for the Scientific Methods Committee  
16 to be a little bit more aggressive in pushing for  
17 the highest level of reliability and validity  
18 that we think is useful for assessing measures  
19 and let the committee tell us, no, you're going  
20 to have to settle for a lower level because  
21 that's not practical and not consistent with the  
22 broad measure development process.

1                   And in that spirit I'm going to  
2                   probably lean to voting yes, but even though I've  
3                   got real mixed feelings about it. Especially if  
4                   there could be -- revive some concept of  
5                   provisional endorsement or temporary endorsement,  
6                   because that's the key step is getting the data  
7                   from multiple sites to assess score-level  
8                   reliability. If you can't simulate it, how are  
9                   you going to do it? So there has to be some  
10                  preliminary mechanism. All these medical schools  
11                  are getting provisionally accredited.

12                  (Laughter.)

13                  MEMBER NEEDLEMAN: They're popping up  
14                  all over the place.

15                  (Laughter.)

16                  CO-CHAIR NERENZ: Matt and then we're  
17                  truly running out of time. We do have some  
18                  updates to do.

19                  MEMBER AUSTIN: I want to maybe just  
20                  go on record as -- I think what Sherrie was  
21                  offering I'd maybe want to echo that. I like the  
22                  idea of maybe having the expectation that they

1 need to provide all four unless they can explain  
2 why that could not be done. All right? So in  
3 Patrick's example for some reason they didn't  
4 have the testing where they could do score-level  
5 reliability testing, then they would need to  
6 explain something. Maybe that they would expect  
7 to have that in the next numbers of years.

8           So I kind of like the idea of  
9 communicating that all four is what would be sort  
10 of appropriate, but then getting them sort of  
11 ways -- sort of what we do a little bit with the  
12 empirical validity testing for maintenance  
13 measures, right? There's the expectation that  
14 they'll do that unless they explain that they  
15 couldn't do that.

16           MS. JOHNSON: And the only thing that  
17 I'll give you on that, Matt, is the way all of  
18 our stuff is written we already have that  
19 expectation, right, and people don't do it for  
20 us. So what we're talking about is are we  
21 actually saying that if you don't come in, we  
22 don't even look at it, right? Or maybe with

1 Sherrie's thing.

2 So it sounds to me like score-level  
3 validity is still a little bit in the testing,  
4 might still be a little bit off. And we  
5 certainly haven't figured out the data element.  
6 Validity, we have to have it, whatever. Final  
7 score-level reliability. Would you be in favor  
8 of us trying to get that as a requirement  
9 regardless of whether it's new or maintenance of  
10 whatever? Again, CSAC can push back at some  
11 point.

12 MEMBER KAPLAN: If you added the  
13 unless the -- could you do the conditional thing?  
14 Unless you provide a really compelling case for  
15 not doing it?

16 MS. JOHNSON: Okay. We'll add that.  
17 Is everybody --

18 MEMBER HYDER: The concern is if it's  
19 a requirement, then it gives this committee less  
20 flexibility to do what they may think is  
21 reasonable, to Sean's point about his own  
22 checklist. If it's a requirement we lose the



1 flexibility there.

2 MS. JOHNSON: Potentially.

3 MEMBER FABIAN: Right. That was my  
4 clarification is if we had it in there now that  
5 we'd really like to see it, then you're not going  
6 to get dinged if you don't have it. That's  
7 different than we'd like to see it and if you  
8 don't have it, you need to have a compelling  
9 justification. And I would support that. I  
10 think that --

11 (Simultaneous speaking.)

12 MS. JOHNSON: Okay. Let's let Larry  
13 be the last because we really want to tell you  
14 about this really interesting project that we've  
15 got going on. Poor Nicolette is ready to tell  
16 you. So --

17 (Laughter.)

18 CO-CHAIR NERENZ: Well, we really have  
19 to move on into the updates. Unless, Larry, you  
20 know that what you say is going to bring this to  
21 closure, let's -- I mean, this is --

22 (Laughter.)

1 (Simultaneous speaking.)

2 PARTICIPANT: Do we get to vote? I  
3 thought we --

4 MEMBER GLANCE: Give me 30 seconds.

5 I think we can vote for what Karen proposed. And  
6 I think it -- I mean honestly, if we've all  
7 decided as a group that it's not enough to have  
8 data reliability and data validity, then the next  
9 step has to be we have to add something. So  
10 that's what we're talking about doing right now.

11 CO-CHAIR NERENZ: Yes. Yes, okay.

12 MS. JOHNSON: All right. Show of  
13 hands?

14 MEMBER O'BRIEN: Did we vote yes? I  
15 know it was 50/50, but that initial question just  
16 about reliability, I mean before everyone in the  
17 room except a couple people raised their hand, so  
18 I hope that doesn't get lost, but there at one  
19 point was a motion yes, we think --

20 MS. JOHNSON: That's what I thought,  
21 yes.

22 MEMBER O'BRIEN: -- score-level

1 reliability is important.

2 MS. JOHNSON: Yes.

3 CO-CHAIR NERENZ: Yes. And now the  
4 same question, score-level reliability.

5 MS. JOHNSON: Yes, score-level  
6 reliability with -- it's an expectation and if  
7 you don't do it, we want to see a good  
8 explanation as to why.

9 MS. WILBON: Of -- no, requirement,  
10 not expectation.

11 MS. JOHNSON: No --

12 MS. WILBON: Requirement, right?

13 MS. JOHNSON: Requirement, but  
14 potentially an --

15 MS. WILBON: Yes.

16 MS. JOHNSON: -- out.

17 MS. WILBON: Okay.

18 MS. JOHNSON: Reliability.

19 MEMBER ROMANO: Or potentially that  
20 there could be a provisional endorsement.

21 MS. JOHNSON: We're not going to  
22 condition endorsement.

1 MEMBER ROMANO: Not going --

2 MS. JOHNSON: That's not on the table,  
3 no.

4 MEMBER GLANCE: But if you allow  
5 measure developers to say but we don't think it's  
6 important we solve for SES, 90 percent of the  
7 measure developers don't include SES. I think we  
8 should require score-level reliability. Let's  
9 take a vote on that.

10 MS. JOHNSON: Let's take a -- require  
11 score-level reliability. Let's put that on there  
12 as that's worst -- that's hard-earned, Sherrie.  
13 Let's see if anybody even goes there. Require  
14 score-level reliability. Show of hands.

15 (Voting.)

16 MS. JOHNSON: Okay. And then Sherrie  
17 would be -- you would have yes if we had put the  
18 expectation in -- thing in there?

19 MEMBER KAPLAN: I would, yes.

20 MS. JOHNSON: Okay.

21 MEMBER KAPLAN: But it would have to  
22 be a requirement for a really compelling case.

1 MS. JOHNSON: It would have to be  
2 really compelling.

3 MEMBER KAPLAN: It wouldn't be like,  
4 oh, well, we don't drop dead to the --

5 (Simultaneous speaking.)

6 MS. JOHNSON: I didn't have time?

7 MEMBER KAPLAN: Yes.

8 PARTICIPANT: So it's required unless  
9 it's not? Is that the --

10 (Laughter.)

11 MS. JOHNSON: And that's our  
12 conundrum.

13 MEMBER GLANCE: Karen?

14 MS. JOHNSON: Yes?

15 MEMBER GLANCE: Could we have one more  
16 question? Score-level validity?

17 MS. JOHNSON: Score-level validity.  
18 Before we were doing it with an and. Now we're  
19 doing it separate.

20 MEMBER GLANCE: But we've already  
21 agreed that we're going to do score-level  
22 reliability.

1 (Laughter.)

2 MEMBER GLANCE: This is like Brexit.

3 (Laughter.)

4 MEMBER GLANCE: One more vote.

5 MEMBER O'BRIEN: Larry, are you saying  
6 score-level reliability or score-level validity  
7 testing?

8 MEMBER GLANCE: Score-level validity  
9 testing, yes. Up or down?

10 (Laughter.)

11 MS. JOHNSON: All right. Score-level  
12 validity testing. Should we require it?

13 (Voting.)

14 MS. JOHNSON: Okay. It's about the  
15 same as it was before. Okay.

16 Score-level validity testing with an  
17 exception of Sherrie's wording?

18 (Voting.)

19 MS. JOHNSON: Got a little higher.  
20 Okay. But not unanimous. Okay.

21 MEMBER O'BRIEN: My score-level  
22 validity and my hand is up. It's just that I

1 think we should vote that -- I mean, as review we  
2 said yes, we're convinced it's valid.

3 MS. JOHNSON: Right.

4 MEMBER O'BRIEN: And the empirical  
5 analyses might be part of what contributed to  
6 that.

7 MS. JOHNSON: Got it. Okay. Thank  
8 you, guys.

9 Nicolette, do you feel like telling us  
10 about --

11 (Simultaneous speaking.)

12 MS. WILBON: Karen, is there enough  
13 time to actually make it worthwhile? I don't  
14 know that it's actually -- 10 minutes, by the  
15 time she gets into it and we have next steps and  
16 stuff at 2:30. It's --

17 MS. JOHNSON: You don't think there's  
18 10 minutes with -- you can tell them about the  
19 project? You don't have to go into detail.

20 MS. MEHAS: Whatever -- I mean  
21 whatever you all prefer.

22 MS. WILBON: I don't know that it's

1 really --

2 MS. JOHNSON: You don't think it's  
3 worth it?

4 MS. WILBON: No.

5 MS. JOHNSON: Okay.

6 MS. WILBON: Honestly.

7 MS. JOHNSON: All right. We're doing  
8 some real neat stuff.

9 (Laughter.)

10 MS. JOHNSON: I will tell you that  
11 it's trying to go beyond thinking about the  
12 individual measures and thinking about how you  
13 group measures and how you use grouped measures  
14 and programs and how you might want to --

15 (Off mic comment.)

16 MS. JOHNSON: Yes. So it's really  
17 exciting, yes.

18 PARTICIPANT: Is that some of the  
19 score-level type stuff that sort of overlaps with  
20 some of this?

21 MS. JOHNSON: It totally overlaps.  
22 And I think some of the genesis of this was



1 something that happened -- I don't remember who  
2 did it, but we were talking about reliability at  
3 the score level and we were talking about how  
4 does that work if you're -- if it's being used in  
5 different ways and different programs, right? So  
6 you have this risk of misclassification and --  
7 but what if you're using a threshold versus  
8 you're pulling based on say the top quartile, or  
9 something like that? And does reliability feel  
10 different depending on how penalties are applied,  
11 right? That was kind of the germ of the idea and  
12 it has gone since this. It's really kind of  
13 interesting stuff.

14 So we'll tell you about it -- maybe  
15 that will -- maybe we'll just tell you about it  
16 on one of our monthly calls. We might want to do  
17 that because I think you'd really enjoy hearing  
18 about it.

19 Okay. All right. What's next?  
20 Public comments?

21 CO-CHAIR NERENZ: No, we're -- there  
22 is no public comment.

1 MS. WILBON: Public comment and then  
2 just next steps. We have our monthly call in  
3 December.

4 CO-CHAIR NERENZ: While you're --  
5 there was a request just for a quick update on  
6 the white papers.

7 Larry, the one that you led, just  
8 quick 10 seconds where it is?

9 MEMBER GLANCE: Sure. So our white  
10 paper has been accepted by Annals of Surgery. It  
11 is in press. It was reviewed by CMS and approved  
12 by CMS. Thank you, everybody, for all your help.

13 (Applause.)

14 CO-CHAIR NERENZ: The internal white  
15 paper was also completely written contribution,  
16 evaluator submit. We learned about the CMS  
17 review process. It is still to my knowledge hung  
18 up in there as it went in there early May. It  
19 may never emerge.

20 (Laughter.)

21 CO-CHAIR NERENZ: I'm serious. I have  
22 no idea. I have no idea what's going on.

1 MS. JOHNSON: It -- yes, so it is  
2 still in the clearance process. So the other day  
3 when Larry's came out, I got an email that said  
4 congratulations, it's out of clearance. So I  
5 expect that kind of email hopefully.

6 CO-CHAIR NERENZ: Like I say, there's  
7 a -- there is --

8 MEMBER GLANCE: David, I just made a  
9 little contribution to CMS and it's --

10 (Laughter.)

11 MEMBER GLANCE: Then I -- it was a  
12 little tweet accompanied by --

13 (Laughter.)

14 CO-CHAIR NERENZ: Be nice. No,  
15 there's a third white paper that Sherrie and I  
16 have been working on through the outline and  
17 first draft stage that I guess I'll just say is  
18 flat out dead in the water in my view because of  
19 the CMS review process, because we can go  
20 through, put a ton of work in this and it could  
21 go to CMS and die. And I will not commit to the  
22 work until I understand its process. It's just

1 -- makes no sense.

2 PARTICIPANT: What's the topic?

3 CO-CHAIR NERENZ: Reliability  
4 standards. And the problem is that in this paper  
5 we may take issue even in passing mention with  
6 certain CMS current policies, and if we do that,  
7 they'll probably kill it. And then we will have  
8 done all the work for nothing. So it's an utter  
9 impediment to writing these white papers. But  
10 that's where we are.

11 PARTICIPANT: Unless we're academics  
12 in which case we let them --

13 CO-CHAIR NERENZ: No, as individuals  
14 we can write whatever we want, but then it  
15 doesn't speak for the group.

16 MEMBER PERLOFF: But there's a backup  
17 plan that a group of folks in their academic  
18 worlds could write a paper that informs the field  
19 if -- as a worst case scenario --

20 MEMBER KAPLAN: But it doesn't carry  
21 the --

22 (Simultaneous speaking.)

1 CO-CHAIR NERENZ: No, any of us can do  
2 that, but the idea when this started now a  
3 year-and-a-half ago or so was that the group  
4 would speak in these papers. And in fact the  
5 authorship would be set up so the core writing  
6 group would be named, but then there would be a  
7 list at the end, essentially everybody. And in  
8 fact PubMed would pick everybody up as an author  
9 because it would speak for the group. And I  
10 think everybody liked that idea, but when we  
11 started down that path we had no idea that CMS  
12 review is part of the process.

13 MEMBER PERLOFF: But it could still be  
14 valuable to the field, just saying. Like  
15 thinking of John Adams' paper, we all see it --

16 (Simultaneous speaking.)

17 CO-CHAIR NERENZ: Oh, sure. And  
18 that's true. It's just a different --

19 MEMBER PERLOFF: Yes.

20 CO-CHAIR NERENZ: -- approach.

21 MEMBER PERLOFF: Right.

22 MS. JOHNSON: Okay. I don't think we

1 have to do the public commenting period, so let's  
2 just tell you about our next steps and let you  
3 guys go. We're -- well, it will take four  
4 minutes to do next steps, so we'll be right on  
5 time.

6 MS. WILBON: So next steps. Basically  
7 at this point you guys have done a great job over  
8 the last two days, so thank you.

9 The main thing that we'll just let you  
10 know is that we have our next kind of bimonthly  
11 call on December 12th, which is a Thursday. It's  
12 a -- it will be a two-hour call. We'll kind of  
13 sit down and look at our notes from this meeting  
14 and bring back some of the core methodological  
15 issues. Maybe just pick one to see if we can get  
16 through it and make some decisions.

17 I know that we are hoping to put forth  
18 potentially a set of recommendations for the  
19 criteria for CSAC in the spring, so we'll  
20 probably use the next set of calls with you guys  
21 to start working through what those  
22 recommendations would be so that we can have kind

1 of a cohesive set of kind of guidance or  
2 recommendations that we'd like to put forth and  
3 figure out kind of when that would be implemented  
4 if it's approved by CSAC.

5 So that's our next kind of hurdle to  
6 cross is to put forth that guidance so that we  
7 can kind of get things cemented in our criteria  
8 and in our guidance so that developers can start  
9 to adjust and start submitting things that is  
10 more in alignment with what you guys would like  
11 to see.

12 MS. JOHNSON: And we also have a few  
13 other next steps just in case you're curious.  
14 Starting next week -- no, the end of this week,  
15 somewhere in there, developers will be sending to  
16 NQF the remainders of their submission forms. So  
17 this is not things that you see, but if you  
18 wondered where's the evidence form, where's the  
19 feasibility stuff, they're sending that in the  
20 next couple weeks. And that's stuff that will be  
21 going to the standing committees.

22 We've already been summarizing the

1 information and your discussions. And this is  
2 stuff that will go to the standing committees.  
3 So it won't be exactly a cut and paste of the  
4 discussion guide, but it will look very similar.  
5 And that's the kind of stuff we will be telling  
6 the standing committees.

7 The measure evaluations by the  
8 standing committees, somewhere in January-  
9 February, depending on the topic, CSAC in June.  
10 So it's still kind of a long process. So things  
11 that you've done today and yesterday we won't  
12 know the final disposition until a few months  
13 down the road, but we will try to come back and  
14 let you know so that we close that loop for you.

15 And then again, the next intent to  
16 submit deadline, which means the next bolus of  
17 specifications and testing attachments, due  
18 January 5th. So that means that we'll be  
19 probably sending assignments to you guys for the  
20 next round probably early February. I think  
21 that's what our time frame is.

22 So with that I hope you have a great



1 holiday.

2 (Laughter.)

3 MS. JOHNSON: Enjoy not doing any  
4 evaluations and we'll catch you after the  
5 beginning of the year. Thank you guys so much  
6 for coming. I so much enjoy these discussions  
7 and I know it's a lot of effort on your part, and  
8 we really appreciate it. Thank you.

9 CO-CHAIR NERENZ: Karen, your boss has  
10 left, but please communicate just how  
11 appreciative the committee is on the quality of  
12 the staff work that has been done.

13 MS. WILBON: And the --

14 CO-CHAIR NERENZ: I feel incredibly  
15 well-supported in this process.

16 MS. WILBON: And the two Chairs.

17 MS. JOHNSON: And our Chairs.

18 (Applause.)

19 CO-CHAIR NERENZ: Thanks everyone.

20 Safe travels.

21 (Whereupon, the above-entitled matter  
22 went off the record at 2:30 p.m.)

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