

NATIONAL QUALITY FORUM

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PULMONARY AND CRITICAL CARE
STANDING COMMITTEE

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WEDNESDAY
MARCH 16, 2016

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The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:00 a.m., Dale Bratzler and David Lang, Co-Chairs, presiding.

PRESENT:

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Chief Medical Officer, Merck and Co., Inc.

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KAREN JOHNSON, MS, Senior Director *

ROBYN Y. NISHIMI, PhD, Consultant

ALSO PRESENT:

SUSANNAH BERNHEIM, MD, MHS, Yale University
School of Medicine,

SHERYL M. DAVIES, MA, Stanford University *

FRANCOIS DE BRANTES, MS, MBA, Health Care
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AMITA RASTOGI, MD, MHA, Health Care Incentives
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MATT SCANLON, MD, Virtual PICU Systems, LLC *

JONATHAN SHAW, MD, MS, Stanford University *

CAROL STOCKS, PhD, MHSA, RN, Agency for
Healthcare Research and Quality *

ANDREW WILSON, MPH, MA, Health Care Incentives

Improvement Institute *

* present by teleconference

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

2 8:05 a.m.

3 DR. NISHIMI: In the meantime, let me
4 go over what happened on day one just to refresh
5 the committee's memory.

6 We had one, two -- 11 measures
7 yesterday. Two of the measures, the Minnesota
8 Community Health measure and Dr. Kleinman's rate
9 measure, not the appropriateness measure, rate
10 measure were consensus not reached.

11 So, those two measures, well, all the
12 measures go out for public comment. But, those
13 two measures in particular we'll pay special
14 attention to the comments and then you will
15 review them and we vote because consensus was not
16 reached.

17 And then, they'll either go forward to
18 the NQF members for a vote as recommended, not
19 recommended or, if you still don't reach
20 consensus, they're marked consensus not reached.

21 For one measure, Larry Kleinman's ED
22 Appropriate Asthma measure, that measure did not

1 advance, was not recommended. It still goes out
2 for comment.

3 The committee may choose, you know,
4 based on, if there's a groundswell of positive
5 comments or something, may choose to take it up
6 and discuss it again.

7 But, by and large, those measures tend
8 not to come back for further committee
9 discussion.

10 So, this is the report that Poonam
11 spoke to yesterday, goes out for NQF member and
12 public comment for 30 days, comes back.

13 The staff -- we all compile the
14 comments, proposed response for you to look at.
15 Some of them are just thanking you for your work.
16 You know, some of them are agreeing with you.

17 And then, there will be some where you
18 might need to discuss or the developer will need
19 to address.

20 So, that was yesterday's work. And
21 then, today's work, we'll do the balance.

22 As I indicated yesterday, we do hard

1 stop and if it looks like we can't even finish
2 the measure by this stopping time, obviously, we
3 won't start it.

4 If we don't finish all the measures
5 today, excuse me, hay fever here, we don't finish
6 all the measures today, then we have the post-
7 comment, not post-comment, the post-meeting call
8 set for next week for us to finish the balance of
9 those.

10 We do have electronic software so, you
11 know, we vote. It's probably easier than the
12 little waving of the wands anyway. So, but
13 that's what will happen if we don't finish.

14 So, I don't want you to worry about,
15 you know, us running over. We're cognizant that
16 folks have time and so we allow for that.

17 Anything else, Poonam, Shaconna?

18 Okay, we're waiting for AHRQ and we'll
19 just have to launch if, obviously, she can't get
20 a hold of her. She'll have to take over.

21 Operator, is she back, Sheryl and
22 Carol?

1 OPERATOR: Carol has just joined.

2 DR. NISHIMI: Okay, great.

3 DR. STOCKS: Hi, this is Carol Stocks.

4 CO-CHAIR LANG: Very good. So, we

5 will --

6 DR. STOCKS: My apologies.

7 CO-CHAIR LANG: Thank you.

8 We will proceed with discussion of
9 three measures this morning which are population
10 health measures pertaining to asthma, COPD and
11 pneumonia, respectively.

12 The first, our leadoff hitter for this
13 morning is 0283: Asthma in Younger Adults
14 Admission Rate. Developer is the Agency for
15 Healthcare Research and Quality.

16 Carol, would you like to briefly
17 discuss the measure, briefly for about two
18 minutes?

19 DR. STOCKS: Sure, thank you for
20 giving me a couple minutes. I'm sorry, I was a
21 little late. I was confused about the time.

22 Work that our program does involves

1 the maintenance of about 100 different
2 indicators. And, by that, I mean the continual
3 process of gathering evidence and getting input
4 from clinicians and empirical testing. Most of
5 the heavy lifting is done by our contractors.

6 And, Sheryl Davies is on the phone,
7 she'll be available to answer more technical
8 questions. She's at Stanford University, our
9 primary contractor.

10 In addition to the validation and
11 gathering evidence, we create software that can
12 be applied to user's data so that they can more
13 easily use the exact specifications for these
14 types of measures.

15 The three measures being reviewed
16 today we call the Prevention Quality Indicators,
17 the PQIs and they've been developed for use with
18 hospital administrative data or billing data type
19 of information that's readily available and
20 routinely created for every patient encounter.

21 The data have been created in
22 electronic format for decades. So, they offer an

1 important reliable source of information on
2 certain aspects of hospital care.

3 The PQI measures are a little bit
4 different from other measures that we have and
5 maybe others that are reviewed for the most part
6 at NQF because they take advantage of inpatient
7 hospital data, not to measure quality of
8 inpatient care but to gain insight into health of
9 the community.

10 So, we view it as a window into the
11 community, one way to look at it. In some
12 respects, what goes on in community hospitals
13 could be seen as a microcosm of what's going on
14 in the community.

15 So, the PQIs can be used as a
16 screening tool to help flag potential healthcare
17 quality problem areas at the population level and
18 that need further investigation.

19 They're based on evidence that
20 hospitalizations for ambulatory care sensitive
21 conditions are potentially preventable given
22 adequate outpatient care.

1 We believe that there is significant
2 room for improvement in this area based on --
3 mainly based on the persistent disparities that
4 we have seen for years now. And, most
5 frequently, those disparities or higher rates are
6 seen in populations that can be described as
7 disadvantaged or vulnerable.

8 The idea behind these measures is not
9 to close the hospital doors or, likewise, the
10 PQIs are not modeled to measure whether
11 appropriate decisions are being made about to
12 admit or not to admit.

13 In this day and age, we -- I guess we
14 assume that under the types of pressures faced by
15 hospitals and physicians, we believe there's a
16 pretty high probability that when individuals are
17 admitted to the hospital, they need to be there.

18 So, the notion behind PQIs is that
19 appropriate quality healthcare in the outpatient
20 or community setting can prevent the need to be
21 hospitalized.

22 Appropriate care is still centered on

1 primary care in the case of some of these
2 pulmonary indicators, have specialty care is
3 playing a very important role as well.

4 But, over the years, I think our
5 understanding of what is being measured through
6 use of ACSC hospitalization rates has become a
7 little broader.

8 And, in essence, depending on how you
9 use them, the PQIs are measuring the quality of
10 the local healthcare system. And that
11 encompasses many things to achieve the management
12 of the population's health needs.

13 To put it another way, we're measuring
14 whether the healthcare system is adequate or has
15 the capacity for meeting population health needs.

16 We do include age and gender as risk
17 adjustment factors when comparing counties or
18 other regions.

19 And, in the more recent software
20 that's being released this spring, we've added
21 percent of persons living in poverty. However,
22 depending on how you're using these measures, the

1 idea of risk adjustment goes a little bit against
2 the concept of what the PQIs are measuring.

3 And, by that, I mean ideally a
4 healthcare system should be able to meet
5 population needs, whether those needs are greater
6 or not.

7 So, I'm going to stop right there. I
8 don't want to take up any more time.

9 Thank you very much for letting me
10 introduce them.

11 CO-CHAIR LANG: Thank you, Carol.

12 We have Bruno and Susan with us also.

13 DR. POLLART: I am, yes.

14 CO-CHAIR LANG: Great, thank you,
15 Susan.

16 DR. POLLART: Sure. Just a note, I'm
17 on the webinar but I'm not seeing any slides and
18 I'm not sure you're going to be able to see my
19 vote.

20 So I have notes, I can participate
21 without seeing the slides, but if my votes don't
22 show up, I think it's an issue with the webinar.

1 MS. BAL: Susan, can you go ahead and
2 just email Poonam. That's P-B-A-
3 L@qualityforum.org with your vote so we can make
4 sure we get those in?

5 Also, if you want to try to refresh
6 your screen, that sometimes relieves that issue.

7 And then, also, before we start, I
8 just wanted to mention that for all three of the
9 AHRQ measures, Mitch Harris is conflicted so he
10 will not be able to vote or discuss these
11 measures.

12 Thank you.

13 DR. POLLART: All right. All right,
14 I've refreshed my screen and nothing's changed.
15 But, I will send my vote.

16 MS. BAL: Thank you.

17 DR. DIGIOVINE: Susan, are you going
18 to start or do you want me to start?

19 DR. POLLART: Yes, I am absolutely --
20 I'm happy to start.

21 So, as was mentioned, this is an
22 outcome measure type, looking at administrative

1 claims, the level of analysis is population
2 through your county.

3 First question is, looking at the
4 evidence and the question for the group is,
5 there's some updated evidence provided related to
6 aspects of hospitalization for pneumonia.

7 But I think our group agreed on our
8 phone call that the underlying rationale for the
9 measure remained reasonable and there was no
10 evidence to repeat discussion or vote on
11 evidence.

12 So, unless there's disagreement, can
13 we move on to gaps in care?

14 DR. NISHIMI: Let's first -- yes --
15 let's just hear from the committee if --

16 CO-CHAIR LANG: Yes, and that -- so,
17 the -- I don't -- before we get to that, just the
18 only issue I have, and I have no one else to
19 bring it up, so I'll bring up now.

20 Is just the age, we've gone running
21 around now. I think we have three asthma
22 measures with three different ages. It certainly

1 would be nice to have asthma measures all have
2 the same age range.

3 DR. NISHIMI: Okay, so --

4 DR. POLLART: Age range here is for
5 discharges for patients 18 and older.

6 DR. NISHIMI: Right. So --

7 CO-CHAIR LANG: It's 18 to 39, it's
8 not 18 and over. At least that's the data that's
9 in front of me.

10 DR. POLLART: The numerator statement
11 I see says 18 and older. Is there new
12 information?

13 CO-CHAIR LANG: Are we looking at
14 0283?

15 DR. POLLART: No, you're right, I'm
16 sorry. I picked up the wrong one. I'm looking
17 at -- that was 0279.

18 DR. NISHIMI: Okay, so --

19 DR. POLLART: Yes, 18 to 39.

20 DR. NISHIMI: We'll emphasize that,
21 mention it again when we hit the specifications,
22 but Bruno, was there anything on evidence you

1 needed to add?

2 DR. DIGIOVINE: No, I agree with
3 Susan. I don't think we need to review it, but
4 leave it to the committee.

5 DR. POLLART: All right.

6 DR. NISHIMI: Does anyone object?
7 Okay.

8 DR. POLLART: All right. So, we're
9 ready to move on in gap in care?

10 Our group discussed the question of
11 whether there was opportunity for improvement and
12 looked like there was data around gap in care,
13 especially as it related to disparities.

14 And, it was looked at from 2009 to
15 2013. And, it appears there were gaps in care.
16 And also, there's some gaps related to community
17 income level.

18 So, our sense was there was
19 opportunity for improvement.

20 CO-CHAIR LANG: Great.

21 DR. DIGIOVINE: Nothing to add.

22 CO-CHAIR LANG: Okay, proceed.

1 DR. POLLART: All right. Bruno, do
2 you want to move on to the next section on --

3 DR. DIGIOVINE: I think we have to
4 vote here, Susan. That's okay, thanks.

5 DR. POLLART: Oh, I'm sorry.

6 CO-CHAIR LANG: It's hard when you're
7 not in the room.

8 DR. POLLART: Yes.

9 CO-CHAIR LANG: I think Jim had a
10 question, though.

11 DR. O'BRIEN: Yes. The question I had
12 I guess is for the developers.

13 I noticed in Table 1 that now we have
14 an average rate of .28 which is now cut in half
15 relative to where it was 2009.

16 At what point do the developers feel
17 like this measure's going to be topped out?

18 DR. STOCKS: I think I'm going to let
19 Sheryl Davies at Stanford answer that.

20 MS. DAVIES: Sure.

21 So, the measure, it's off, you're
22 right. And, in fact, hospitalizations in general

1 have been decreasing over time.

2 One thing that we look at here,
3 instead of just the overall population is we look
4 at variation in hospitalization rates. Because
5 we're looking at population healthcare, we do
6 take into account issues such as disease
7 prevalence or other community health factors that
8 do impact the measures.

9 Those are part of the measure concept
10 that we're measuring.

11 And so, as long as there are
12 disparities that are visible, as there, you know,
13 still are with low income populations.

14 And, our data and certainly, you know,
15 in the literature, we continue to observe
16 disparities with certain minority groups.

17 I would say that we're not there yet.

18 DR. O'BRIEN: Thank you.

19 And then, also, just to clarify,
20 because I think there's a lot of -- it appears to
21 be that some of the analysis for this measure
22 crosses over 275.

1 It, I assume, but please clarify if
2 not, that the risk adjusting, the reliability and
3 the validity was all done on the entire
4 population and not broken up by age groups for
5 those two groups? Does that make -- does that
6 question make sense and is that accurate?

7 MS. DAVIES: Okay. So, the
8 reliability testing, you know, all the testing
9 that's done within the measure testing forum and
10 those are all done using the age groups that
11 apply to that measure.

12 And so, in this case, it would just be
13 the younger adult population.

14 DR. O'BRIEN: But, the disparities
15 point that you made, it looks like that includes
16 the two different age groups in the model. So,
17 looking at the disparities, that's all asthma,
18 all this group together, is that correct?

19 MS. DAVIES: Yes, yes, and the -- so
20 in the disparities table that you received, we
21 stratified that population.

22 DR. NISHIMI: Anything else? Ready to

1 vote?

2 CO-CHAIR LANG: Yes, voting on
3 performance gap.

4 MS. AMIRAULT: Performance gap for
5 measure 0283, your options are, one high, two
6 moderate, three low and four insufficient.

7 MS. GORHAM: For the people on the
8 phone, we're having a bit of a technical
9 difficulty moment. Give us one minute. As you
10 can still email or send your votes in via chat.

11 DR. KAZEROONI: Who do you want us to
12 email the votes to?

13 MS. BAL: That's only for Susan to
14 send her vote to P-B-A-L@qualityforum.org. But,
15 everyone else who has access to the chat should
16 vote that method.

17 Thank you.

18 DR. KAZEROONI: Thank you.

19 DR. POLLART: So, I tried to send mine
20 through the chat, will you let me know if it
21 arrived otherwise I'm teed up to send the email.
22 But, that's just a slower process.

1 MS. BAL: We did not receive it.

2 DR. STOCKWELL: Did you all receive
3 other votes via chat or should we vote again?

4 MS. BAL: We received all the chat
5 votes, thank you.

6 And Susan, we received your email vote
7 as well.

8 DR. NISHIMI: Okay. Go ahead and,
9 Janine, reannounce.

10 MS. AMIRAULT: So, performance gap for
11 0283, one for high, two moderate, three low and
12 four insufficient.

13 MS. BAL: Could everyone vote one more
14 time? We're missing two votes. Thank you.

15 And, for the people online, that's
16 only for people in person. Thank you.

17 MS. AMIRAULT: Okay. Four high, 17
18 moderate, one low and zero insufficient.

19 And based on the percentage, we can
20 move forward.

21 CO-CHAIR LANG: Reliability?

22 DR. DIGIOVINE: So, you wanted me to

1 do this part?

2 DR. POLLART: Yes, that'd be great,
3 Bruno.

4 DR. DIGIOVINE: No, that's fine,
5 perfect.

6 So, in terms of reliability, the
7 developer noted that they did signal-to-noise
8 ratios as their test of reliability and have a
9 signal-to-noise ratio of .75 or with risk
10 adjustment to .74. So, it would certainly seemed
11 like they had good evidence of high reliability.

12 DR. POLLART: Yes, and Bruno, I think
13 you pointed out when we did the discussion that
14 there some concern about low populations that the
15 reliability doesn't meet the thresholds for
16 counties with eligible populations under
17 approximately 3,800 individuals.

18 And, the developer spoke to that in
19 their phone call. Do we need to discuss that
20 again?

21 CO-CHAIR LANG: Is there any further
22 discussion?

1 All right, we'll proceed then to vote
2 on reliability.

3 MS. AMIRAULT: Reliability for measure
4 0283, one high, two moderate, three low or four
5 insufficient.

6 Again, reliability for 0283.

7 Five high, 16 moderate, one low and
8 zero insufficient.

9 And, based on the percentage, we can
10 move along.

11 CO-CHAIR LANG: Proceeding to
12 validity.

13 DR. DIGIOVINE: All right. So, in
14 terms of validity, again, the developer did a lot
15 of nice sort of statistical testing around
16 predictors of outcomes in the population.

17 I think here, the one thing that did
18 come up in our discussion, probably the main
19 thing that came up in the discussion is that as
20 Carol said at the beginning, I mean, this is
21 supposed to be a measure of health system
22 quality.

1 And, in their model, access to care is
2 not a significant factor. So, when they look at
3 what predicts hospitalizations, it's prevalence
4 of risk factors, health behaviors and
5 socioeconomic status.

6 So, although these clearly are
7 important measures for a community, I think there
8 is some question around whether they are valid if
9 the question is, are they -- if access to care is
10 not a significant factor, whether you're really
11 measuring health -- the quality of the
12 healthcare.

13 I think that would be the one question
14 I'd have for the developer. I think, otherwise,
15 everything they've done shows that they've looked
16 at the question of validity in pretty good depth.

17 Susan, if you have anything to add?

18 DR. POLLART: I do not, thanks.

19 MS. DAVIES: So, this is Sheryl
20 Davies.

21 I can address -- oh, go ahead. Go
22 ahead, Carol.

1 DR. STOCKS: I was just going to say
2 that we didn't mean to imply that access to care
3 was not a part of what's driving the
4 hospitalization rates for ACSC conditions.

5 It's a number of things that are
6 driving it. I think the concept is that the
7 healthcare system should be able to meet the
8 population needs and, clearly, access to care is
9 a big part of that.

10 It's just that over time, I think our
11 concept has expanded a little bit to recognize
12 that putting -- having the right physicians in
13 place and even having access to insurance may not
14 be all of the answers.

15 CO-CHAIR LANG: Yes, I think just to
16 amplify this, I just want to sharpen our
17 understanding of the goal of the measure.

18 The rationale, as stated on the
19 measure says that the measure -- it says with
20 appropriate pharmaceutical and other outpatient
21 management, the risks of hospitalizations
22 decreased.

1 So, I think what we're -- I think what
2 Bruno was raising is a point that, you know, what
3 is the goal of the measure?

4 Because I think the rates correlate
5 most closely with socioeconomic factors as
6 opposed to, you know, access or aspects of
7 healthcare.

8 So, if you could respond to that just
9 so you can sharpen our understanding of the
10 measure, I think that the committee would
11 appreciate that.

12 DR. STOCKS: Well, the concept is that
13 the healthcare system is not only the physician's
14 office and whether the patient is able to fill
15 the prescription. There's a lot of factors going
16 on.

17 And, many of those factors can be
18 mediated by a community or a system, ideally,
19 it's a rather lofty goal, but it's one that we
20 believe is very important.

21 And so, the system should be able to
22 meet the community's healthcare needs.

1 Does that answer the question?

2 DR. SHAW: And, this is Jonathan Shaw,
3 I'm a primary care physician. This is very near
4 to my heart.

5 And, would just say that, currently,
6 looking at things like insurance coverage and
7 ratios of physicians in the area or access to
8 care, but things like vaccination rates, and
9 especially in the next few PQIs, pneumococcal and
10 influenza vaccination rates, tobacco cessation
11 programs which definitely are influenced by
12 primary care as well as public health have a
13 strong influence and correlate strongly with
14 socioeconomic factors.

15 So, it may not be as narrow as the
16 traditional access to care measures of how many
17 physicians in the area, but those are also access
18 to care issues.

19 CO-CHAIR LANG: Is there any further
20 discussion regarding the validity of the measure?

21 And, then we will proceed with the
22 vote on validity.

1 MS. AMIRAULT: Validity for 0283, one
2 for high, two moderate, three low or four
3 insufficient.

4 DR. NISHIMI: Ella, can you submit
5 your vote or resubmit it? It's not showing up in
6 chat.

7 MS. AMIRAULT: Zero high, 17 moderate,
8 five low and zero insufficient.

9 And, based on the percentage, we can
10 move forward.

11 DR. DIGIOVINE: So, in terms of --

12 DR. POLLART: I can talk about --

13 DR. DIGIOVINE: Oh, go ahead, Susan.

14 DR. POLLART: Yes, in terms of
15 feasibility, this is a simple one. All the data
16 elements are defined fields in electronic claims
17 and so the measurement's readily available on
18 administrative billing and claims data.

19 So, the committee felt that it was
20 straightforward and feasible.

21 CO-CHAIR LANG: Is there any further
22 discussion on feasibility? Bruno, were you going

1 to say something?

2 DR. DIGIOVINE: No, that's fine.

3 CO-CHAIR LANG: Okay.

4 We'll proceed to vote on feasibility.

5 MS. AMIRAULT: Feasibility for measure
6 0283, one high, two moderate, three low or four
7 insufficient.

8 Nineteen high, two moderate, one low
9 and zero insufficient.

10 And, based on the percentage, we can
11 move forward.

12 CO-CHAIR LANG: Usability?

13 DR. DIGIOVINE: Usability -- I'll go
14 ahead, Susan.

15 Again, our group thought it clearly
16 very usable being used in public reporting by
17 lots of different states and by CMS.

18 They were able to show improvement in
19 rates of hospitalization between 2011 to 2013.
20 No, sort of unexpected consequences.

21 We thought this was very usable.

22 CO-CHAIR LANG: Any further discussion

1 by the committee or questions for the developer?

2 Let's proceed to vote on usability,
3 please?

4 MS. AMIRAULT: Usability and use for
5 measure 0283, one for high, two moderate, three
6 low or four insufficient.

7 Thirteen high, nine moderate, zero low
8 and zero insufficient.

9 And, based on the percentage, we can
10 move forward.

11 CO-CHAIR LANG: Thank you.

12 So now, we're going to vote on the
13 overall measure or overall on the measure.

14 Is there any discussion?

15 DR. DIGIOVINE: Just remind me, at
16 what point do we talk about other measures,
17 harmonization has, you know, been brought up.

18 DR. NISHIMI: We have to be through
19 all of them because of the time constraints. We
20 might not get to that. We'll get to it on the
21 phone call, but I have made a note in the record
22 that you feel strongly that this whole age range

1 needs to be addressed.

2 CO-CHAIR LANG: On the -- yes, we --
3 so then, we will proceed to a vote.

4 MS. AMIRAULT: For overall suitability
5 for measure 0283, one for yes or two for no.

6 DR. NISHIMI: Ella, can you submit
7 your vote again?

8 MS. AMIRAULT: 21 yes and one no.

9 DR. NISHIMI: Okay, so the measure
10 will be reflected as recommended in the report.

11 CO-CHAIR LANG: Thank you.

12 So now, we will proceed to measure
13 0275: Chronic Obstructive Pulmonary Disease or
14 Asthma in Older Adults Admission Rate.

15 Carol, would you -- is there -- do you
16 wish to make additional comments regarding this
17 measure before we proceed?

18 DR. STOCKS: No, I don't think so.

19 CO-CHAIR LANG: All right.

20 The measure will be discussed by Jim
21 O'Brien and Ken Benson.

22 Take it away, gentlemen.

1 MS. BAL: Sorry, just one second.

2 Cathy, can you please work with Susan
3 so she can get the webinar working for her?
4 Thank you.

5 Sorry, go ahead, I just wanted to make
6 sure.

7 MR. BENSON: Okay, this is a
8 previously endorsed outcome measure undergoing
9 annual maintenance review.

10 It was first released in 2007. New
11 information has been provided which is a review
12 of material and that new evidence pretty much
13 supports the rationale for this.

14 We see a gap in this in that COPD is
15 the third leading cause of death in the United
16 States and of the leading causes of death, it's
17 the only one that continues to rise.

18 Performance suggests the gap still
19 exists.

20 And, any comments at that time?

21 DR. O'BRIEN: This measure is
22 analogous to the one we just discussed. It's

1 just the older age group and then COPD winds up
2 being added in. So, you're going to hear a lot
3 of the same analysis and everything else as we go
4 through it.

5 CO-CHAIR LANG: May I ask about the
6 rationale of including COPD combined with asthma
7 as opposed to making, you know, separate measures
8 since they're different conditions, as we all
9 know?

10 DR. O'BRIEN: Do you want the
11 developers to comment?

12 CO-CHAIR LANG: That's a question for
13 the developer.

14 DR. STOCKS: Jonathan, would you like
15 to answer that?

16 DR. SHAW: Sure.

17 There was eight on the expert panel
18 consensus in 2009 and they convened on all the
19 PQIs and, recognizing that there's a lot of
20 diagnostic uncertainty in older adults and
21 uncertainty in coding between asthma and COPD.

22 The management at the admission level

1 was often identical or very similar. So, that's
2 the rationale there. Definitely some
3 uncertainty.

4 But, you know, the patterns are very
5 different among the age 40 and above and goes up
6 strongly with age.

7 CO-CHAIR LANG: Additional discussion?

8 Yeah, I would just ask, I guess, I
9 don't know if it's in the data anywhere, but
10 whether there's any data looking at the rates of
11 hospitalization for patients who would fit asthma
12 and those for whom it would fit COPD to see
13 whether that overlap that we know does exist
14 clinically actually is reflected in your data?

15 MS. DAVIES: So, this is Sheryl
16 Davies.

17 We don't report that here. In our
18 data, you know, we do see a mix of diagnosis
19 codes. You know, we can't know exactly, you
20 know, what underlies those diagnosis codes, but
21 we do see a mix of diagnosis codes with
22 predominance, and I'll have to look up the number

1 if the committee is interested, the predominant
2 diagnosis is COPD in this age group.

3 CO-CHAIR LANG: Additional discussion?

4 Yes?

5 DR. LAMPONE: I just had a comment,
6 and this would probably cross over to the prior
7 measure that we just reviewed. And, this is for
8 the developer.

9 Have you seen communities based on the
10 data develop programs or what impacts they're
11 having in the community to help drive this data?
12 I think it's important data to know at the
13 geographic area and the drivers of the
14 exacerbation of COPD and asthma and
15 hospitalization rates.

16 But, how are the communities and
17 providers in those communities using this data so
18 we can capitalize on the information we have?

19 MS. DAVIES: So, we don't -- oh, go
20 ahead, Carol.

21 DR. STOCKS: No, you go ahead.

22 MS. DAVIES: Yeah, so, you know, we

1 don't, especially, you know, AHRQ being part of
2 the federal government, collects systematic data
3 about the use of measures.

4 So, what we do observe is that these
5 measures are used quite frequently within public
6 health programs and within state reporting.

7 Within the research, they are used as
8 outcomes measures in this case and with the prior
9 measure. We do see them being used in research
10 and otherwise as they -- in conjunction with
11 other measures such as the prevalence of COPD or
12 asthma and certainly issues such as air quality
13 or, you know, within the research, environmental
14 pollution or job-related pollution and smoking
15 rates.

16 So, I mean, I'm not sure if I'm
17 answering your question directly, partially
18 because we don't have a systematic way of
19 monitoring use.

20 But, in general, these measures are
21 very widely used as screening tools for, you
22 know, looking at utilization of population

1 health.

2 DR. LAMPONE: Fair enough. Okay.

3 DR. GROSSBART: With reference to that
4 question, the organization I'm affiliated with
5 has a Medicare Shared Savings Program. So, this
6 is one of the ACO measures that CMS has mandated
7 or is analyzing for each of those covered lives
8 within our and everyone else's Medicare Shared
9 Savings Program.

10 And, we've hired a hundred care
11 managers who do, among other things, try to
12 manage patients with COPD and keep them out of
13 the hospital. So, this is having an impact, you
14 know, in the trenches here.

15 CO-CHAIR LANG: Is there further
16 discussion regarding evidence?

17 Then we will -- oh, Steve, are you
18 okay?

19 Then we will proceed to the vote.

20 MS. AMIRAULT: Evidence for 0275, one
21 for yes, two for no. Again, evidence for measure
22 0275.

1 Okay, 22 yes and zero no.

2 So, based on the percentage, we can
3 move forward.

4 CO-CHAIR LANG: Risk -- gap?

5 MR. BENSON: In terms of gaps? You
6 know, the -- we think that there is a pretty
7 significant gap in the new evidence. What's
8 introduced supports that.

9 There are some questions in there of
10 how these gaps arrived. Some apparently
11 contradictory information on the rate of
12 hospitalization for blacks relative to whites.

13 And then, another items that says
14 there's little variation between blacks and
15 whites. A little confused by that, but overall,
16 the performance data does suggest a gap.

17 CO-CHAIR LANG: Is there additional
18 discussion or questions for the developer?

19 Thank you, then we'll proceed to vote
20 on performance gap.

21 MS. AMIRAULT: Performance gap for
22 measure 0275, one for high, two moderate, three

1 low or four insufficient. Again, performance gap
2 for 0275.

3 Six high, 16 moderate, zero low and
4 zero insufficient.

5 Based on the percentages, we can move
6 on.

7 CO-CHAIR LANG: Reliability?

8 DR. O'BRIEN: So, the reliability
9 testing was done similarly to the previous
10 measure, it was signal-to-noise ratio.

11 The performance was actually better in
12 the deciles than it was for the previous measure
13 with just one -- the smallest that the decile
14 with the counties with the lowest population just
15 came below the specified threshold.

16 I did have a question for the
17 developers. There's mention of two different
18 risk adjusting models, one that's just age and
19 gender and then the other one that talks about
20 including some measure of socioeconomic status.
21 It mentions that model's available.

22 Which of the two is actually in use?

1 DR. STOCKS: Typically, it's the age
2 and gender or no risk adjustment, depending on,
3 you know, what, you know, the users are most
4 interested in measuring.

5 So, as you know, there's a lot of
6 issues around measuring or risk adjusting for
7 socioeconomic status and indicates of these
8 measures, particularly when you're trying to
9 identify disparities, it can mask disparities.

10 But, some users do use the poverty
11 adjustment which, you know, is available on the
12 software as an option to compare like
13 communities.

14 DR. O'BRIEN: So, I guess for the NQF
15 staff, is this committee then voting to improve
16 all different ways that this might be used? So,
17 non-risk adjusted, risk adjusted with
18 socioeconomic status, without socioeconomic
19 status in the model?

20 DR. NISHIMI: Yes.

21 CO-CHAIR LANG: Is there further
22 discussion or questions for the developer

1 concerning reliability?

2 Then, we will proceed to vote.

3 MS. AMIRAUULT: Reliability for measure
4 0275, one high, two moderate, three low or four
5 insufficient.

6 Three high, 19 moderate, zero low and
7 zero insufficient.

8 Based on the percentage, you can move
9 on.

10 DR. O'BRIEN: Regarding validity,
11 again, same as the previous measure, two
12 different pieces.

13 One's face validity in which there's
14 an expert panel convened. This group wound up
15 supporting the measure with some concern which is
16 based on their second level of support.

17 Some of their concerns were similar to
18 what we talked about.

19 And, there was also the same empirical
20 validity testing looking at principle components
21 that, again, found an association with health
22 behaviors and socioeconomic status.

1 CO-CHAIR LANG: I have a question for
2 the developers.

3 There's a notation in the proposed
4 measure that patients with severe chronic
5 respiratory disease had been excluded because
6 COPD asthma differs in the subgroup from patients
7 with COPD asthma lung.

8 Could you elaborate on that, please?

9 DR. STOCKS: Jonathan, do you want to
10 take this as a clinician?

11 DR. SHAW: Yeah, I think it's in
12 reference -- if you looked at the exclusions, I'm
13 trying to pull them up in front of me, but that's
14 on the Excel appendix.

15 It's congenital lung diseases, cystic
16 fibrosis, rare, but, you know, definitely of
17 significant prevalence conditions that we didn't
18 feel captured the community health measure of
19 being exceptions.

20 And, likely be focused and more
21 specialized hospitals, urban regions.

22 DR. STOCKS: And, we do align our

1 measures. These specifications, the exclusion,
2 actually originally arose within the pediatric
3 asthma measure during an expert consensus process
4 and -- during our 2009 consensus process.

5 The panel has recommended that we
6 extend the exclusion, although it doesn't
7 actually exclude that many numerator cases.

8 They recommended that we include this
9 exclusion because these patients received
10 different types of care and their
11 hospitalizations probably reflect different
12 factors.

13 CO-CHAIR LANG: All right, fair
14 enough.

15 Are there any other questions for
16 developers? Any other comments?

17 All right, seeing no further
18 questions, comments, we'll proceed to the vote.

19 MR. AMIRAULT: Validity for measure
20 0275, one for high, two moderate, three low or
21 four insufficient.

22 Two high, 18 moderate, two low and

1 zero insufficient.

2 Based on the percentage, we can move
3 on.

4 CO-CHAIR LANG: Feasibility?

5 DR. O'BRIEN: This is based on
6 administrative billing and claims data as well as
7 U.S. Census data and the software is readily
8 available from AHRQ.

9 CO-CHAIR LANG: Any further discussion
10 questions?

11 Please, Bruno?

12 DR. DIGIOVINE: I don't want to go
13 back to validity, but just as you made your
14 point, Dave, I looked at the exclusion criteria
15 and they are all around pediatric diagnoses.

16 And so, I do have some concerns that
17 they're not excluding adult diseases that would
18 fit into what I think they're trying -- so, they
19 have congenital bronchiectasis, but they don't
20 have bronchiectasis.

21 So, it would strike me that there
22 probably needs to be some retooling of the

1 exclusionary criteria to include adults.

2 CO-CHAIR LANG: Yeah, I haven't been
3 able to pull it up on my screen, either. But, I
4 recall, you know, wondering about conditions like
5 Churg-Strauss and allergic bronchopulmonary
6 aspergillosis and how these other conditions were
7 handled.

8 Would the developers wish to comment
9 further?

10 MS. DAVIES: Well, so --

11 DR. STOCKS: Is that -- go ahead,
12 Sheryl.

13 MS. DAVIES: Yes, those particular
14 conditions were not brought up by our expert
15 panel in 2009, but, like Carol said, we can
16 certainly revisit those conditions and look at
17 their frequency within the numerator population.

18 DR. NISHIMI: Okay, so in the comments
19 to the developers and the record of the report,
20 we'll make that indication.

21 CO-CHAIR LANG: So, we're on
22 feasibility.

1 So then, where are we with respect to
2 that issue, then? We'll revisit this?

3 DR. NISHIMI: Well, no. You can
4 revote based on that, otherwise, it'll just be a
5 recommendation to the developer that they take a
6 look at those adult exclusions.

7 CO-CHAIR LANG: That's fine.

8 DR. NISHIMI: If you --

9 CO-CHAIR LANG: Is that okay with the
10 --

11 DR. NISHIMI: Is that okay with --

12 CO-CHAIR LANG: Is there anybody wish
13 to revote?

14 DR. NISHIMI: Okay, so then --

15 CO-CHAIR LANG: All right. So, then
16 we're --

17 DR. NISHIMI: -- it'll just be a
18 comment.

19 CO-CHAIR LANG: Okay, thank you for
20 that clarification.

21 So then, we'll proceed to vote on
22 feasibility.

1 MS. AMIRAULT: Feasibility for measure
2 0275, one for high, two moderate, three low or
3 four insufficient.

4 14 high, 8 moderate, zero low and zero
5 insufficient.

6 Based on the percentage, we can move
7 forward.

8 CO-CHAIR LANG: Excellent. We're
9 proceeding to usability.

10 DR. O'BRIEN: So, this is in use as
11 mentioned in some of the discussion in a wide
12 variety of ranges including the Medicare Shared
13 Savings Program down in Cincinnati.

14 There has been improvement from 2011
15 to 2013 in this rate. The developers suggest
16 over 104,000 fewer hospitalizations. It's not
17 clear what's triggering this improvement, whether
18 it's intentional or it might be also changes in
19 qualifications for hospitalizations or reduction
20 in hospitalizations overall.

21 CO-CHAIR LANG: Is there further
22 discussion or questions?

1 Please, Dale?

2 CO-CHAIR BRATZLER: So, I had, you
3 know, on the previous measure, we talked a little
4 bit about how the measure was being used and, you
5 know, I think it makes sense in large shared
6 savings programs and potentially in community
7 care organizations.

8 You know, Oregon's been using some of
9 these because they're kind of population-based
10 performance metrics.

11 I did have a little concern about
12 what's the minimum sample size that this measure
13 works at?

14 And, the reason I raise this question,
15 I had to go back and look at our QRUR report.
16 But, now, CMS is using PQI 5, so this is 0275 for
17 COPD and asthma at the level of the individual
18 practice as a part of the QRUR, which concerns me
19 a bit that that's really not population level
20 evaluation and it's actually being used as part
21 of the value modifier.

22 So, I question whether that's an

1 appropriate use or whether there's the minimum
2 sample size that should be, you know, that you
3 can actually apply this performance metric to?

4 I'm not sure if my question is
5 completely clear, but I do have concerns about
6 some of the use of the metric.

7 DR. STOCKS: Can we address that as
8 developers?

9 DR. NISHIMI: If you can hold off, we
10 have a committee follow-up first.

11 DR. STOCKS: Okay.

12 DR. MURRAY: I guess what I'm trying
13 to ask was were we asking for a remedy, you know,
14 like a notification on when you're using this
15 metric, it cannot be used in a size smaller than
16 X. Is that what we're asking?

17 Because that might apply to some of
18 other metrics that we're looking at, too.

19 CO-CHAIR BRATZLER: To me, I think it
20 goes to the validity of the measure. The
21 validity may be very good at the population
22 level, but how small does the population get

1 where the measure is not valid or, you know, I
2 don't know if I'm, again, asking the right
3 question, but I'm interested to see what the
4 developers say.

5 But, I do have concerns because I went
6 back -- I had to go back real quickly and search
7 the CMS methodology, but they explicitly state
8 that they're using PQI 05 at the practice level
9 as a part of the value modifier now.

10 So, I'm concerned about the sample
11 size or the population size that this is being
12 applied to.

13 DR. NISHIMI: Go ahead, AHRQ.

14 DR. STOCKS: So, the measure that CMS
15 is using, as we know, and the materials with the
16 footnote there, is an adaptation of the PQI. So,
17 the measure before you today is the population
18 health measure.

19 We provide the information on what CMS
20 uses because it's one of the most visible ways
21 that admission rates themselves are being used.

22 And, as you heard before, you know,

1 it's a, you know, within those programs, we can
2 see, you know, the action being taken.

3 However, the testing that we provide
4 today and all the information is based on the
5 population measure.

6 We cannot speak to, you know, the
7 minimum sample size with inference. It's a CMS
8 program.

9 When you change the denominator
10 population, you change rates, you change the
11 distribution across the measured entities. And,
12 those all, all of those factors will actually
13 impact the signal-to-noise ratio.

14 So, you know, we, as AHRQ, are, and
15 we, as the measure developer under contract with
16 AHRQ, are bringing before you the population
17 health-based measure and we can speak to what we
18 observed.

19 And that is that, for this particular
20 measure, there are some reliability concerns for
21 small counties. And for those counties, we
22 recommend using the smoothed rates. And, the

1 smoothed rates actually account, I guess, you'd
2 call it a reliability adjustment.

3 So, it will account for variation and
4 reliability for those very small counties.

5 CO-CHAIR LANG: Steve, did you want to
6 say something?

7 DR. GROSSBART: Just a comment, is it
8 a measurement developer's responsibility for the
9 measure being used liberally and CMS does have a
10 tendency to do that quite a bit among others.

11 DR. NISHIMI: No, it's -- we don't
12 place the implementation burden on the developer.
13 And, yes, CMS does use this measure and other
14 measures towards its own ends.

15 DR. O'BRIEN: Although, I would offer
16 that that probably would be considered an
17 unintended consequence that should be identified.

18 CO-CHAIR BRATZLER: Yes, so I agree.
19 And, I just -- when I -- because I kind of, as we
20 were having the conversation, went and searched
21 the CMS website real quick and they explicitly
22 identified PQI 05 as the methodology behind the

1 metric that they put in the QRUR that they hold
2 individual practices accountable for.

3 So, I understand that's not AHRQ's
4 fault and it's not the fault of this measure. I
5 understand that. But, I do -- I think, you know,
6 James's point is a good one, that it is an
7 unintended consequence.

8 And, if you to the CMS website, it
9 says this is the PQI 05 measure that's being used
10 to hold a practice level, you know, accountable
11 for admission rates for asthma COPD.

12 CO-CHAIR LANG: Bruno?

13 DR. DIGIOVINE: Yes, I think you just
14 pointed out that it's not the role of the
15 developer and it's not the -- I guess, it's not
16 AHRQ's role. I guess the question is, is it
17 NQF's role? Is it our role, as a committee, or
18 this organization's role to say, this measure is
19 only approved for measurement at this level?

20 DR. NISHIMI: And, that's what we do.

21 DR. DIGIOVINE: Okay.

22 DR. NISHIMI: You're voting on it and

1 that's what the report clearly indicates, the
2 level of analysis population.

3 CO-CHAIR LANG: Is there additional
4 discussion, addition questions for the
5 developers?

6 As I see no further questions,
7 discussion, we'll proceed to a vote on usability.

8 MS. AMIRAULT: Usability and use for
9 measure 0275, one for high, two moderate, three
10 low or four insufficient.

11 DR. NISHIMI: David, can you resend
12 your vote? David?

13 DR. STOCKWELL: Yes, I'm here. Sorry,
14 I'm having access problems, just a sec.

15 DR. NISHIMI: If you want to email it
16 to P as in Peter, B as in boy, A as in --

17 DR. STOCKWELL: Yes, I'll do that.
18 I've got her email.

19 DR. NISHIMI: Okay.

20 DR. STOCKWELL: Thank you.

21 Okay, just sent.

22 DR. NISHIMI: Okay.

1 MS. AMIRAULT: Would everyone mind
2 just pointing just pointing one more time? Thank
3 you.

4 Three high, 15 moderate, four low and
5 zero insufficient.

6 Based on the percentage, you can move
7 on.

8 CO-CHAIR LANG: All right, so now,
9 we're going to proceed to vote on the overall
10 measure.

11 Discussion? Questions for the
12 developer?

13 Seeing no further questions,
14 discussion, we'll vote on the overall suitability
15 for endorsement of the measure.

16 MS. AMIRAULT: For overall suitability
17 for Measure 0275, one for yes, two for no.

18 Eighteen yes, four no.

19 So, based on the percentage, this will
20 be recommended.

21 CO-CHAIR LANG: We're now moving on to
22 our third measure, our third population health

1 measure, 0279: Bacterial Pneumonia Admission
2 Rate.

3 Carol, would you like to -- or Sheryl,
4 would you like to make a few comments about this
5 briefly before we proceed?

6 DR. STOCKS: No, I don't think so.
7 Thank you.

8 CO-CHAIR LANG: Very well, the measure
9 will be reviewed by Susan Pollart and Rich
10 Murray.

11 Evidence?

12 DR. MURRAY: This is NQF Measure 0279,
13 Bacterial Pneumonia Admission Rate, PQI 11.

14 And, this is an outcome measure. The
15 data source is from claims, and the level of
16 analysis is at the population level -- county or
17 city.

18 I don't know if this one is also being
19 used by CMS at the practice level, but if it is,
20 we should consider that same discussion that Dale
21 just brought up.

22 The evidence here, you know, includes

1 providing the rationale that supports the
2 relationship of the health outcome, in this case,
3 admission for pneumonia.

4 Two processes are structures and care
5 and the developer says that their rationale for
6 the measure is that access to high quality care,
7 early intervention and appropriate treatment
8 including pharmaceutical treatment will minimize
9 the likelihood of mild respiratory conditions
10 progressing to pneumonia reducing the likelihood
11 of hospitalizations.

12 There is no requirement for a
13 literature review, but they did review some
14 additional literature.

15 And, the new question for the
16 committee is that, although the developer
17 provides updated evidence related to aspects of
18 hospitalization for pneumonia, does the committee
19 agree that the underlying rationale for the
20 measure remains reasonable? And, there is no
21 need for the discussion or vote of the evidence.

22 CO-CHAIR LANG: Yes, so the underlying

1 rationale for the outcome measure hasn't changed
2 since the last endorsement review. So, unless
3 there is an objection from anyone on the
4 committee, there's not any need for any vote.

5 DR. MURRAY: And the numerator and
6 denominator have not changed.

7 CO-CHAIR LANG: Okay. Then, we will
8 proceed without voting to performance gap.

9 DR. POLLART: I can step in if you
10 want me, Richard.

11 MR. MURRAY: Sure.

12 DR. POLLART: Looking at gaps, there
13 was evidence of disparity, particularly on older
14 men both socioeconomic status and in rural areas.
15 So, the group felt that there were gaps in care,
16 warranting it as a national performance measure.

17 DR. MURRAY: And, there were no
18 disparities related to race, right? Just to male
19 patients 65 and over and patients with the lowest
20 income and also patients living in rural
21 locations.

22 DR. POLLART: Yes, that's what was

1 reported.

2 DR. MURRAY: Which further supports
3 the variation in care.

4 CO-CHAIR LANG: Is there further
5 discussion?

6 Bruno, yes?

7 DR. DIGIOVINE: A couple of questions.

8 One is, the disparities that are
9 reported, are those -- is there data that the
10 developers provided that I'm not seeing right
11 here, or is that just based on a literature
12 review or something else?

13 And then, I don't know if this is here
14 or in validity. I guess there's still this --
15 this one, for me, is much harder to understand
16 how much healthcare can intervene in preventing a
17 pneumonia admission.

18 It just strikes me as not -- the face
19 validity of that, to me, is difficult to
20 understand.

21 DR. MURRAY: Although the data that
22 they provide in the performance gap of the

1 overall document, you know, shows sort of
2 progressive decline in the observed rate in the
3 period of 2009 to 2013.

4 DR. DIGIOVINE: So, does the developer
5 have some health system improvement that they
6 think correlates with that decrease in pneumonia
7 rates?

8 DR. SHAW: In the evidence -- yes,
9 this is Jonathan Shaw.

10 There's very strong evidence that
11 pneumococcal vaccinations as well as flu
12 vaccination reduces hospitalization rates in a
13 given area.

14 DR. MURRAY: And, while we're looking
15 at those data, could we ask the developer to
16 clarify in the table that's under the performance
17 gap section, there's a -- I don't know if it's
18 typo or not, but under the very last row, year
19 2013, the standard deviation is 2.43, a striking
20 drop from the previous four years. Do you see
21 that?

22 MS. DAVIES: I can address -- yes, I

1 can address that.

2 And, it is actually, we provided some
3 updated tables in the distribution of the PQI is
4 an interesting distribution. I won't go into the
5 details of it.

6 But, as you know, distributions,
7 particularly outliers can impact the standard
8 deviations.

9 We provided updated tables taking out
10 those outliers just for clarification.

11 DR. MURRAY: Okay, thank you.

12 DR. YEALY: I had one question about
13 the performance gap and the disparities.

14 Is it -- it looks like male sex and
15 age over 65 is a big drivers, but those are big
16 drivers of mortality prediction when you develop
17 acute pneumonia, at least if you use the
18 pneumonia severity index.

19 So, this is kind of circular; of
20 course, they would drive this particular event
21 because, in fact, men die more often with the
22 same level of pneumonia than a woman does and

1 people over 60, the base way you get points in
2 the pneumonia severity index is your age if it's
3 over 50.

4 So, I wonder about half of the
5 performance opportunity actually being exactly
6 what we're looking for? It's you want those
7 folks admitted. It's not -- or at least more
8 proportionally admitted.

9 I'm not sure I'm seeing the problem
10 exactly here.

11 DR. SHAW: These are not -- these are
12 potentially preventable, not unnecessary
13 admissions. We're not saying that these aren't
14 necessary.

15 So, in terms of the potentially
16 preventable, I'd go back to the effective high
17 rates of pneumococcal vaccinations, early
18 outpatient detection should still influence the
19 population level rates regardless of the fact
20 that, yes, when the elder male or elder pneumonia
21 patient presents, they should be admitted.

22 DR. O'BRIEN: Is there a population-

1 based measure of pneumococcal vaccination and flu
2 vaccination rates already available?

3 DR. NISHIMI: NQF has endorsed
4 pneumococcal vaccination influence and
5 vaccination measures, yes.

6 DR. MURRAY: It would be interesting
7 to compare the change in that over time with the
8 change in this.

9 DR. DIGIOVINE: So, also, earlier, we
10 heard about outreach for trying to prevent COPD
11 admissions and asthma admissions. Is there
12 anybody reporting that they're doing outreach to
13 try to prevent pneumonia admissions?

14 DR. SHAW: So, in the evidence -- so,
15 this is the measure evidence form under the --
16 there is a reference to a program within the VA
17 that showed success and it was focused on
18 vaccination. And, it showed significant
19 decreases after that, that after -- it's on page
20 7 of the evidence form.

21 CO-CHAIR LANG: Okay, we have Crystal
22 and then Todd.

1 I'm sorry, Don? Don? Oh, you didn't
2 put your -- okay.

3 Todd?

4 DR. DORMAN: So, I guess it's less a
5 question and just a comment.

6 I think what's confusing me a little
7 bit here is the statement that appropriate
8 pharmaceutical treatment with the degree to which
9 the likelihood of milder respiratory conditions
10 progressing to pneumonia, and I think that's the
11 question.

12 Where is the evidence that there's
13 some intervention for milder respiratory
14 conditions? What's being presented is
15 vaccination, which doesn't fit what that sentence
16 says and I think that's the disconnect for me.

17 DR. SHAW: This is Jonathan, again.

18 There is a large truck of pneumonias
19 which can be treated outpatient if caught early,
20 maybe not in the older population per se, but,
21 you know, just looking at all population, all
22 ages.

1 And so, you know, with early access to
2 care, many of these patients will be treated for
3 "walking pneumonia" and avoid hospitalization.

4 CO-CHAIR LANG: I also have a question
5 for the developer.

6 The measure is entitled Bacterial
7 Pneumonia Admission Rate, yet what you're
8 tracking is discharges.

9 So, I'm just wondering, you're using
10 the discharge diagnosis as a proxy for
11 admissions, so I'm wondering whether you can
12 reconcile this for us? Is there any data you
13 have that implies that it's apples and apples?

14 DR. STOCKS: In the type of data that
15 we're using, the records are created at the time
16 of discharge and the principle diagnosis is the
17 one that is adjudged to be the major cause of
18 that admissions. Sometimes that, the first
19 impression or the admitting diagnosis is not what
20 it turns out to be.

21 We believe the discharge diagnosis --
22 and, actually, these records aren't even created

1 until the time of discharge.

2 Do you have anything to add, Sheryl?

3 CO-CHAIR LANG: I just had a
4 clarification --- so, are you using discharge
5 claims data, or are you doing chart review
6 discharge diagnoses?

7 DR. STOCKS: It's discharge claims,
8 not claims, but billing data created by the
9 hospitals and, of course, those billing records
10 are based on the coders looking at the medical
11 records.

12 CO-CHAIR LANG: Okay. So, it's from
13 the hospitals themselves, not the payers or CMS?

14 DR. STOCKS: That's correct.

15 CO-CHAIR LANG: Okay.

16 DR. MURRAY: So, this measure
17 underestimates the actual admission rate by some
18 amount related to say, death or transfer, is that
19 right?

20 DR. STOCKS: No, we would include
21 cases. So, transfers are only excluded in one
22 direction to avoid double counting of

1 hospitalizations.

2 DR. MURRAY: Okay.

3 DR. STOCKS: And, deaths would be
4 included. It's just when the diagnosis -- so, in
5 this case and the case of a principle diagnosis
6 here, you know, that principle diagnosis is the
7 diagnosis that, quote, occasions, principally
8 occasions, the admission.

9 And so, you know, we don't observe a
10 huge, you know, difference between, you know,
11 admission and discharge, in this particular case.

12 You would only observe that, for
13 instance, if somebody thought somebody had
14 pneumonia and then at the end of the
15 hospitalization, they figured out that it wasn't
16 really pneumonia, then it would be what's called
17 a rule-out diagnosis.

18 Rule-out diagnoses are not codable as
19 a principle diagnosis or a secondary diagnosis.
20 So, we're actually capturing, you know, what
21 diseases that are recorded by the physicians.

22 CO-CHAIR LANG: Thank you.

1 Are there any additional questions for
2 the developers or comments? We're on performance
3 gap, and we're going to vote on performance gap.

4 MS. AMIRAULT: Performance gap for
5 Measure 0279, one for high, two moderate, three
6 low or four insufficient.

7 One high, 11 moderate, 10 low and zero
8 insufficient.

9 And, this is grey zone.

10 CO-CHAIR LANG: Okay. We will move
11 forward with -- we have to discuss reliability.

12 DR. MURRAY: So, on reliability, the
13 developer indicates that there were some changes
14 made to the measure specifications since the
15 prior endorsement review.

16 They added several codes including
17 staphylococcal pneumonia, methicillin-susceptible
18 staph pneumonia.

19 So, a number of codes were added and
20 some additional exclusions. They did repeat the
21 reliability testing and they also, let's see,
22 they did this at the measure score level using

1 more current data.

2 And, they did a risk adjustment model
3 as well using data from the Healthcare Cost and
4 Utilization Project state and patient database in
5 40 states representing 89 percent of the country.

6 And, as the summary of their testing,
7 they reported a reliability testing, not at the
8 individual element level, but at the measure
9 level with a signal-to-noise ratio of .97 which
10 they say is very high.

11 And, when they added social
12 demographics statistics to the risk adjustment
13 model, the signal-to-noise ratio was about the
14 same at .96.

15 So, the question is, are we confident
16 that this is sufficiently reliable to be useful
17 to look at changes in essentially quality of
18 care?

19 CO-CHAIR LANG: Susan, is there any
20 additional comments you wish to make?

21 DR. POLLART: Yes, no, I think that
22 summarized it.

1 CO-CHAIR LANG: Great.

2 DR. POLLART: I think the other
3 question was were the appropriate codes included?
4 But, as was mentioned, a number were added that I
5 think are sufficient.

6 CO-CHAIR LANG: Additional comments,
7 other members of the committee, questions to the
8 developers?

9 Seeing none, we will proceed to vote
10 on reliability.

11 MS. AMIRAULT: Reliability for Measure
12 0279, one being high, two moderate, three low or
13 four insufficient.

14 Six high, 13 moderate, three low and
15 zero insufficient.

16 And, based on the percentage, you can
17 move along.

18 CO-CHAIR LANG: Validity? Susan?
19 Rich?

20 DR. POLLART: Yes, I can start with
21 that.

22 So, the validity testing level was at

1 that measure score and face validity only was
2 tested.

3 It was tested within -- from four
4 clinical expert panels involving 73 panelists and
5 was convened in 2008 to 2009. The panels
6 indicated the measure was useful.

7 And, I think our group asked whether
8 a panel convened in 2008 to 2009 was -- if those
9 recommendations were still applicable? But the
10 panels did indicate it was useful.

11 CO-CHAIR LANG: Rich, any additional
12 --

13 DR. MURRAY: I guess threats to
14 validity, there are, you know, issues of
15 exclusions. There are issues of miscoding.
16 There's the sickle cell disease.

17 You know, so the question is, is are
18 the exclusions consistent with the evidence and
19 are they sufficient for us to have confidence in
20 the validity in terms of these? Those are the
21 main threats, I think.

22 DR. POLLART: Yes, the point was made

1 still about --

2 DR. MURRAY: And coding.

3 DR. POLLART: Yes, there were about a
4 little over 69,000 discharges excluded because of
5 the diagnosis in the immunocompromised state
6 which --

7 DR. MURRAY: Right.

8 DR. POLLART: -- if you replace those
9 folks, you'd increase your numerator by over ten
10 percent. So, are they appropriately or
11 inappropriately excluded from the measure when
12 you remove the immunocompromised state?

13 DR. MURRAY: So, the ability to be
14 confident about the presence or absence of
15 immunocompromised state would sort of -- that
16 would probably increase the uncertainty of the
17 measure.

18 CO-CHAIR LANG: Bruno?

19 DR. DIGIOVINE: Yes, I had two
20 questions.

21 One was either for the developer or
22 for others if they understand it. I don't

1 understand the way the sense of validity is
2 reported by the panel.

3 There's four levels of support with
4 different median scores and I'm not sure I
5 understand what all of that means.

6 And, the second is, this is now the
7 third measure, the other two statistical tests
8 were done to assess validity, and I'm wondering
9 why that wasn't done specifically for this
10 measure?

11 DR. STOCKS: Sure, so when we do the
12 face validity testing, we asked several questions
13 about usability and the different aspects of the
14 measure, very similar to what the NQF panel is
15 doing when we ask, you know, questions of
16 reliability.

17 In this case, we asked them to rate
18 different aspects that would contribute to the
19 face validity of the measure and the usability.

20 In that particular study, we were
21 looking at different levels and different
22 applications of the measure. And so, you'll see

1 the different ratings there. They just reflect
2 the purpose of that study.

3 In the case of the empirical analysis,
4 the study that we used to assess the empirical
5 validity of the measure was focused on chronic
6 disease measures. And, did not actually include
7 the acute PQI, so that's why they're not included
8 here.

9 DR. DIGIOVINE: So, just on the face
10 validity piece, you're saying you asked the
11 panel, do they fully support the use and over --
12 on a 9-point Likert scale? And, their answer was
13 somewhere between seven and nine?

14 But, then you asked them, again, do
15 they have general support with some concerns, and
16 they had the same degree of agreement?

17 DR. STOCKS: So, those -- so, we asked
18 them about the overall usefulness of the measure
19 or a different application. In this case, we're
20 reporting on the population health application.

21 And, for that, in comparison between
22 counties, and for that, they rated on a Likert

1 scale and we used the RAND Appropriateness
2 Method, the adaptation of that method to then
3 rate the measure. We convened two -- or then
4 categorized the support.

5 We convened two panels here, I think
6 that's what you're probably noticing. We're
7 testing kind of a different approach because the
8 nominal panel technique, which is typically used
9 as, you know, a group of, you know, 8 to 15, you
10 know, individuals.

11 There are some chances for bias,
12 depending on the particular folks that you have
13 on that panel. And so, we were testing a
14 different approach where we would combine the
15 nominal group with a delta group.

16 So, we also convened a much larger
17 group that did not meet in person but they
18 received feedback from the other group, and that
19 study is also published, and it's referenced
20 there.

21 So, that's the reason you see two
22 ratings there, it's because we had two separate

1 panels that interacted with each other but they
2 were considered separately.

3 CO-CHAIR LANG: Is there additional
4 discussion, questions for the developers?

5 Yes, Don?

6 DR. YEALY: You know, I noticed that
7 the measure is called a measure but focused on
8 bacterial pneumonia.

9 But, it actually looks like aside from
10 the coding, what you're really assessing is
11 community acquired pneumonia.

12 I understand that a ton of these may
13 be coded as bacterial pneumonia. Has there been
14 any validity check on the frequency in which this
15 truly is bacterial?

16 In other words, there was some
17 microbiologic evidence of it being bacterial?

18 You know, in my world and most
19 published world, a third would be about the most
20 that you had any hard data on.

21 And, I suspect that those comments
22 that you got in 2008 were about community

1 acquired pneumonia, not specifically about
2 bacterial pneumonia. We throw the terms around
3 interchangeably, but they're not exactly the same
4 things.

5 So, that's my validity question, not
6 are the data sets big enough to be examined again
7 and again. Is this really bacterial pneumonia
8 we're talking about?

9 DR. STOCKS: That's a fair concern.
10 And, I think we could consider changing the
11 measure. You're absolutely right that this is
12 most reflects community acquired pneumonia.

13 The name of this measure, you know, a
14 legacy name going back to the early
15 conceptualization of ambulatory care sensitive
16 condition. The idea was to -- that, you know,
17 many community acquired pneumonias are bacterial.

18 You'll notice in the code list that we
19 do include unspecified pneumonias and this
20 captures exactly what you're speaking about is
21 that, you know, most pneumonias don't have, you
22 know, either it's not done or we cannot actually

1 obtain a culture -- a positive culture
2 bacterially, but they're treated empirically.

3 And so, that is something we can
4 certainly consider is, you know, a change to the
5 name to reflect community acquired pneumonia.

6 DR. MURRAY: Just as a follow up
7 question. If you're going to take bacterial
8 pneumonia out of the name, does that mean that
9 we're comfortable having somebody with a viral
10 respiratory tract infection with infiltrates
11 that, of course, cultures nothing bacterial and
12 that that would now be in the numerator?

13 DR. STOCKS: I would like to clarify
14 that we don't actually include codes for virals.
15 So, if the physician does make it as a viral
16 pneumonia, it would not be included in here.

17 DR. MURRAY: Okay.

18 DR. STOCKS: That's, you know, differs
19 from, you know, some of the CMS measures of, you
20 know, pneumonia mortality, et cetera.

21 So, if it's specified as such, then it
22 would not be.

1 DR. MURRAY: It would not be? Okay.

2 DR. POLLART: The committee said the
3 added codes are discussed adding staph,
4 methicillin-resistant, MRSA staph. But, what
5 would codes -- the previous codes?

6 DR. STOCKS: I'm sorry, I'm not sure
7 I understand the question.

8 DR. POLLART: Yes, that's all right.
9 I'm just kind of -- you talk about added codes,
10 the original codes were ICD-9-CM or ICD-10
11 diagnosis code for bacterial pneumonia.

12 DR. STOCKS: Yes, all the codes that
13 are included are included in the technical
14 specification that's been provided in the Excel
15 spreadsheet. That has all the codes. These are
16 just new codes that were added, usually because
17 they've been introduced into the coding system.

18 CO-CHAIR LANG: Okay, further
19 discussion?

20 All right, we will proceed to vote on
21 validity.

22 MS. AMIRAULT: The highest eligibility

1 for validity for 0279 is moderate, so the options
2 are two moderate, three low or four insufficient.

3 One high, 9 moderate, 12 low or zero
4 insufficient.

5 And, based on the percentage, this is
6 grey zone and we'll move on.

7 CO-CHAIR LANG: Okay, feasibility?

8 DR. MURRAY: Feasibility. So, all the
9 data elements are in defined fields in electronic
10 claims. The measure is based on readily
11 available administrative billing and claims data.

12 The AHRQ software is publically
13 available and people have over ten years of
14 experience using it with and there are no fees.
15 So, the feeling should be that it's feasible.

16 CO-CHAIR LANG: Any concerns, members
17 of the committee, regarding feasibility?

18 Seeing none, we'll proceed to vote,
19 feasibility.

20 MS. AMIRAUULT: Feasibility for Measure
21 0279, one for high, two moderate, three low or
22 four insufficient.

1 Seventeen high, 3 moderate, 2 low and
2 zero insufficient.

3 Based on the percentage, we'll move
4 along.

5 CO-CHAIR LANG: Feasibility?

6 DR. POLLART: The current use of the
7 measure is publically reported, and it's used in
8 accountability programs.

9 Improvement results were reported.
10 There are -- the PQI 11 hospital admission rate
11 decreased by 87,000 fewer hospitalizations from
12 2011 to 2013.

13 The committee felt that usability and
14 use were -- could be used to further the goal of
15 high quality efficient healthcare.

16 CO-CHAIR LANG: Dale?

17 CO-CHAIR BRATZLER: So, two things,
18 I'll raise my issue about unintended consequence
19 again, because this is one of the measures that,
20 while designed for population level evaluation,
21 it's being used at the practice level, again.
22 And, that's, again, not AHRQ's fault, I

1 understand that. It's not the measure
2 developer's fault.

3 My second issue, though is, I know
4 data that's presented that the rate for this
5 measure is going down. I certainly know in our
6 institution, with the availability of a wide
7 variety of panels to identify viral pneumonia in
8 adults that we're seeing a fairly dramatic
9 reduction in the number that have unassigned
10 causes that used to be assumed to be bacterial.

11 And, now, you know, you know, you're
12 finding metapneumovirus and respiratory syncytial
13 virus and all sorts of viruses in adults. And
14 so, perhaps, they're being coded as viral,
15 they're not including the numerator any more, but
16 that reduction in the numerator over time may
17 simply be that we're much, much better in
18 diagnosing viral pneumonia in adults which didn't
19 used to do very consistently.

20 So, I have some questions about
21 whether the measure is improving or are our
22 diagnostic ability for viral pneumonia has

1 improved a lot over time.

2 Which then raises, for me, the
3 question influenza vaccine clearly an important
4 intervention to improve this metric, pneumococcal
5 vaccine probably important. But, there are whole
6 bunch of viral pneumonias that are being
7 diagnosed now for which we don't see.

8 CO-CHAIR LANG: Further discussion?

9 We'll proceed to vote on usability.

10 MS. AMIRAULT: Usability and use for
11 0279, one high, two moderate, three low or four
12 insufficient.

13 Five high, 11 moderate, 6 low and zero
14 insufficient.

15 Based on the percentage, we'll move
16 forward.

17 CO-CHAIR LANG: Now, we are
18 considering the overall suitability of this
19 measure for endorsement.

20 Is there further discussion?

21 We will proceed to vote.

22 MS. AMIRAULT: Overall suitability for

1 0279, one for yes, two for no.

2 Thirteen yes and 9 no.

3 Based on the percentage, this is grey
4 zone.

5 DR. NISHIMI: Okay, are we ready to
6 take up the next one?

7 CO-CHAIR LANG: Yes, we're proceeding
8 to the next measure, 0708: Proportion of Patients
9 with Pneumonia That Have a Potentially Avoidable
10 Complication During the Episode Time Window.

11 Would the -- are the developers on the
12 phone? Would they wish to make a comment?

13 MS. GORHAM: I'm sorry, Karen Johnson?

14 MS. JOHNSON: Yes, I'm here.

15 MS. GORHAM: Okay. Are you starting
16 with the intro?

17 MS. JOHNSON: Yes, if that's how you
18 want me to do it.

19 DR. NISHIMI: No, Karen's going to
20 address during the reliability. So, Amita and
21 Andrew -- not Andrew -- yes, is it Andrew and
22 Francois, go ahead.

1 Karen, just jump in when we get to
2 reliability.

3 MS. JOHNSON: Okay, great. Thanks.

4 DR. RASTOGI: Thank you.

5 This is Amita so with ACHC.

6 We would first like to thank the
7 members of the standing committee for the
8 thoughtful review of this measure and the
9 comments that we received last week during the
10 call.

11 Before addressing some of the
12 comments, we want to clarify a few points about
13 this measure because this is a resubmission.

14 In the original measure, which was
15 endorsed a few years ago, we had three categories
16 of avoidable complications. We have removed one
17 and kept the other two.

18 The one that we removed dealt with
19 complications associated with comorbidities. A
20 patient that may have other similar conditions.
21 Then we thought that those complications would be
22 best addressed with that main condition itself.

1 So, in other words, the prior endorsed
2 measure had broader complications than this one,
3 you know.

4 Second, we want to address the
5 reliability piece. We created a very high
6 threshold of reliability prior to use of this
7 measure, asking that the measure users determine
8 the appropriate sample size prior to calculating
9 a risk standardized score and reporting
10 performance.

11 This sample size is determined by the
12 specific data set being analyzed and
13 significantly reduces the potential of
14 misclassification of a provider.

15 The goal is to create a fair balance
16 between the need for accountability on outcomes
17 of scales and an assessment of the actions of
18 physicians and facilities in influencing those
19 outcomes.

20 The pneumonia PAC measure, or the
21 potentially avoid complication measure, is really
22 centered around the patient's experience with an

1 episode of care.

2 PACs measure adverse events that can
3 be experienced by a patient and that when they
4 occur lead to poorer overall quality and higher
5 cost of care.

6 As such, they are very useful for
7 physicians and facilities in the move to
8 alternative payment models because of reduction
9 in PAC's reduces cost of care while improving
10 overall patient outcomes, helping to meet two of
11 the three goals in the tripling.

12 So, up front, we would like to offer
13 a few clarifications from the discussion from
14 last time.

15 Very briefly, the first one are
16 patients are included in the denominator as being
17 hospitalized with pneumonia as the discharge
18 diagnosis on the inpatient claim specifies
19 pneumonia.

20 However, if the discharge diagnosis is
21 amended to be septic shock, the patient is no
22 longer included.

1 If the patient has a pre-existing
2 condition such as bronchiectasis that can be
3 identified in claims prior to the pneumonia
4 trigger date, that pre-existing condition gets
5 flagged as comorbidity and is used a risk factor
6 to adjust on.

7 So, we do not count this in the
8 numerator for the measure in the diagnosis even
9 if it appears in subsequent claims because now,
10 it's considered as a risk factor and a pre-
11 existing condition.

12 The originally endorsed measure
13 included all types of pneumonia in its
14 definition, making it rather heterogeneous
15 population in the denominator.

16 So, we have modified the measure to
17 separate out well defined diagnosis of healthcare
18 acquired pneumonia such as ventilator-associated
19 pneumonia and aspiration pneumonia.

20 However, there are a few diagnosis
21 codes that are less well defined or specific and
22 can be used to identify either a community

1 acquired or the healthcare acquired.

2 In certain instances, the diagnosis
3 codes were left in, but then they apply uniformly
4 in the measurement process.

5 And finally, the workbook that is
6 attached within the submission addresses several
7 details including the risk factors that were
8 flagged when present and included in the severity
9 models, they include PAC rates for each provider
10 and their risk standardized rates.

11 Importantly, this measure is a
12 reflection of relative performance, not absolute
13 performance. The extent of which this
14 imprecision in a specific administrative claims
15 data set exists, that imprecision should be the
16 same for all providers and not affect the
17 relative performance rate.

18 Thank you.

19 CO-CHAIR LANG: Thank you.

20 James, Chana? Evidence?

21 DR. O'BRIEN: So, as mentioned, this
22 is an outcome measure. The level of analysis is

1 actually specified as potentially being the
2 clinician, the facility or even population.

3 This is adult patients age 18 or older
4 who have an encounter, either inpatient or
5 outpatient, that's associated with pneumonia who
6 then are followed for one month and looked at to
7 see if they develop one of these what are called
8 PACs, the potentially avoidable complications.

9 As the developer mentioned, there are
10 two different types of these.

11 The first one is one that is thought
12 to be directly related to the pneumonia itself.

13 The second one are ones that the
14 developers suggest are patients safety failures.

15 This is an outcome measure and so,
16 obviously, it is one up for maintenance, so the
17 evidence discussion is a little bit different
18 than if we were looking at maybe a process
19 measure.

20 And, we'll get to a little bit of the
21 specification. I think that on the face it,
22 reducing preventable avoidable complications

1 obviously is very much directed towards patients
2 and would be appropriate.

3 I think the question for the committee
4 that we'll have to decide is whether or not as
5 specified this measure actually accomplishes
6 that.

7 CO-CHAIR LANG: According to the NQF
8 algorithm for evidence, this is eligible for a
9 pass rating, as the underlying rationale is the
10 same since the last NQF endorsement review.

11 So, we don't have to vote, if the
12 committee agrees.

13 Okay, seeing no objection, we'll
14 proceed to performance gap.

15 Oh, please?

16 DR. YEALY: I guess I'm still a little
17 bit troubled by on the evidentiary basis. It
18 looks to me the PACs would be largely dominated
19 by inpatient care, yet, what's included is both
20 inpatient and outpatient.

21 And, there's got to be an overwhelming
22 ascertainment bias because we just simply don't

1 look, you know, people don't get pressure sore
2 evaluations at home every day. They don't get
3 the pressure sores either, but the truth is, we
4 don't look anywhere near as closely as say with
5 DVT and phlebitis, whatever else you pick up.

6 And so, I'm struggling here to see,
7 this does -- this looks like a hospital-based
8 measure wrapped in another set of clothing. Not
9 that there's anything wrong with trying to cut
10 back on complications.

11 The other problem I have is that the
12 PACs aren't weighted, so respiratory failure and
13 phlebitis count the same. They strike me as
14 dramatically different preventable events. One
15 is, you know, unfortunate, but not a particularly
16 big deal. The other one is, you know, awful and
17 potentially life-threatening.

18 And so, that's why I have concerns.
19 I wasn't part of the previous evaluation of this,
20 it's just, on face value, it looks -- it doesn't
21 seem right to me.

22 CO-CHAIR LANG: Would the developers

1 wish to elaborate further on the measure?

2 DR. RASTOGI: So, regarding the rating
3 of the PACs, we agree that all PACs are equally
4 rated and the whole idea here is that if a
5 patient develops one complication, it quite often
6 sets off a roller coaster and has many, many
7 complications.

8 So then, that particular patient will
9 still be counted as a yes or a no, so the
10 complication is there.

11 When you're measuring performance of
12 providers, for example, say physicians managing
13 the pneumonia condition, then we will hold them
14 accountable. But then, what percentage of their
15 patients had these complications?

16 If it is one patient who went bad and
17 had a lot of bad complication, then it would not
18 adversely affect them.

19 However, if they are consistently bad
20 and many of their patients or a majority of them
21 had potentially avoidable complications, then
22 they will stick out as an outlier.

1 So, it's a relative performance
2 measure and that's everybody would be measured
3 according to the same yardstick.

4 DR. LAMPONE: I just wanted to add a
5 comment on that.

6 As you look at our elder population,
7 more and more of those patients are being treated
8 in the home setting and there may be less
9 opportunity to impact, intervene or prevent some
10 of these complications in the home.

11 When you get into a lot of assisted
12 living facilities where you have large
13 populations of these, I think those same problems
14 exist, less so in skilled nursing facilities.

15 But, I think you'll have a difficulty
16 and you may find there are cohorts of a medical
17 practice that treat many of these patients in an
18 assisted living or in the home.

19 So, you may have some skewed data in
20 that agreement.

21 DR. YEALY: You know, again, that
22 reply strengthens my concerns.

1 So, I'll give you two physicians, one
2 who surveils every day for phlebitis and provides
3 wonderful care, the other one does nothing and
4 has they both have four events happen, one has
5 four respiratory failures, the other one has four
6 phlebitis, they get patted on the head and they
7 look the same by this measure.

8 And, yet, they're wildly different
9 levels of care and quality. And I'm just not
10 certain that, as constructed, this dichotomous
11 approach can give us the feedback that we need.

12 DR. O'BRIEN: I suspect that under the
13 scientific acceptability, that will be the
14 opportunity for talking about that.

15 There are other concerns, I think,
16 also around the way this is specified.

17 CO-CHAIR LANG: Todd?

18 DR. DORMAN: Just a simple question of
19 clarity.

20 Is mortality considered a PAC?

21 DR. RASTOGI: No, we don't
22 specifically look for that. Mortality is a

1 separate measure.

2 DR. DORMAN: Although the list of PACs
3 that are included, I'm dubious that you can die
4 without having one of them.

5 DR. RASTOGI: That's right. We don't
6 count it separately, but if the patient had, say,
7 respiratory failure and died, then the
8 respiratory failure would be picked up as a PAC.

9 DR. DORMAN: I asked related to the
10 home mortality. So, we just discussed the
11 attempt to improve quality by outpatient home
12 management of pneumonia in which case I wonder
13 how all of these would be picked up, coded and
14 that's why I asked.

15 DR. RASTOGI: Right, and our measure
16 is tested at the below 65 population. So, yes,
17 these are valid concerns for the entity.

18 DR. NISHIMI: Is there anything else
19 specifically related to evidence? We've kind of
20 skipped ahead a little, so I'm trying to bring us
21 back a little bit.

22 And, there didn't seem to be any

1 indication to vote. Is that the Chair's
2 assessment on evidence?

3 CO-CHAIR LANG: My understanding is
4 that, based on the NQF algorithms, this is
5 eligible for a pass rating.

6 DR. NISHIMI: Right.

7 CO-CHAIR LANG: But, does the
8 committee believe that it's appropriate to vote
9 on the evidence? Yes? No? Maybe? No? No.

10 We'll proceed then to performance gap.

11 DR. O'BRIEN: The developers don't
12 present actual gap. They do present some
13 performance scores for 82 facilities and 170
14 providers that show a median performance for --
15 in the 60 percent range, with an interquartile
16 range that varies from in the 40s up to the 70s
17 to 80s.

18 There's not that I could find any
19 analysis related to gender, socioeconomic status,
20 race or ethnicity or geographic differences.

21 MS. WEST: A majority of the data that
22 were provided for gap were related to the

1 pneumonia itself and not specific to the PACs.
2 That was one of the big discussion points that we
3 had during our work group meeting.

4 DR. SCHINDLER: And, Chana, I don't
5 know if this gets at the same point, but is there
6 or are there data -- I guess I'm a little unclear
7 of why we're looking at PACs only in the context
8 of pneumonia. And, maybe I missed that in the
9 beginning.

10 But do patients with pneumonia look
11 wildly different from other acutely ill patients
12 in terms of their PAC rate?

13 MS. WEST: Not that we saw in any of
14 the data that were provided. So, that might be a
15 question for the developer and anything that they
16 saw that the did not provide.

17 DR. O'BRIEN: And, it might come to
18 usability, what I read, the majority of the PACs
19 that are reported are actually PACs associated
20 things like bypass surgery, so aren't even
21 specific to this diagnosis.

22 DR. NISHIMI: Does the developer want

1 to address those comments?

2 DR. RASTOGI: So, yes, maybe I'm
3 unclear about the question. Is that related to
4 the performance issues?

5 DR. O'BRIEN: So, I think the question
6 was related to why PACs associated with pneumonia
7 as opposed to PACs in general or other diagnoses?
8 What's the reason to tie it to pneumonia?

9 DR. RASTOGI: Right, right. So, our
10 potentially avoidable complications go beyond
11 just direct pneumonia PACs.

12 So, we mention that, you know,
13 appropriate use antibiotics and up-front care can
14 reduce some of the respiratory kind of
15 complications that are related to pneumonia.

16 And then, the type 2 PACs which are
17 often are seen because of, you know, say, the
18 pressure sores, line sepsis and all that could be
19 avoided by better processes and care.

20 DR. DIGIOVINE: I think that --

21 DR. DE BRANTES: This is Francois de
22 Brantes.

1 If the question is about whether or
2 not there are other measures for similar
3 pulmonary conditions or other pulmonary
4 conditions, other measures of avoidable
5 complications, the answer is yes.

6 We have measures of potentially
7 avoidable complications for dozens of conditions,
8 both chronic, acute and procedural. And, we've
9 submitted those in different stages to the
10 National Quality Forum for review.

11 DR. DIGIOVINE: So, I guess two
12 comments.

13 One is, the data seems or the
14 submission seems to argue that there's a
15 performance gap because there's variability.

16 But, as we've pointed out, the
17 patients are not required to be admitted for
18 pneumonia. So, I think there's going to be
19 natural variability because some patients are
20 going to be outpatient and some are going to be
21 inpatient.

22 Also, a lot, I think, I know James

1 will get to this later, but a lot of these PACs
2 are things that I think a lot of us believe are
3 present on admission.

4 So, a patient who gets -- you said you
5 excluded patients with septic shock, but my
6 understanding is, as long as septic shock isn't
7 the first diagnosis, you're not excluding septic
8 shock.

9 And so, I think a lot of the
10 variability also could just be based in
11 variability in the way people code and the way
12 people abstract charts.

13 So, I'm not sure what you're positing
14 as the performance gap.

15 DR. RASTOGI: So, coming back to the
16 septic shock situation, yes, if the patient, and
17 as the previous discussor also explained, that
18 the claims data, the discharge diagnosis is the
19 one that the hospitals code and report on the
20 claims.

21 So, if the discharge diagnosis was
22 changed to septic shock, then that patient will

1 fall out of the denominator as well. It would
2 not be considered as a pneumonia admission, but
3 maybe the patient was admitted and it was only
4 the in sepsis at the time of admission.

5 DR. DIGIOVINE: But, you're describing
6 administrative data as if it means that the first
7 thing we write on a code sheet is the only
8 diagnosis and everything else is a complication.
9 And, that's not the way we code charts, certainly
10 not the way physicians diagnose and treat.

11 So, on any given patient, I might say
12 pneumonia with shock and then the second patient
13 I might say septic shock from pneumonia. Those
14 are not different.

15 DR. RASTOGI: So, the hospital -- the
16 septic shock patient will most likely be
17 hospitalized and then the hospital diagnosis will
18 determine whether the patient will be kept in or
19 not.

20 Hospitals alter the claims, the
21 admitting diagnosis is often changed to be the --
22 to be modified and then the discharge diagnosis

1 is what was the final discussion during that
2 admission, whatever the physicians said was the
3 real reason that the patient got hospitalized.

4 If the septic shock developed while
5 the patient was in the hospital, admitted for
6 pneumonia and then eventually progress and went
7 south, then the septic shock would not be the
8 discharge diagnosis.

9 CO-CHAIR LANG: Are there additional
10 comments or questions for the developers
11 regarding performance gaps specifically?

12 Seeing none, we will proceed to vote
13 on performance gap.

14 MS. AMIRAULT: Performance gap for
15 Measure 0708, one being high, two moderate, three
16 low or four insufficient.

17 Two high, two moderate, 13 low and six
18 insufficient.

19 So, this does not pass.

20 MS. BAL: And, as mentioned earlier,
21 since this is a maintenance measure, you can
22 choose to move forward with reserve status, but

1 you heard the stipulations and it's really up to
2 you, your decision to make.

3 CO-CHAIR LANG: Let's take a hand
4 vote. The vote is whether to proceed with the
5 understanding that if we do consider -- if we do
6 continue to consider this measure, it would be a
7 reserve status or to suspend further
8 consideration of the measure, in which case, the
9 measure would have failed.

10 Okay, so all those in favor of
11 continuing to consider the measure with the
12 understanding it may proceed to reserve status,
13 please raise your hands.

14 Those who would wish to suspend
15 further consideration of the measure?

16 Anyone who has not voted or who
17 abstained?

18 I will note that among those present
19 here, the vote was unanimous for option to, to
20 not consider the measure further.

21 DR. NISHIMI: There was one vote to
22 continue by electronic submission.

1 CO-CHAIR LANG: Give us just a minute
2 here.

3 All right, the schedule says that
4 we'll take a break at 10:15. We're a little --
5 we're going to take a break now until 10:15 and
6 then we will reconvene.

7 Thank you.

8 (Whereupon, the above-entitled matter
9 went off the record at 10:03 a.m. and resumed at
10 10:21 a.m.)

11 CO-CHAIR BRATZLER: All right, let's go
12 ahead and get started.

13 So the one thing that we need to do
14 that we didn't complete from the initial
15 conversation this morning is talk about
16 discussion of the related and completing
17 measures. So staff has pulled the list here of
18 all the measures that we've reviewed since
19 yesterday on asthma. And there are quite a few
20 of them. There are nine different measures.

21 I can read the numbers if you want.
22 But I think the gist of the conversation is about

1 are there any other areas of these metrics that
2 we want to relate to the developers to think
3 about harmonizing or recognizing some competition
4 between the measures.

5 So two issues that have already been
6 addressed multiple times by this group are that
7 some of the measures have different data sources,
8 some of them measure different populations of
9 patients. Now there's been a fairly consistent
10 message about asking the developers to look at
11 harmonizing on age ranges where appropriate
12 because there's a number of these measures that
13 have had different age ranges.

14 But any other issues that this
15 committee -- based on the asthma measures that
16 we've talked about -- would like to send back to
17 the developers as consideration to work with
18 other developers around some harmonization or
19 alignments.

20 Yes, Bill.

21 DR. GLOMB: So you mentioned -- you
22 mentioned the data sourcing and you mentioned the

1 age range harmonization. The only other one that
2 I think that I'd consider is the diagnosis. What
3 constitutes the diagnosis of asthma.

4 We have had -- we have had single, you
5 know, a single diagnosis. We've had two-plus
6 diagnoses. It would be nice if we could come up
7 with a standardization for what is chronic
8 persistent asthma, what is asthma, what is not
9 asthma.

10 CO-CHAIR BRATZLER: Yeah. So
11 harmonization of the denominators in certain ways
12 of making sure we have consistency of the codes
13 used to identify, particularly things like
14 persistent asthma which the codes are sometimes
15 difficult to -- other things which you recall
16 from the past two days now in discussions of
17 asthma metrics?

18 CO-CHAIR LANG: I don't know if you had
19 mentioned it, but did we have something come up
20 with risk adjustment for these folks?

21 DR. NISHIMI: You didn't have a
22 standard recommendation. You discussed risk

1 adjustment for some. Some of them were, you
2 know, the process measures and so it didn't
3 really come up.

4 CO-CHAIR LANG: Okay.

5 DR. NISHIMI: We can make a general
6 comment that those that do have the risk
7 adjustment, they need to take a look at
8 standardizing the approach for risk adjustment.

9 Is that what you're indicating?

10 CO-CHAIR LANG: Sure.

11 DR. NISHIMI: Anything else? Okay.

12 CO-CHAIR BRATZLER: I'm trying to walk
13 through the list just to make sure I recognize
14 all of the measures. We have a host of different
15 measures by different developers, different
16 settings, so.

17 Anything else that we need to talk
18 about that we want to bring back to the
19 developers -- and then all of that information
20 would then come back to us as a committee on one
21 of our conference calls in the future.

22 DR. NISHIMI: Okay.

1 CO-CHAIR BRATZLER: Ready to move
2 forward?

3 DR. NISHIMI: Yes.

4 CO-CHAIR BRATZLER: Do you want to take
5 it or do you want me to take it? I'll go ahead
6 with this.

7 Okay. So the next measure on the list
8 is 0035. It's Pediatric ICU Unplanned
9 Readmission Rate by Virtual PICU Systems. On the
10 phone, hopefully, is Matt Scanlon to do an
11 introduction of Measure 0035. I'm sorry, 0335.
12 I'm sorry.

13 MS. BAL: First, I would just like to
14 mention that Mitch Harris is also conflicted on
15 these -- all three of these PICU measures, just
16 so everyone knows. And that -- Kathy, could you
17 see if Matt from the PICU group is on the phone,
18 or anyone else from PICU -- Virtual PICU Systems?

19 THE OPERATOR: Matt has not joined yet.
20 And I don't see anyone else on the line.

21 CO-CHAIR BRATZLER: So what we'll do is
22 we'll -- so as noted, Matt may be expecting the

1 call to start at 10:30, so that may be why he is
2 not here yet. Why don't we go ahead, either
3 David or Bill, and discuss evidence, and then
4 we'll go from there.

5 DR. GLOMB: Okay. I'll just go ahead
6 and start if you're okay with that, David. Then
7 I'll let --

8 DR. STOCKWELL: Yeah, sure.

9 DR. GLOMB: I will just -- let me kind
10 of do a little bit of a mini-discussion of our
11 presentation since we don't have them on yet.

12 Again, this is about PICU unplanned
13 readmission rates, looking at the total number of
14 patients requiring unscheduled readmission to the
15 ICU within 24 hours of discharge or transfer.
16 The rationale is that this measure be used in
17 conjunction with one of the other measures we'll
18 discuss, 0334, which is severity-adjusted length
19 of stay. Because theoretically you could game
20 your length of stay measurements by prematurely
21 discharging patients and then they get readmitted
22 because they weren't really ready to go out the

1 first time. And this would balance that measure
2 out.

3 The numerator -- it's a fairly simple
4 math equation. It's the number of unplanned
5 readmissions within 24 hours after discharge or
6 transfer from the PICU per 100 patients. And
7 it's in children only under 18 years of age.
8 Excluded are all above 18 years of age.

9 DR. SCANLON: I'm sorry to interrupt.
10 This is Matt Scanlon. I just wanted to let you
11 know I have joined the call.

12 CO-CHAIR BRATZLER: Thanks, Matt.

13 DR. SCANLON: Okay.

14 CO-CHAIR BRATZLER: We're going to go
15 ahead and talk evidence and then we'll let you --

16 DR. SCANLON: Perfect.

17 CO-CHAIR BRATZLER: -- give a little
18 brief introduction to the metric.

19 DR. GLOMB: I'm going to throw an
20 asterisk in and ask for discussion by the
21 committee. This is termed as an outcome measure,
22 readmission being -- is it really an outcome

1 measure or is it a process failure, that's a
2 question that I have for this.

3 This measure was originally endorsed
4 eight years ago and it's up for revisiting at
5 this time.

6 So some of the evidence, outcome
7 measure of unscheduled readmission within 24
8 hours, indirectly measures process, those
9 decisions related to discharging the patient
10 while directly measuring a PICU resource
11 utilization due to unplanned readmissions. So in
12 that sense I suppose it's an outcome, but not
13 necessarily a patient-directed outcome.

14 The developer, again, would like to
15 balance this measure along with 0334 to make sure
16 that those -- that those are accurate
17 measurements. And I think that's appropriate.

18 One of the questions for the
19 committee, for our work group was, was there at
20 least one thing that the provider could do to
21 change based on the measured result? And there
22 really wasn't anything identified within this, so

1 obviously it's thought that an unplanned
2 readmission is a failure and, you know, maybe
3 they shouldn't have been discharged yet or
4 there's something missing from the process of
5 transferring the patient to a step-down unit or
6 the ward. And there the developer tests that the
7 rationale and evidence of the outcome have not
8 changed since this was last endorsed for review.

9 And so that's one of the things we
10 need to decide is whether or not the evidence
11 basis has changed and if there's any need for
12 repeat discussion or vote on the evidence.

13 CO-CHAIR BRATZLER: So, David, do you
14 have anything to add to Bill's introduction there
15 on evidence?

16 DR. STOCKWELL: No. I would just
17 suggest that if used as a measure on its own it
18 probably doesn't make sense, but paired with the
19 other measure as a compliance -- however that
20 gets combined, I'm still not clear how that
21 actually happens or what the process part is.
22 But standing on its own it's probably less of a

1 useful measure and you may not be able to make
2 changes for it. But as used as a balancing
3 measure to tell you whether or not you are overly
4 aggressively discharging your patients out of the
5 ICU, it's much more helpful in that regard.

6 CO-CHAIR BRATZLER: Okay. So what I'm
7 going to do at this point is ask -- before we
8 vote on or decide whether we are going to vote on
9 evidence or not, I'm going to let Matt give a
10 brief introduction to the measure, which we
11 didn't do before we started that conversation.

12 So, Matt, if you want to go ahead for
13 two or three minutes.

14 DR. SCANLON: Sure. And I apologize
15 for being late. I'm working in the ICU this
16 morning, so it's been juggling things.

17 So as the first speaker that I caught
18 mentioned, the unplanned readmission measure
19 metric was first introduced eight years ago and
20 has been reapproved once in its history. And the
21 intent has always been to use it as a balancing
22 measure to the issue of length of stay.

1 In the ICU -- in the pediatric ICU
2 world, at least using the VPS data, there is a
3 wide range in length of stay between
4 organizations. But one of the factors that could
5 influence that is the potential for gaming by
6 prematurely discharging patients and then having
7 to readmit them within a short time period.

8 When the measure was originally
9 created, the Joint Commission actually had a
10 metric of unplanned readmission at 48 hours.
11 They've since dropped that. We felt that that
12 was not necessarily sensitive enough to reflect a
13 premature discharge, and so we developed a
14 measure. And there was some literature that
15 suggests 24 hours was a reasonable place to look
16 at. And that was the foundation of that.

17 We have found -- and I apologize
18 because this was done in response to the
19 questions we received, so it's not in the
20 original submission but it's available to provide
21 -- that there was a statistically significant
22 correlation with a Pearson correlation

1 coefficient of negative .398 between unplanned
2 readmissions and severity-adjusted length of
3 stay. That is, organizations that have a shorter
4 length of stay also have higher rates of
5 unplanned readmission, which is not necessarily
6 surprising and is exactly why we felt these two
7 measures should go hand in hand.

8 So I can speak more to specific
9 questions. But let me stop there and let you
10 take it from there.

11 CO-CHAIR BRATZLER: All right. Thank
12 you, Matt.

13 Then before we go forward with our
14 conversation about evidence I wanted to ask NQF
15 staff that I know it's been mentioned that there
16 is a formal pairing process of saying that one
17 measure doesn't stand without the other. Can you
18 tell me about that?

19 DR. NISHIMI: So in NQF's internal
20 system and in the public-facing material that's
21 exactly what is said. As with other measures, it
22 doesn't prevent, you know, external implementers

1 from doing what they want to do.

2 In this case, however, because VPS
3 holds the software and there's a proprietary
4 mechanism, they in effect, you know, control much
5 more tightly than it would for any other measure
6 the fact that they are paired. But in terms of
7 our public-facing information it's very clear
8 that they're paired.

9 DR. DiGIOVINE: Can I just ask on that?
10 I'm just noticing on the front of the first page
11 of our measure it specifically when asked -- the
12 statement is if paired, what is the reason the
13 other measure is included? And it says not
14 applicable. And if it says if this measure is
15 paired or grouped give the NQF number and title,
16 and it's blank.

17 DR. SCANLON: So Matt Scanlon here.
18 And this is -- and if I misspeak, please, NQF
19 staffers, correct me, but the implications and
20 connotations of pairing, as I've been through
21 this for eight years, have changed over time.
22 And four years ago I don't remember a specific

1 reason but there was a reason at the NQF level
2 that they did not want to do a formal pairing.
3 So that's why we carried that forward. That was
4 not because we felt they were disassociated. In
5 fact, the language we use in the measure suggests
6 otherwise.

7 But again, there was some technical
8 reason that at the time that term pairing was
9 felt to be inappropriate. And I can't speak
10 further to what that rationale was.

11 DR. NISHIMI: Yeah, and I'm afraid I
12 can't help either because I wasn't here. But I
13 can tell you that in the current internal, what
14 we refer to as OPUS, and the external Quality
15 Positioning System search you will see that it's
16 paired.

17 DR. DiGIOVINE: So you are saying it --
18 despite what it says on here, these actually are
19 paired measures.

20 DR. NISHIMI: It indicates that this
21 measure should be used with 0334, yes.

22 MS. BAL: Also a clarification. We

1 started that process after the form was
2 submitted, so that's why. The way that it was
3 submitted it was not paired at the time. But we
4 are in the -- we've processed it to be paired
5 now.

6 CO-CHAIR LANG: We have had other
7 measures and we will have this afternoon to reach
8 that line, was made out with the other measure
9 listed with the number.

10 CO-CHAIR BRATZLER: So at this point
11 we've had a conversation about evidence. Is
12 there any other discussion of evidence? This is
13 a already-endorsed measure, so it's a maintenance
14 measure so we do not have to vote on evidence if
15 the committee agrees.

16 So how many -- any other discussion?

17 (No response.)

18 CO-CHAIR BRATZLER: Then how many
19 committee -- anybody raise your hand if you think
20 we need to re-vote the evidence for the measure.

21 (No response.)

22 CO-CHAIR BRATZLER: Okay, seeing none,

1 we will go ahead with discussion of gap.

2 DR. GLOMB: David, do you want to take
3 the gap discussion?

4 DR. STOCKWELL: Yes. Yeah, sure.

5 So there are recognizable gaps within
6 VPS. The range is between zero and 1.6 percent
7 of patients. And so that I think will satisfy
8 the thing that was concerning that was mentioned
9 just a bit ago was that there hadn't been any
10 real change noted over time. But I know that
11 that's something that we will talk about later.

12 And also, just jumping to disparities,
13 there were not really any disparities noted in
14 this measure from VPS. So we will note it in the
15 paired measure a little bit later.

16 DR. GLOMB: Yeah, I just want to add,
17 the only thing that came up disparities-wise had
18 to do with whether a child had insurance or had
19 no insurance whatsoever. And the uninsured kids
20 were sicker when they got there. Their lengths
21 of stays were shorter and their mortalities were
22 probably higher. That was the only thing that

1 stuck out. And not surprising.

2 CO-CHAIR BRATZLER: So I just have to
3 ask the question, is zero to 1.67 percent that
4 substantial of a gap between PICUs? It seems
5 like a fairly narrow range.

6 DR. STOCKWELL: So I guess I would say
7 that it seems that there is -- and, yes, this is
8 evidence based on what Matt just told us again
9 this morning -- but if there is a reasonable
10 spread, enough to show that there's a moderate
11 correlation, negative correlation between the two
12 measures then that, to me, would say that it
13 would be at least meaningful enough to show that
14 there is some gap.

15 CO-CHAIR BRATZLER: I think Tom has --

16 DR. LAMPONE: And I just wanted to
17 clarify, William had made a comment on
18 disparities. And if I heard you correctly, there
19 was a disparity between insured and uninsured.
20 Uninsured presented with more advanced or more
21 complicated disease, but had a shorter length of
22 stay and had a higher mortality.

1 DR. GLOMB: Not necessarily related.
2 Those last two are not necessarily related.
3 That's not proven by the evidence. So that's not
4 --

5 DR. LAMPONE: Okay.

6 DR. GLOMB: -- clear to us from the
7 evidence.

8 DR. LAMPONE: Okay.

9 DR. GLOMB: And you'll see that same
10 statistic throughout all three of these measures
11 we're about to talk about.

12 DR. LAMPONE: Okay. And did we see any
13 statistics that looked at readmission to the ICU
14 in those populations.

15 DR. GLOMB: Yes. Between insured and
16 uninsured.

17 DR. LAMPONE: Okay. So there was a
18 disparity there with the --

19 DR. GLOMB: There was a disparity
20 there.

21 DR. LAMPONE: -- base of the measure
22 which is looking at readmissions.

1 DR. GLOMB: That's correct.

2 DR. LAMPONE: Okay.

3 DR. GLOMB: That's correct. It wasn't
4 huge but it was statistically significant.

5 DR. DiGIOVINE: I think throughout this
6 I'm going to be struggling with the idea that
7 this is -- I think we are saying this isn't an
8 important measure by itself but it's important
9 because it's balancing something else, which I
10 struggle with.

11 And I guess I just wonder whether the
12 developer has ever thought to do what I think we
13 still do, which is if the patient is readmitted
14 to the ICU within 24 hours, just to count that
15 all as the same admission and then make their
16 length of stay admission A plus admission B and
17 use one measure as the quality measure around
18 length of stay.

19 DR. SCANLON: So there's a couple
20 factors there. One is that not all readmissions
21 to the ICU can be viewed as a breakdown in care
22 or as management-related. Some are calculated

1 decisions that patients are transferred and then
2 for a change in the condition, unrelated, or
3 maybe because of a bed crisis within a unit they
4 move a patient out with full knowledge that the
5 patient is coming back, which is why we have been
6 very careful in the software and in the data
7 dictionary to break down what the definition of
8 scheduled versus unscheduled is.

9 I think we also know anecdotally, and
10 this was true at the time these measures were
11 originally developed, that some of the centers
12 that had very short lengths of stay admitted that
13 they pushed kids out to keep those numbers low.
14 And so I think the issue is -- I don't know that
15 we could presume to just staple all within 24
16 hours together. And, you know, I guess we could
17 say unscheduled readmissions should be compiled
18 onto the original one.

19 But having said that, that's not been
20 what's been described at least in our review of
21 the literature. And so that would be really
22 almost creating a new metric for length of stay

1 which is -- for ICU length of stay which I don't
2 know that we -- that would be breaking new
3 ground. That doesn't mean we shouldn't do it,
4 but I think that would take a lot more reflection
5 and investigation of just the validity of that,
6 never mind how the community would view that.

7 CO-CHAIR BRATZLER: So back in the
8 room. Edgar?

9 DR. JIMENEZ: Yes. Just -- I'm
10 completely in agreement with the statement they
11 made.

12 But one more thing is that we have
13 been seeing readmission rates that are potential
14 problems with even the hand-off of patients, you
15 know, where that's not appropriate, you know,
16 transference of care. So it's something that we
17 are paying attention very closely.

18 CO-CHAIR BRATZLER: James?

19 DR. O'BRIEN: I'm wondering -- and the
20 developer maybe can comment about this, in the
21 adult ICU literature there's certainly
22 appreciation for a combined end point of ICU-free

1 days, which is days alive not in the ICU, which
2 does incorporate both the possibility of people
3 being readmitted to the ICU, how long they're in
4 the ICU, and mortality all in one measure. I
5 don't -- if you can comment whether or not that's
6 reached the pediatric literature?

7 DR. SCANLON: Not that I'm aware of.
8 And I think, at least from the standpoint of
9 measure development one of the challenges is that
10 the data from administrative data sets is often
11 problematic because of the lack of specificity
12 about hours spent in the ICU and rather making
13 determinations by midnight census as to where a
14 patient is. You know, if you could admit a kid
15 to the ICU, transfer them out, admit them and
16 transfer them out again, and if all that happened
17 within a single day it wouldn't show as an ICU
18 admission at all.

19 The VPS is a clinical database. And
20 because we don't have currently the hospital days
21 but rather just the ICU days, it was technically
22 not feasible without trying to use the data

1 source that we felt was more problematic. And
2 again, to my knowledge, although certainly
3 there's some smart people on your panel who may
4 feel otherwise, I have not seen the ICU-free days
5 make it into the pediatric literature very far.

6 CO-CHAIR BRATZLER: So I'm going to
7 pull us back just a little bit. So we've made
8 several suggestions that almost sound like
9 material changes to measures that would require
10 us to go through the whole process that we went
11 through yesterday about whether a whole new
12 measure should be developed. So I'm going to
13 pull us back to discussing the measure that we
14 are presented with, which is what we have to
15 decide today.

16 So are there any other discussions
17 about gap? Yes, Bruno.

18 DR. DiGIOVINE: Just let me just then
19 clarify. Everything we're going to ask, are you
20 asking is there a performance gap in, for
21 example, in readmissions as a standalone measure?
22 Or are we asking is there a performance gap for

1 length of stay for which readmissions would be an
2 important thing to look at?

3 DR. NISHIMI: They stand alone.

4 CO-CHAIR BRATZLER: Any other questions
5 or clarifications?

6 (No response.)

7 CO-CHAIR BRATZLER: Okay. Let's move
8 forward and vote on gap.

9 MS. AMIRAULT: Performance gap for
10 Measure 0335, 1 being high, 2 moderate, 3 low, or
11 4 insufficient.

12 (Voting.)

13 MS. BAL: Ella, could you please resend
14 your vote.

15 (Voting.)

16 MS. AMIRAULT: Zero high, 12 moderate,
17 eight low, one insufficient.

18 We're going to do a re-vote.

19 DR. STOCKWELL: Does that mean even for
20 the folks on the phone?

21 CO-CHAIR BRATZLER: Yes.

22 DR. NISHIMI: No, they're fine. No, we

1 have the phone votes. So, we're looking for 22.

2 MS. BAL: Just give us one second.

3 MS. AMIRAULT: Okay, performance gap
4 for 0335, 1 being high, 2 moderate, 3 low, or 4
5 insufficient.

6 (Voting.)

7 MS. AMIRAULT: Zero high, 13 moderate,
8 eight low and one insufficient.

9 Based on the percentages you have gray
10 zone. And we'll move along.

11 CO-CHAIR BRATZLER: Okay, so we'll go
12 ahead with the conversation. The next will be
13 reliability.

14 DR. STOCKWELL: So reliability that the
15 numerator is total number of -- all of this is
16 stuff you would expect -- total number of
17 unplanned readmissions within 24 hours of
18 discharge or transfer from the ICU. The
19 denominator is 100 PICU discharges for those less
20 than 18 years of age. And then the exclusions
21 are older than 18 -- 18 and older.

22 Data selection is essentially

1 electronic clinical data as well as some
2 administrative data. And during our discussions
3 there weren't concerns about the reliability for
4 the specifications and for the testing. There is
5 not new data. The developer noted that a
6 separate proportion using previously-established
7 methods, therefore no further reliability
8 assessment is indicated.

9 CO-CHAIR BRATZLER: Any other --

10 DR. STOCKWELL: I don't.

11 CO-CHAIR BRATZLER: Yes?

12 DR. LAMPONE: This is for the
13 developer. When you look at the data, what
14 percentage of it is administrative? Could you
15 tell us?

16 DR. SCANLON: Zero.

17 DR. LAMPONE: Okay. So it's all --

18 DR. SCANLON: We --

19 DR. STOCKWELL: I'm sorry about that.

20 DR. SCANLON: I'm sorry.

21 DR. STOCKWELL: Sorry Matt, that was
22 just -- this is the challenge of looking at this

1 as an individual, versus some of the other ones
2 that we are going to discuss in a little bit. So
3 that's my fault, sorry about that.

4 CO-CHAIR BRATZLER: All right, so go
5 ahead.

6 DR. SCANLON: Oh, I'm sorry, is there
7 a question I didn't answer? I'm just --

8 DR. LAMPONE: So none of the data is --
9 it's all administrative data?

10 DR. SCANLON: No. None of the data is
11 administrative.

12 DR. LAMPONE: Okay.

13 DR. SCANLON: No. It is clinical data.
14 It's entered by clinicians. We have, to the
15 minute, times of entry and departure from the
16 ICU, which is why we can provide very detailed
17 calculations.

18 CO-CHAIR BRATZLER: So just to clarify,
19 because there's no new reliability data
20 presented, because the measure is broadly in use
21 and already endorsed, we don't have to vote on
22 reliability either. We can make the decision to

1 move on with the conversation about validity.

2 So anyone who wants us to go ahead and
3 vote on reliability, raise your hand.

4 (No response.)

5 CO-CHAIR BRATZLER: Seeing none, we
6 will go ahead and discuss validity.

7 DR. GLOMB: I'll go ahead and talk
8 about that.

9 Again, under the validity testing I
10 guess one of the -- the question before our
11 committee is, are the specifications consistent
12 with the evidence. And I guess I have a counter-
13 question. And that is, does unscheduled
14 readmission equal poor quality of care.

15 The assumption is there, intuitively
16 suggested. I don't think that I would oppose
17 that. I just wonder whether the evidence is there
18 and, therefore, that would mean that the validity
19 would be in question if it's not. I know we
20 voted on the evidence not being necessary. I
21 just think we're making a jump looking at this
22 measure in isolation.

1 CO-CHAIR BRATZLER: Chana and then
2 we'll go to David.

3 MS. WEST: So I was looking through all
4 the documentation and I didn't see a clear
5 indication on what they're characterizing as
6 planned versus unplanned in terms of the PICU
7 admission, so.

8 CO-CHAIR BRATZLER: Matt, can you
9 comment on that, planned versus unplanned?

10 DR. SCANLON: Absolutely. The
11 operational definition that we -- in fact is part
12 of our ongoing inter-rater reliability -- was the
13 admission to the ICU, whether it's an admission
14 or a readmission, known about 12 hours before it
15 occurred?

16 So, for example, if we have a kid that
17 12 hours before they're coming to the ICU that
18 someone calls and says we need a bed for this,
19 that reflects that this is a conscious choice.
20 It's not a -- either a deteriorating child or a
21 child that was prematurely transferred out and
22 needs to come crashing back to the ICU.

1 So while you could argue that the 12-
2 hour window of knowledge -- the foreknowledge
3 about a child is arbitrary, there was some
4 literature -- and I apologize, I don't have the
5 reference in front of me -- that supported that.

6 And then as part of the ongoing -- as
7 I said, the inter-rater reliability -- that, as
8 well as the internal validation checks of the
9 software, we look for those. And anything that
10 seems out of -- potentially misclassified, so for
11 example, an unscheduled patient admission from
12 the PACU triggers a review at the site level to
13 make sure that that was properly classified.

14 MS. WEST: So this is reliant on manual
15 documentation that's then entered in the
16 software? Or am I missing something in the work
17 flow.

18 DR. SCANLON: No. So at the unit level
19 all ICUs know who is scheduled to come into their
20 ICU. That's part of running an ICU. And if we
21 know if they are essentially scheduled for a bed
22 greater than 12 hours in advance, that's treated

1 as a scheduled readmission versus an unplanned --
2 I'm sorry, a scheduled admission rather than an
3 unplanned admission.

4 Then separate from that is the
5 question of were they just discharged from the
6 ICU. So a patient who left the ICU could come
7 back to the ICU for either planned reasons, and
8 thus scheduled, or unplanned reasons which would
9 be the unplanned readmission to the ICU.

10 Did I answer your question?

11 MS. WEST: Yes and no. So the time
12 period that you're looking at -- and just, you
13 know, to clarify, I'm a NICU nurse so I
14 understand all the processes.

15 DR. SCANLON: Okay, sure.

16 MS. WEST: But in terms of the 12-hour
17 time frame that you're talking about, is there
18 some literature --

19 DR. SCANLON: Yes.

20 MS. WEST: -- that speaks to it being
21 a 12-hour time window or --

22 DR. SCANLON: Again, at the time of the

1 measure development there was a -- there was at
2 least one reference that we used. I don't -- and
3 I apologize, I don't recall what that is at this
4 point. But the rationale being that in our world
5 it's not uncommon for a patient to be discovered
6 to have a problem and they need an ICU bed. And
7 so the question was what cut-off would constitute
8 having enough warning to manage the patient.

9 And part of this also gets to the
10 larger macro issue of providing adequate nursing
11 and other resources to care for the patient. So
12 there's wide ranges -- just speaking of -- and
13 this may be a little off topic, but in our ICU in
14 Milwaukee, which is a 72-bed pediatric ICU with
15 three floors, our pure medical floor, the
16 unplanned -- or unplanned admission rate is 90
17 percent, meaning 90 percent of patients we don't
18 know they're coming 12 hours in advance, which is
19 a giant care issue because it's hard to plan for
20 a party if you don't know who's coming.

21 In the case of readmissions, we use
22 the same definition to say was this readmission

1 planned to come, in other words, an elective,
2 conscious decision, or not. And there was a
3 reference for the 12 hours. I apologize, I don't
4 recall what that is and would have to go back and
5 see if I can pull that for you.

6 CO-CHAIR LANG: So, Matt -- go ahead,
7 Bruno.

8 DR. DiGIOVINE: Sorry, David.

9 Matt, certainly in the adult world it
10 is not uncommon for people to hang out in our
11 wards for 12 hours waiting for a bed. Does that
12 not happen in pediatric hospitals?

13 DR. SCANLON: Oh yeah, oh definitely.
14 Wait, waiting for an ICU bed?

15 DR. DiGIOVINE: Yes.

16 DR. SCANLON: I think that that is --
17 I don't know that there's any -- there may be
18 literature. I'm not familiar with any literature
19 about that being an ongoing problem in the ICUs
20 in the pediatric world. Getting into the ICU is
21 not an issue. Getting out of the ICU back to the
22 floors is more of a problem in our world. And I

1 would defer to the other intensivists on the
2 panel to speak to that, the pediatric
3 intensivists.

4 DR. STOCKWELL: David Stockwell.
5 That's our experience as well.

6 CO-CHAIR LANG: Yeah. So, Matt, this
7 is David Lang. Appreciate your elaborating on
8 these issues. And I'm coming at this from -- I'm
9 not a critical care physician so I don't have the
10 kind of content expertise that others do around
11 the table. But looking at this from more of a
12 distance, I actually looked up and Googled the
13 definition of an intensive care unit.

14 It's a designated area of a hospital
15 facility dedicated to the care of patients who
16 are seriously ill.

17 It would seem to me -- I'll just throw
18 this out there because it's going to come up, you
19 know, later today we're dealing with other ICU
20 measures, and your measure is coupled with a
21 length of stay and a mortality measure -- it
22 would seem to me that the intensive care unit

1 setting in terms of what characterizes the
2 designated area, and also the nature of the
3 patients who are seriously ill would vary
4 substantially from the referral center to the
5 community hospital, yet they are both classified
6 as quote, unquote ICUs or, in your case, PICUs.

7 We have dealt with a number of
8 measures where we have adjusted for socio-
9 demographic factors. But how are you adjusting
10 for the case mix and other variation in, you
11 know, the different ICUs?

12 DR. SCANLON: So there's a couple
13 things. Let me -- that's a great question.
14 Thank you.

15 First of all, all the unplanned
16 readmissions are not risk adjusted, but the
17 length of stay measure and the mortality measure,
18 our SMR measure, are risk adjusted using peer-
19 reviewed published algorithms for severity of
20 illness to a handle for that aspect.

21 At the software level and in our
22 reports one of the things we can do is look at,

1 by organization type, other differences. So you
2 could look at SMR or unplanned readmission by
3 both hospital type and unit type. And we can
4 break that down by is this a community hospital,
5 an academic hospital, a free-standing children's
6 hospital. Granted, if people don't participate
7 in the software, which is how I can obtain data
8 and look at these differences, then obviously I
9 can't comment on an organization that isn't
10 submitting.

11 But what we do, if anything, is
12 stratify by like characteristics when we are
13 doing internal comparisons for benchmarking to
14 say, is a hospital or is a given ICU performing
15 on par with its peers? Because of, as you said,
16 the wide difference.

17 I think -- but as a larger community
18 of providing critical care services to children,
19 that begs the question of should you be in the
20 business at all? And that's more, it's not
21 necessarily -- well, I think it's actually very
22 germane to the NQF process because you can have

1 hospitals that open up -- a community hospital
2 that opens up a PICU just to say they have a
3 PICU, but that doesn't mean they should be caring
4 for sick kids there.

5 And so by looking at differences in
6 length of stay, unplanned readmissions and
7 mortality, you can start to say, is this
8 appropriate care for a child in that setting, or
9 should that care even be offered.

10 CO-CHAIR BRATZLER: Okay, so we're
11 discussing validity at this point. Any other --
12 yes, Bill.

13 DR. GLOMB: If I can ask the developer
14 to comment on one other aspect in the validity
15 section here that will apply to the next two as
16 well, it has to do with questions that were
17 raised at our work group meeting about the IRR
18 process.

19 DR. SCANLON: Yes.

20 DR. GLOMB: You didn't go into a lot of
21 detail.

22 DR. SCANLON: I can provide that today.

1 DR. GLOMB: If you could do that. And
2 what are you doing in terms of inter-rater
3 reliability ongoing testing, or was there --

4 DR. SCANLON: Oh, yeah, I can address
5 both of those.

6 So when a given center is coming on
7 board to use the software, first of all there's a
8 training process for data collectors. And the
9 data collectors have to be a nurse by background
10 or a physician, so that we're not having
11 administrative clerks, for example, extracting
12 charts.

13 The initial IRR process is that they
14 are provided with five patient records which are
15 de-identified. And then they do their
16 abstraction. And we review that compared to the
17 gold standard answers to see how they're doing.
18 And all sites that come on board have to do that
19 and meet a certain threshold of concordance
20 greater than 90 percent before they'd even be
21 allowed to start submitting data.

22 That process is then done quarterly

1 with each data submission where they do at least
2 one chart each quarter to make sure that they're
3 maintaining their quality. If there's any
4 question about the accuracy or the -- or if
5 there's essentially discordance in that, that
6 data is quarantined and they go through a re-
7 training process. And until they maintain -- get
8 their IRR up, there's no more flow of that data
9 into the data pool.

10 Right now our quarterly aggregate IRR
11 rates are greater than 96 percent. The last two
12 quarters are 96.81 and 97.76 percent.

13 So I don't know if that answers your
14 question.

15 DR. GLOMB: It does, thank you.

16 DR. SCANLON: Okay.

17 CO-CHAIR BRATZLER: All right. So any
18 other conversations or questions about validity?

19 (No response.)

20 CO-CHAIR BRATZLER: Okay. At this time
21 we will go ahead and vote.

22 MS. AMIRAULT: Validity for 0335, 1

1 being high, 2 moderate, 3 low, 4 insufficient.

2 (Voting.)

3 MS. AMIRAULT: Three high, 13 moderate,
4 five low, and zero insufficient. And based on
5 the percentage we can move along.

6 CO-CHAIR BRATZLER: Okay. So we move
7 to discussion of feasibility. And I did want to
8 note that, as all of you are aware, this is a
9 proprietary measure. So we'll go to the
10 discussion of feasibility.

11 DR. STOCKWELL: So it's David, I'm
12 going to start. The feasibility aspect of this is
13 really, as you've heard, a simple process of
14 gathering the data. There is I think low
15 feasibility questions in that regard.

16 The other item to consider in this
17 section is that proprietary item. And we
18 clarified during our work group meeting that
19 proprietary measures are certainly something that
20 the NQF allows. And I -- Matt can give you the
21 real numbers, but I know that the vast majority
22 of the ICUs across the country -- PICUs across

1 the country participate in this. And so I just -
2 - we note that challenge to feasibility.

3 But if you wanted to do this, I think
4 we have to consider this as a standalone measure.
5 If you wanted to calculate your own unplanned
6 readmissions rate, there are certainly no
7 barriers to doing that in and of itself.

8 CO-CHAIR BRATZLER: Anything to add,
9 Bill?

10 DR. GLOMB: No. Just that it is very
11 feasible for those who are members of the
12 software program, for which there are varying
13 fees. And more time intensive, perhaps more room
14 for variation in scoring for those who are not on
15 board, who would have to do a manual review.

16 CO-CHAIR BRATZLER: James.

17 DR. O'BRIEN: So, again, as an adult
18 intensivist, I would love to have somebody do
19 some of this data for us. And I don't think we
20 would ever be able to get the funding to have
21 somebody collect all this data.

22 Is this -- so I guess, obviously, this

1 is done a lot in pediatric ICUs. What percentage
2 of pediatric ICUs currently have this software?
3 And how much of this is chicken and egg. How
4 much do they have the software because NQF has
5 these measures, and how much did they have the
6 software before NQF had these measures.

7 DR. SCANLON: The software has been in
8 existence since roughly -- well, the first
9 generation of software started in 2004 and
10 predates the NQF -- our involvement with the NQF
11 measures. Or, I'm sorry, the creation of these
12 NQF measures.

13 The percent -- and I've got people
14 from VPS with me on the call, so someone may
15 email me -- but I don't know the percent of ICUs
16 in the nation that have it. We have over 100
17 ICUs -- pediatric ICUs participating. The
18 majority -- the overwhelming majority are U.S.
19 There's actually some pediatric ICUs in Saudi
20 Arabia and one Canadian ICU that are on board
21 also.

22 There is a separate software that's

1 being used by cardiac ICUs, or some cardiac ICUs.
2 And some cardiac ICUs -- pediatric cardiac ICUs
3 are actually using both software. But I would
4 say -- I would venture to say the majority of
5 pediatric ICUs is correct.

6 I just got an email. It's currently
7 135 sites are using the software. So I just
8 don't know the denominator of how many pediatric
9 ICUs there are in the U.S.

10 CO-CHAIR BRATZLER: So I'm just going
11 to throw out that this fee-based registry type
12 data submission is not uncommon. American College
13 of Surgeons, American College of Cardiology --
14 there's a host of it's fee-based where you
15 actually have to pay somebody to capture your own
16 data and then pay a fee to participate, so.

17 James?

18 DR. O'BRIEN: Does the developer have
19 any sense of what the cycle time is for
20 completing a patient record?

21 DR. SCANLON: I don't know. That
22 actually depends on how long the patient stays.

1 And it varies. There's a number of strategies.

2 We ask the patient to be registered in
3 the software shortly after admission. But then
4 completion, if a patient -- and as you look at
5 the length of stay data which is truncated at 30
6 days, it's not unheard for pediatric patients to
7 stay the better part of a year. Those are
8 outliers. But so while there's ongoing updating,
9 the patient is not submitted into the finalized
10 data pool until their clinical experience is
11 complete, be it through death or discharge.

12 So I can't give you a specific answer
13 because of the range of length of stay.

14 CO-CHAIR BRATZLER: Any other --

15 DR. SCANLON: Having said that, for
16 every discharge the data is then submitted within
17 a quarter.

18 CO-CHAIR BRATZLER: Any other
19 conversations about feasibility?

20 (No response.)

21 CO-CHAIR BRATZLER: We'll go ahead and
22 vote.

1 MS. AMIRAULT: Feasibility for 0335, 1
2 being high, 2 moderate, 3 low, or 4 insufficient.

3 (Voting.)

4 MS. AMIRAULT: Three high, 13 moderate,
5 five low and zero insufficient. Based on the
6 percentage we'll move along.

7 CO-CHAIR BRATZLER: And we'll go on to
8 discussion of usability and use.

9 DR. GLOMB: I'll go ahead and start off
10 usability.

11 I think this is probably where some of
12 our discussion came in our on work group.
13 Currently the measured data are not aggregated
14 and publicly reported. There are a couple of
15 hospitals that do put that up on their websites.
16 And I suspect it's because they're doing well in
17 the scoring, so it's a useful selling point.

18 The public funding body in California
19 does require that any PICUs involved -- they put
20 this up publicly through the children's pediatric
21 healthcare -- California Children's Services. And
22 we've heard about the number of centers involved.

1 I guess one of the biggest questions
2 -- and again maybe this is as a standalone, if
3 we're looking at this by itself -- is that a two-
4 year data collection from January 1, 2012 to the
5 end of December 2014 -- I'm sorry, that's three
6 years -- showed that there was no increasing or
7 decreasing trend for the overall rate of
8 unscheduled readmissions. So with that much data
9 we've not seen any movement in the rates going
10 on.

11 In terms of potential harms, the
12 developer had said previously that there's a risk
13 of miscapturing the time of the original
14 discharge. Since this is a time-dependent
15 measure, you know, missing it by a minute could
16 mean that you get a different score one way or
17 the other.

18 CO-CHAIR BRATZLER: David, any other
19 comments about use or usability?

20 DR. STOCKWELL: No. I think it's well
21 covered.

22 CO-CHAIR BRATZLER: One question I did

1 have to your point about no change in the trends
2 over time. I know this measure is not risk
3 adjusted. The other two are but this one is not.

4 So do you have any sense, Matt, about
5 overall risk for the patient population over
6 time? In other words, if you have a sicker
7 population over time, no trend may actually
8 reflect some improvement, the patients are sicker
9 now than they used to be when they get to a
10 pediatric ICU.

11 DR. SCANLON: I don't know the answer
12 to that off the top of my head. I would have to
13 -- I have looked at that for given ICUs as part
14 of developing reports for them, but I honestly
15 can't tell you off the top of my head. Again, I
16 have people in the background who are probably
17 trying to answer that for you and I can share it
18 as soon as I get that.

19 But I don't know that there's been a
20 dramatic upswing in severity of illness over
21 time. I don't know, David, if you have any sense
22 of that.

1 DR. GLOMB: I have two comments. One
2 has to do with the -- and Chana brought it up and
3 we had brought that up before -- PICUs are really
4 not cookie cutter. As a PICU and NICU doc, I can
5 say that they're not cookie cutter in the same
6 way that a NICU tends to be somewhat cookie
7 cutter. Because it revolves around what
8 specialists are available at a specific
9 children's hospital, what types of illness and
10 disease they deal with primarily.

11 Different -- across Texas for
12 instance, different children's hospitals have a
13 completely different spectrum of disease that
14 they might take care of. If you've got a patient
15 who needs this, they go to that children's
16 hospital, a patient who needs this, they go to a
17 different one.

18 So it's bothered me that without risk-
19 adjusting that it's a little bit of an apples and
20 oranges comparison across the way.

21 The other thing is -- the other
22 question is this doesn't point to a specific --

1 it doesn't get us in the direction of where do I
2 need to improve to get my rate down. It just
3 says my rate's too high, comparably.

4 DR. SCANLON: So this is Matt Scanlon.
5 I would agree with that last point. I think at a
6 individual level, you know, what's helpful is
7 looking at this and then reviewing those
8 unplanned readmissions. Once, originally in the
9 -- I think it was the first set of endorsed
10 measures -- there was actually a systematic
11 review of unplanned readmissions as a mandate or
12 as a measure through the NQF process. And that
13 was dropped at the last cycle. And I don't
14 recall the specifics of why.

15 So, yeah, I think the number in and of
16 itself is only as useful as what you do with it.
17 The reason we provide this in peer review or
18 peer-type summary data to institutions as part of
19 participation is so that they can look and see
20 how they're doing compared to peers. And then
21 they have to dig in and figure out why. Just as
22 any quality improvement process.

1 CO-CHAIR BRATZLER: Edgar.

2 DR. JIMENEZ: Just a comment here that
3 we try to take into consideration the statistics
4 -- demographic statistics with the pressure on
5 PICUs. And it's going to be pretty stable for
6 the next few years, whether it's actually in the
7 population over 65, I think we'll see as we talk
8 over the next few measures. We're going to have
9 a much, much higher ratio or a disproportionate
10 ratio of demand for acuity of care in the older
11 population. This is going to be something that
12 we're going to be seeing over the next ten years.

13 DR. SCANLON: I think the other thing
14 where there's an implication which may affect
15 these numbers is with the change in reimbursement
16 model and a move from fee-for-service, I think
17 there's going to be increasing pressure to move
18 children out of ICU, which may lead to unintended
19 consequences.

20 CO-CHAIR BRATZLER: That's a very good
21 point.

22 Any other conversation about usability

1 or use? Yes, Todd.

2 DR. DORMAN: I guess I will just share
3 a local. So actually for 27 years we have been
4 tracking readmission rates to adult ICUs. We
5 started with definitions of 72 hours. Found that
6 to be overly-sensitive. Forty-eight hours, and
7 then probably for about 15 years have been
8 looking at 24 hours. And find them very useful,
9 not as the raw rate but as the drive towards the
10 gap analysis that Matt is referring to to
11 understand. And it clearly identified hand-offs
12 mentioned by Edgar as a significant player.

13 But there are others, including the
14 tie to high-volume, high-pressure days and the
15 pressure for early discharge. Not that anybody
16 would move somebody out that they believe was
17 unstable, but you have those unknown patients
18 that get impacted. And that has led to a change
19 in health system resources in order to deal with
20 those days, which has then been reflected by a
21 decrease in the unscheduled readmission rates.

22 So I think there have been some hard

1 examples of the data driving beneficial change.

2 CO-CHAIR BRATZLER: Any other
3 conversations about use or usability?

4 (No response.)

5 CO-CHAIR BRATZLER: Okay. We'll go
6 ahead and vote.

7 MS. AMIRAULT: Usability and use for
8 0335, 1 being high, 2 moderate, 3 low, or 4
9 insufficient.

10 (Voting.)

11 DR. NISHIMI: David. David, can you
12 resubmit your vote?

13 DR. STOCKWELL: I didn't submit it yet
14 but I had to send it by email. Do you see it
15 there?

16 (Voting.)

17 MS. AMIRAULT: Zero high, 14 moderate,
18 seven low and zero insufficient. Based on the
19 percentage we can move forward.

20 CO-CHAIR BRATZLER: And then we'll have
21 our final vote on overall suitability,
22 recognizing remember when we discussed gap that

1 this measure was in the gray zone. So there will
2 be further discussion down the road because of
3 that point.

4 MS. AMIRAULT: Overall suitability for
5 0335, 1 being yes and 2 being no.

6 (Voting.)

7 MS. AMIRAULT: Twelve yes, nine no.
8 And based on the percentage this is in the gray
9 zone. CO-CHAIR LANG: Okay, Dale and
10 I are continuing to do a tag team here. So I'm
11 going to take the next measure, 0334, PICU
12 Severity-adjusted Length of Stay.

13 Matt, or would you, would developers
14 wish to make a brief statement regarding this
15 measure before we proceed?

16 DR. SCANLON: Yes. The concept of
17 severity-adjusted length of stay was initially
18 put forward by Dr. Murray Pollack who has been a
19 pioneer in real metrics around the ICU, both in
20 terms of severity-adjusted algorithms and looking
21 at utilization. And we have been using this for
22 a number of years to allow for risk adjustment,

1 but also look at utilization as a -- and the
2 impact on, potentially, patients and families.

3 Again, in our minds to look at this
4 without looking at unplanned readmissions is
5 short-sighted and leads to the potential for
6 gaming, which I think for any national measure is
7 always a potential concern.

8 So I think that sums up the overview
9 and then we can take it based on individual
10 questions.

11 CO-CHAIR LANG: Thank you, Matt.

12 David, Dale, you're up.

13 DR. STOCKWELL: Sure. It's David, I'll
14 do it.

15 So it sounds this is an maintenance
16 evaluation of an outcome measure. There is not
17 really new evidence presented at this time,
18 although there is, you will hear about an updated
19 adjustment, severity wellness adjustment
20 algorithm, but the data is internally adjusted
21 and there's evidence to that point. But in terms
22 of evidence of the use of this, the focus on the

1 ICU and the length of stay has been well-
2 documented as something that is worthy of
3 reflection for any medical director of an ICU.

4 CO-CHAIR LANG: Thank you, Matt.
5 Evidence.

6 CO-CHAIR BRATZLER: And the only thing
7 I would add is this is reported as an,
8 essentially, an observed to an expected ratio
9 based on severity of illness with the child.

10 CO-CHAIR LANG: Thank you. I meant to
11 say David. Thank you, David, and thank you,
12 Dale.

13 The underlying rationale for this
14 outcome measure hasn't changed since the last NQF
15 endorsement review. So this also is appropriate
16 to proceed without a vote, unless anyone wishes
17 to do otherwise. Please raise your hand, if so,
18 otherwise we will proceed.

19 (No response.)

20 CO-CHAIR LANG: Thank you.

21 Performance gap. Dale, David.

22 DR. STOCKWELL: So in the performance

1 gap the data that the developer provides shows a
2 severity-adjusted length of stay ratio between
3 .66 and 1.8, with the median being 1.01. And
4 they note that there is no decrease or increase
5 in trends over time. So that part I think is
6 fairly well satisfied.

7 The question about disparity really is
8 highlighted here, even further compared to the
9 last measure, where again you see that uninsured
10 children have a disparity with shorter length of
11 stay in the PICU. They note that there is also a
12 greater physiologic derangement on admission, and
13 that may lead to a higher mortality.

14 And the developer also notes that it
15 may reflect pre-hospital practice independent of
16 the care provided by the ICU. They do then move
17 into stratifying by rates next to the age groups,
18 gender and insurance again. And there were
19 several differences amongst all those. We can go
20 through that if the committee would like.

21 Ultimately the committee felt that
22 there was a performance gap but using this as

1 something for disparities may not be, may not be
2 as useful as it is for just the overall ICU
3 performance.

4 CO-CHAIR BRATZLER: And the only thing
5 I'll add is that I think when we talked we were
6 actually -- you know, I was impressed that there
7 is much more substantial variation in risk
8 severity-adjusted length of stay between units
9 than we saw with the previous measure. I mean
10 the ratios were substantially different across
11 the various PICUs.

12 CO-CHAIR LANG: Further discussion?
13 Questions for the developer?

14 (No response.)

15 CO-CHAIR LANG: Seeing none, we will
16 proceed to vote. Janine.

17 MS. AMIRAULT: Performance gap for
18 0334; 1 being high, 2 moderate, 3 low, and 4
19 insufficient.

20 (Voting.)

21 MS. AMIRAULT: Six high, 13 moderate,
22 2 low, and 0 insufficient. Based on the

1 percentage we move on.

2 CO-CHAIR BRATZLER: So we'll go on to
3 discuss reliability. Reliability, essentially
4 the same conversation that we had about the last
5 measure. The measure site is captured, all of
6 the measures, but the three measures that this
7 group produces come out of the same data set. So
8 based on inter-rater reliability testing we heard
9 the conversation early, the reliability testing
10 is done at the data element level. And they
11 provided the evidence of the consistency of the
12 data collection across programs. And they have
13 ongoing continuous reliability testing as a part
14 of submitting and participating in the database.

15 CO-CHAIR LANG: Additional discussion?

16 MR. STOCKWELL: I have nothing further.

17 CO-CHAIR LANG: David, were you going
18 to say something?

19 MR. STOCKWELL: No, sorry. Just that
20 I didn't have anything further.

21 CO-CHAIR LANG: Okay, thank you.

22 Okay, we will proceed to vote

1 reliability.

2 MS. AMIRAULT: Reliability for Measure
3 0334; 1 being high, 2 moderate, 3 low, 4
4 insufficient.

5 (Voting.)

6 MS. AMIRAULT: Nine high, 12 moderate,
7 0 low, 0 insufficient. Based on the percentage
8 we'll move forward.

9 CO-CHAIR LANG: Validity.

10 DR. STOCKWELL: So with validity the
11 developer, as you said, had taken an established,
12 published method called the PRISM III, and has
13 now updated that with their own internal data and
14 provided validity testing of that. They
15 essentially just compared a training data set to
16 an independent validation set and found that they
17 had reasonable validity after looking at the
18 various different components of that.

19 And I believe that the committee was
20 comfortable with the assessment that was
21 provided.

22 CO-CHAIR BRATZLER: And I don't have

1 anything to add.

2 CO-CHAIR LANG: Further discussion?

3 Yes, Bill?

4 DR. GLOMB: I have a question for the
5 developer.

6 There was a decision to truncate the
7 length of stays at 30 days. And I know why that
8 is, because all of our units have that one child
9 who's been there for 9 months, 10 months, a year-
10 and-a-half. But is there any validity in the
11 literature for doing that? I have not seen it
12 and I just wondered how you made that decision?

13 DR. SCANLON: That decision was not our
14 decision. That was the decision of Dr. Pollack
15 based on his review of his -- the collaborative
16 database he was part of or headed up. And that
17 was the, I think that was the PICU use project
18 that led to that originally.

19 And so why they chose 30, I don't
20 recall, recall the exact rationale, but it was
21 based on analysis of their data that they drew
22 the line at 30 days to deal with those outliers

1 that you mentioned. And again, that's a peer-
2 reviewed manuscript that we essentially used the
3 methodology of.

4 DR. GLOMB: Thank you.

5 CO-CHAIR LANG: Further discussion?

6 (No response.)

7 CO-CHAIR LANG: We'll proceed to a
8 vote. Janine.

9 MS. AMIRAULT: Validity for 0334; 1
10 being high, 2 moderate, 3 low, and 4
11 insufficient.

12 (Voting.)

13 MS. AMIRAULT: Six high, 13 moderate,
14 1 low, and 1 insufficient. Based on the
15 percentage we'll move on.

16 CO-CHAIR LANG: Feasibility.

17 CO-CHAIR BRATZLER: So for feasibility,
18 exact same conversation as the previous. This is
19 a proprietary measure. We heard that about 135
20 different PICUs are actually participating. The
21 data abstraction happens at the level the
22 individual unit captures the patient level, and

1 is submitted via a registered software that's
2 used.

3 So I don't have anything different to
4 add from the previous discussion.

5 DR. STOCKWELL: Yes, it's David. I
6 agree.

7 CO-CHAIR LANG: Bruno?

8 DR. DiGIOVINE: I just think in the
9 prior discussion we did make the point that you
10 could probably get your readmission rates without
11 having the software. I think there is no way to
12 get a severity-adjusted length of stay without
13 having the software.

14 DR. SCANLON: I'm not sure -- this is
15 Matt Scanlon -- I'm not sure that I would agree
16 with that. I think that, again, you would have
17 to have, you would have to track your length of
18 stay. I am nervous about the use of
19 administrative data for those purposes, but
20 that's just my perspective.

21 And separate from that you can
22 calculate severity of illness on all of the

1 children and then do the math accordingly. It
2 would be an odious task, which is why we built
3 the software and automated it, but there is no
4 barrier to actually doing it long-hand, if you
5 will.

6 CO-CHAIR BRATZLER: And I think, you
7 know, you're right that the risk model actually
8 is in the public domain; it has been published
9 several times.

10 CO-CHAIR LANG: Further discussion?

11 (No response.)

12 CO-CHAIR LANG: If not, we'll proceed
13 to vote.

14 MS. AMIRAULT: Feasibility for 0334; 1
15 being high, 2 moderate, 3 low, or 4 insufficient.

16 (Voting.)

17 MS. AMIRAULT: Three high, 13 moderate,
18 5 low, and 0 insufficient. Based on the
19 percentage we'll move forward.

20 CO-CHAIR LANG: Usability.

21 DR. STOCKWELL: So the usability is
22 also very similar as the last time. There are no

1 publicly-supported measures utilizing this.

2 Although there are a large number of ICUs that do
3 report it.

4 Sorry for the background noise, by the
5 way.

6 So very similar to the last
7 conversation we had on the last measure.

8 CO-CHAIR LANG: Further discussion?
9 Going once. Going twice.

10 (No response.)

11 CO-CHAIR LANG: Janine.

12 MS. AMIRAULT: Usability and use for
13 0334; 1 being high, 2 moderate, 3 low, or 4
14 insufficient.

15 (Voting.)

16 MS. AMIRAULT: Zero high, 14 moderate,
17 6 low, and 1 insufficient. Based on the
18 percentage we'll move on.

19 CO-CHAIR LANG: We are now considering
20 the overall suitability of the measure for
21 endorsement.

22 Comments from members of the

1 committee, questions for the developer?

2 (No response.)

3 CO-CHAIR LANG: Seeing neither, we will
4 proceed to vote.

5 MS. AMIRAULT: Overall suitability for
6 0334; 1 being yes and 2 being no.

7 (Voting.)

8 MS. BAL: David, did you vote?

9 DR. STOCKWELL: I did. I need to do it
10 by email though.

11 MS. BAL: Okay.

12 MS. AMIRAULT: Eleven yes, 10 no. This
13 is in the gray zone.

14 CO-CHAIR BRATZLER: Okay. So we'll
15 move on to the next measure, which is the third
16 of the measures from Virtual PICU Systems.

17 CO-CHAIR LANG: If I could just
18 interrupt you for a moment. There is an issue
19 regarding scheduling that I just want to raise.
20 And it is that after, if you could look ahead
21 beyond this measure which is the third of three
22 that relate to PICU, we have two measures, 703

1 and 702, that are related: one concerning
2 mortality, the other concerning length of stay.

3 It would seem that it would be -- I
4 mean to me it would make more sense to couple
5 those measures and either do them both before or
6 both after lunch rather than splitting it up.

7 We also have a member and public
8 comment session. I just wanted to get the views
9 of the group as to whether there was a preference
10 as to how to proceed and deviate from the
11 schedule as it, as it exists.

12 MR. BENSON: I would suggest we do the
13 two coupled after lunch. We are a half hour off
14 from the schedule anyway.

15 CO-CHAIR LANG: Excellent. Is that a
16 motion, Ken?

17 Does somebody want to second?

18 (Motion seconded.)

19 CO-CHAIR LANG: Very good.

20 All in favor.

21 (A show of hands.)

22 CO-CHAIR LANG: Excellent.

1 Opposed? Extensions?

2 (No response.)

3 CO-CHAIR LANG: Very good; motion
4 carries. Thank you, Ken.

5 CO-CHAIR BRATZLER: All right. So
6 we'll proceed with Measure 0343, PICU
7 Standardized Mortality Ratio or discuss -- well,
8 Matt, do you have any initial introduction? Very
9 similar to the previous ones.

10 DR. SCANLON: Yes, it's a variation on
11 what we've discussed. I mean the concept of
12 standardized mortality ratio is well-published.
13 It's been adopted by the IHI as part of their
14 Move Your Dot campaign. And essentially it's a
15 way of looking at observed over expected
16 mortality based on appropriate risk-adjustment
17 modeling.

18 And so that's what we've been doing,
19 providing that both at a unit level. It's
20 available at a patient level, although it's
21 really inappropriate to use for an individual
22 patient as it's more of a population metric.

1 And then for comparisons across
2 clusters of units.

3 CO-CHAIR BRATZLER: Okay. So our
4 discussants are Bill and Ella.

5 DR. GLOMB: Ella, do you want me to
6 start or do you want to start? She's not on?

7 CO-CHAIR BRATZLER: It's the Bill show.

8 DR. GLOMB: It's me. Okay, let's roll.

9 So essentially this is using the PRISM
10 III software which has, again, been used,
11 identified, not only measures but in literature,
12 to calculate a predicted mortality based on
13 physiological risk: vital signs, chemistries, et
14 cetera. And that is the numerator.

15 And then the denominator is all deaths
16 that occur within the unit. So your predicted
17 rate should ideally be the ones who are dying.
18 And those who are not predicted, shouldn't be, to
19 put it succinctly.

20 It's all children under 18 years of
21 age who have been in the unit for greater than
22 two hours, with at least two consecutive sets of

1 life-compatible vital signs. So you're not dying
2 when you roll through the doors of the ICU. If
3 you are, you don't get counted in this, in this
4 study.

5 And moving on to the evidence, again
6 this relates only to that single outcome,
7 mortality. I think we can all agree this is an
8 outcome measure here. And there's discussions
9 here about summary of the evidence and the use of
10 the tool, the PRISM III tool, looking at the
11 morality ratios.

12 I will just read through that real
13 quickly. There's three caveats from the
14 developer with regard to the literature on the
15 value of using this SMR calculation. Use of a
16 calibrated tool for severity adjustment has been
17 identified as important.

18 Recent publication in "Critical Care
19 Medicine" 2012, identified that the use of a
20 physiology-based tool in calculating standard
21 mortality ratio is superior than using any
22 administrative data, and that the premature

1 transfer of patients from the ICU can lower the
2 SMR -- guess people are dying elsewhere --
3 creating a potential gaming. But use of this, of
4 Measure 0343 in combinations with this one also
5 then addresses that potential.

6 So the question for the committee, is
7 there at least one thing the provider can do to
8 achieve a chance for the measure results. This
9 doesn't specifically point to something you can
10 do differently other than not let them die if
11 they weren't expected to.

12 You know, that's, that's the evidence
13 basis.

14 CO-CHAIR BRATZLER: So again, since
15 this is a maintenance measure, really no change
16 in the evidences is there that -- since the
17 previous endorsement. And we have to decide
18 whether or not we vote on the evidence or not.

19 DR. GLOMB: That's correct. The only
20 evidence that changed is the addition of another
21 tool. I believe that came along chronologically
22 since the last endorsement.

1 CO-CHAIR BRATZLER: Right. The updated
2 algorithm.

3 DR. GLOMB: Right.

4 CO-CHAIR BRATZLER: Right.

5 DR. YEALY: Yes, and that's my
6 question. Do we know that this stratification
7 tool retains its precision and accuracy over time
8 or if it drifts away and, therefore, any
9 differences are really not good care but just the
10 tool not performing well? I don't know if the
11 developer has information about that.

12 DR. SCANLON: We have actually
13 recalibrated the tool, as I understand it, for
14 exactly the reason of drift over time. And while
15 it wasn't published in a peer review, there has
16 been a white paper that I believe was presented
17 at a meeting on that issue by a number of the
18 physicians involved with the software product.

19 So we are keenly aware of that and the
20 need for recalibration. The original, one of the
21 initial severity of illness tools, PRISM II,
22 which was the obvious predecessor to PRISM III,

1 suffered that exact issue. So it got to a point
2 where Dr. Pollack and others were telling members
3 of the community not to use it because it hadn't
4 been recalibrated.

5 So we've got a very large number of
6 patients in the data set now. And because of
7 that we are able to reassess and recalibrate as
8 needed.

9 CO-CHAIR BRATZLER: Any other questions
10 or comments about the evidence? Bruno?

11 DR. DiGIOVINE: It's not about
12 evidence. I don't know if you want me to hold.
13 I can hold it. It's about the definition of
14 mortality.

15 My only question is you talk about
16 gaming with pediatric -- counting a death only if
17 it happens in the ICU. Why not use hospital
18 mortality? Or is there background that you could
19 share with us as to why just ICU and not
20 hospital?

21 DR. SCANLON: There's a couple
22 different reasons. And again, I would also ask

1 that the other panel members weigh in if they
2 disagree with me.

3 The majority of deaths in pediatrics
4 that are non-hospice-related deaths occur in
5 pediatric ICUs. Deaths outside the ICU are
6 relatively rare phenomena. And actually while
7 there were some centers that have published that
8 they had a problem with that, the institution of
9 rapid response teams have made those incredibly
10 rare.

11 So other than hospice patients, I'll
12 tell you the patients who are other status, who
13 are palliative and moved out of ICUs in a subset
14 of organizations that have those resources, most
15 pediatric deaths occur in ICUs, right or wrong.

16 CO-CHAIR BRATZLER: Any other questions
17 of conversations about evidence?

18 (No response.)

19 CO-CHAIR BRATZLER: So I'm going to ask
20 for a hand vote. Do raise your hand if you want
21 to re-vote the evidence base here.

22 (No response.)

1 CO-CHAIR BRATZLER: Okay, seeing none,
2 we will go on and discuss the performance gap.

3 DR. GLOMB: I'm going to go ahead and
4 talk about gap here.

5 This current performance data came
6 from 79 PICUs, as we learned earlier, up to 135
7 using software.

8 And the unit level standardized
9 mortality rate was fairly broad, between almost
10 none to 2, which is twice what would be expected.
11 So during 2014, the median unit level mortality
12 rate was .92, and the mean level was .97; so
13 pretty much right where you would expect them to
14 be at the 1.0, which is what is predicted based
15 on the tool.

16 The patient level mean SMR for 2014
17 was not statistically different from 1. So
18 again, using the tool, looking at the individual
19 patient, predictions were pretty accurate.

20 For performance over time, similar to
21 the previous two measures there has been no trend
22 noticed, no increasing or decreasing trend over

1 the three years of data collection for this
2 particular measure.

3 The disparities are similar to what
4 we've seen all along, that the uninsured children
5 have significantly shorter lengths of stay,
6 greater physiological derangement on admission,
7 and that the hospital mortality was higher.

8 In terms of race, ethnicity, age
9 groups, gender, insurance, payer, the younger the
10 child, the higher SMR -- though not very much
11 higher. And if you were a teen in a kids' ICU,
12 your rate of mortality was slightly lower, .89.
13 But there were no statistically significant
14 differences in race, in the race or ethnic
15 groups. There were no statistically significant
16 differences in managed care versus commercial
17 insurance, versus Medicare, managed care, self-
18 pay, et cetera. And there were no statistically
19 significant differences found in gender or sex.

20 So that, at least looking at
21 disparities, there doesn't appear to be a gap.
22 There is a gap if you run this across units.

1 CO-CHAIR BRATZLER: Yes, I was shocked
2 by the breadth of the gap, or at least the SMR.
3 I think it does need to be in the public domain.
4 But anyway.

5 Don, I think your name's been up and
6 you didn't have anything. Yes, nothing.

7 So any other conversation or questions
8 or discussions about gap?

9 (No response.)

10 CO-CHAIR BRATZLER: Okay, seeing none,
11 we will go ahead and vote.

12 MS. AMIRAULT: Performance gap for
13 0343; 1 being high, 2 moderate, 3 low, and 4
14 insufficient.

15 (Voting.)

16 MS. AMIRAULT: Four high, 11 moderate,
17 5 low, and 0 insufficient. Based on the
18 percentage we'll move on.

19 CO-CHAIR BRATZLER: Okay. Discuss
20 reliability.

21 DR. GLOMB: So under reliability I
22 think we've discussed the logistics of the

1 measure. There is no calculated algorithm
2 stated. That's part of the proprietary software
3 package here.

4 With regards to reliability testing,
5 this takes us back again to that inter-rater
6 reliability review, which is an ongoing process.

7 I don't have anything else. Again, we
8 had those, we had those concerns expressed --
9 we've discussed them already -- that different
10 units have different characters, different types
11 of disease processes which might alter the
12 predicted unit, unit-based predicted mortality.
13 But I think that's been explained pretty well by
14 the developer because that's done at the patient
15 level.

16 So I think we were pretty comfortable
17 with reliability.

18 CO-CHAIR BRATZLER: So any questions or
19 other comments about reliability?

20 (No response.)

21 CO-CHAIR BRATZLER: Seeing none, we'll
22 vote.

1 MS. AMIRAULT: Reliability for 0343; 1

2 --

3 CO-CHAIR BRATZLER: So I'm going to ask
4 real quick, do we need to vote? Raise your hand
5 if you think we need to vote on reliability
6 because it hasn't changed.

7 (No response.)

8 CO-CHAIR BRATZLER: So we'll go on and
9 discuss validity

10 DR. GLOMB: Again, these are all
11 standardized definitions. It's an established
12 method, established in the literature, and has
13 been part of multiple measures in the past. It
14 relates to some of the measures we have already
15 discussed today. The IRR seems to speak to that.

16 In terms of threats to the validity,
17 let's talk a little bit about the exclusions.
18 For the purposes of this measure, and I think
19 within the software utilized to calculate the SMR
20 itself, it's relegated to children under 18 years
21 of age only. Those who have been in the unit
22 over two hours and/or more than two consecutive

1 sets of vital signs consistent with life.

2 And they exclude the palliative care
3 cases, those who were likely to die. Those
4 patients are left out of this mix. It also does
5 not include the pre-term infants, post-gestation
6 36 weeks and below because the tool was not
7 validated on that population.

8 Again, it kind of takes us a little
9 bit back though to the character of the unit.
10 There are some pediatric ICUs that are an
11 extension of the neonatal intensive care unit. A
12 lot of their volume relates to former preemies
13 moving up either post-operatively or at a cut-off
14 time designated in the hospital. That might play
15 into the statistics a little bit.

16 I think that our concerns, there is
17 some concern that missing data could also skew
18 results in a small volume PICU and make some big
19 changes. And that, again, doesn't really point
20 us to a specific actionable change that one might
21 see in care.

22 That's all.

1 CO-CHAIR BRATZLER: And then I
2 actually, so I have one other issue that I think
3 I'd raised on the work group. And I don't
4 imagine that you guys have looked at it, but I
5 was struck by the fairly wide distribution of the
6 SMR and wondered if we needed, if there needed to
7 be some consideration of hierarchical modeling at
8 the unit level, such as is done by a number of
9 other mortality and other measures for different
10 programs, which might take into account some of
11 that difference in case mix, but also some of
12 that difference in maybe just issues related to
13 pure quality of care.

14 DR. SCANLON: Yes, we've started to
15 look at that. And I think that's worth
16 exploring.

17 In part, one of the issues that the
18 algorithms that the calculations are based on
19 were not developed with any hierarchical
20 modeling. So part of it is do we --
21 understanding what are the implications of
22 applying that. Where we handle it at an

1 individual unit level is presenting like data to
2 like in terms of unit characteristics.

3 So when we report data, units pick,
4 for the purpose of ongoing quality, units pick
5 characteristics where they want to match to other
6 ICUs, such as number of beds, do you offer this
7 service versus that service. And then we
8 benchmark against those to provide accurate
9 reporting but not at the national level.

10 Again, the issue varies. This is not
11 necessarily nationally reported because there is
12 no -- and while we can publish that on the VPS
13 website, there is no market for that data, sadly.

14 When we looked at variation within the
15 SMR, we certainly found that the standard
16 deviation within the lowest performing set, those
17 with SMRs 1.2 to 3, have actually more variation
18 but and they don't, they drift within that area.
19 But in the lower SMRs, .8 to 1.2 diversity, 0 to
20 .8, there is very little movement of those ICUs,
21 suggesting that those ICUs are fairly stable in
22 their outcomes. But it's the low performers that

1 tend to have a lot of variation from period to
2 period.

3 CO-CHAIR BRATZLER: Edgar.

4 MR. JIMENEZ: Just a quick thing. In
5 the adult population and something that we'll be
6 seeing in the public reporting will be an issue
7 with initiatives playing leapfrog and stuff like
8 that. They're looking at using the standardized
9 reporting algorithms as seeing ICU performance
10 because there needs to be, we probably get the
11 problem has been we haven't had a good tool so
12 far to do it, but there needs to be a
13 stratification, as you were mentioning, of
14 systems, you know, that would allow basics,
15 programs there where they can handle basic things
16 and more sophisticated move over to higher acuity
17 centers.

18 CO-CHAIR BRATZLER: Don.

19 DR. YEALY: I have a question for the
20 developers about the palliation exclusion. Are
21 there any guardrails around that with respect to
22 either timing or location? I don't, we don't

1 have a pediatric unit in our place.

2 Are there similar measures in an adult
3 way if you -- one way to change your mortality
4 measure is to get everybody on palliation pretty
5 quickly. They still die, they just die
6 differently. That may be a wonderful thing but
7 it's probably not the intent of the measure isn't
8 to improve, you know, the deployment of
9 palliation.

10 So my question is how do you handle
11 that? Are there some guardrails around when
12 someone's excluded for palliation? Had to be X
13 amount of time before the time of death or
14 location of it?

15 DR. SCANLON: So I'm going to have to
16 have my behind-the-scenes people send me the
17 operational definition. But my understanding is
18 these are patients admitted to the ICU purely for
19 palliative reasons, not a patient who has altered
20 code status or limitations on support in the ICU.

21 So if a patient came in because of
22 some devastating event, was cared for, and then

1 was proceeding to or heading towards death and
2 was placed in palliative status, that was not --
3 those are not excluded. Those are incorporated
4 in the model so that we don't have that problem
5 of gaming there.

6 It's patients that -- there's a few
7 centers, and this is where this came in, who
8 would admit patients purely for palliative
9 purposes. And that's where the exclusion
10 applies.

11 CO-CHAIR BRATZLER: Any other questions
12 about validation, validity testing?

13 (No response.)

14 CO-CHAIR BRATZLER: Okay, we can go
15 ahead and vote.

16 MS. AMIRAULT: Validity for 0343; 1
17 being high, 2 moderate, 3 low, or 4 insufficient.

18 (Voting.)

19 MS. AMIRAULT: Two high, 15 moderate,
20 3 low, and 0 insufficient. Based on the
21 percentage we'll move on.

22 CO-CHAIR BRATZLER: And I think the

1 last question is about -- oh, I'm sorry, yes,
2 feasibility.

3 DR. GLOMB: So feasibility is similar
4 to the previous two measures. You have access to
5 the software because you're a member of the group
6 or you have an electronic medical record, then
7 you'd be able to get this data.

8 If you have no electronic medical
9 record you could do -- well, like what Matt said,
10 it was an odious manual review and data entry.
11 And obviously they're paying for the man hours
12 for that. And you could have access to scoring
13 as well. But it is certainly doable in both
14 environments; one easily and one less easily.

15 CO-CHAIR BRATZLER: Any other
16 discussion of feasibility?

17 (No response.)

18 CO-CHAIR BRATZLER: Okay, we'll vote
19 it.

20 MS. AMIRAULT: Feasibility for 0343; 1
21 being high, 2 moderate, 3 low, or 4 insufficient.

22 (Voting.)

1 MS. AMIRAULT: Three high, 14 moderate,
2 3 low and 0 insufficient. Based on that
3 percentage we're moving on.

4 CO-CHAIR BRATZLER: And then
5 usability/use.

6 DR. GLOMB: So nothing new on the
7 usability. The statistics are the same. This
8 really isn't being publicly reported. Some
9 hospitals might use this voluntarily, and others
10 in California Children's Services if this is
11 posted information.

12 No changes in the trends over time.

13 I'm curious if the developer has any
14 thoughts about why we've not seen any movement
15 there based on their data collection.

16 DR. SCANLON: I'm sorry, movement in
17 the SMR or movement around public reporting?

18 DR. GLOMB: No, movement in the SMR
19 itself. I'm sorry.

20 DR. SCANLON: Well, again I think at a
21 unit level the SMR, the median should be around 1
22 if the calculation is accurate. I think that the

1 issue is that you wouldn't -- first of all I
2 would say compared to adult mortality in ICUs,
3 pediatric mortality is about 2.7, I think,
4 percent, so it's pretty low to start with. So
5 moving that dot is, in a statistical fashion is
6 pretty challenging.

7 I think a second issue is the question
8 of whether all deaths are, one, preventable and,
9 two, whether a death is appropriate or
10 inappropriate. There are, at the risk of being
11 controversial, one could argue there are such a
12 thing as good deaths.

13 But I think the other issue is that
14 because of the lack of a mandate for public
15 reporting of this, while NQF has to date provided
16 a mechanism to publicly report these, or a
17 validated metric, there is not a market force.
18 And while one of the previous speakers spoke to
19 leapfrog demanding that from the adults, the
20 relative cost of pediatric ICUs, while very
21 expensive, pales in comparison to adult care.
22 And so we're not on their radar, rightly or

1 wrongly.

2 I think, looking at the range of the
3 SMR that we -- one of the previous speakers
4 commented on, it's disturbing to me that there's
5 not attention to this and that you could actually
6 see that SMR would at least be 1 across the
7 board, if not below 1. And there has certainly
8 been dramatic improvement in CLABSI rates in
9 pediatric ICUs. We're pretty good at keeping
10 those kids alive. Even if they did a CLABSI for
11 this, I don't know that that was a big source of
12 mortality.

13 So that's a multi-pronged answer. But
14 I think the lack -- where there is room for
15 improvement, the lack of national attention to
16 this, be it by joint commission or any public
17 reporting body with the exception of the
18 California system, certainly has not put any
19 pressure for centers to improve.

20 CO-CHAIR BRATZLER: James.

21 DR. O'BRIEN: I think some of this also
22 just goes back to recalibrating or respecifying

1 the model, is that you're going to wind up then
2 again regression to median, you're going to get
3 back to a 1 as every time you do it, which makes
4 it challenging with these risk-adjusting models
5 as we change the model year over year of knowing
6 whether or not there's actual improvement.

7 CO-CHAIR BRATZLER: Kenneth.

8 MR. BENSON: As I understand the
9 purpose of these measures is to help the process
10 improve, improving the quality of healthcare.
11 And what I find troubling in this and the two
12 previous ones has to do with gathering
13 information and presuming the data is correct,
14 and it comes to conclusions that could lead other
15 people to improve their healthcare. that that
16 information is not being gotten out there.

17 Now, the developer said there's a lack
18 of interest. I don't understand this. I'm just
19 at a loss on how, if we're going to take the time
20 to do this, there is not a mechanism to get it
21 out to the people who could use this to improve
22 their quality. Keeping it locked in a box

1 doesn't help anybody.

2 CO-CHAIR BRATZLER: Yes. So I mean I
3 will simply comment that for -- I think Matt made
4 the point very well -- for programs like
5 Medicare, the adult population, which are very,
6 very expensive and they use a lot more ICU care
7 and other extensive care, lots and lots of payers
8 now are mandating, whether it's Medicare or other
9 private payers, mandating that this data be put
10 into the public domain.

11 That simply hasn't happened, it
12 doesn't sound like, for pediatric ICU care, and
13 there just aren't payers out there mandating that
14 this information -- the payment models haven't
15 pushed it to go to the public domain. So.

16 DR. SCANLON: This is Matt again. I'm
17 sorry. I couldn't agree more with your
18 frustration. We would love that, not just
19 because we have this software package, but as
20 someone who is passionate about improving the
21 care of children, it's very frustrating to me
22 that there's no national hunger for this.

1 So, you know, you can use the NQF sway
2 or whatever within the bailiwick of NQF, but use
3 your sway to influence it. That would be great.
4 I would love to have an audience let's say with a
5 national metric that needs to be on the newspaper
6 and whatnot because, you know, the range from 0
7 to 2 for an SMR is, is disturbing.

8 DR. O'BRIEN: So I guess for the
9 developer then you mentioned a requirement that
10 for participating centers they have to pay a fee.
11 They have to have a nurse or a physician who is
12 specifically trained and show that they are able
13 to abstract this data correctly. Is it possible
14 for you to include in your participation
15 agreement that those organizations that are going
16 to participate have to publicly report their
17 performance?

18 DR. SCANLON: I don't know the answer
19 to that. And I say that as I am one of the
20 clinical developers. I am not one of the
21 officers of the program. And so I need to be
22 very careful not to speak outside my range of

1 expertise and authority.

2 Is it possible? Yes.

3 I don't know what that would mean for
4 participation. And I think one implication is
5 that programs that have a poor SMR may just
6 choose to drop out so they don't have to report.
7 I think, you know, saying that's the terms of
8 using the software, again, people who look good
9 will use it, people who have problems, the
10 quickest way is just quit paying to use the
11 software and then you don't have a problem.

12 And that's a cynical view but I think
13 that's where having nationally-mandated public
14 reporting, be it by payers or other bodies, is
15 what's missing here.

16 CO-CHAIR BRATZLER: Steve.

17 DR. GROSSBART: I think one of the
18 quandaries here is that this NQF endorsement is
19 for a proprietary product. And, you know, the
20 cynic in me says this is a marketing strategy.
21 The data is not really being used for what the
22 NQF expects the data to be used for, which is for

1 public reporting, accountability. And it's just
2 it's we're giving an endorsement and it's going
3 nowhere except within the confines of the
4 vendor's, of the developer's business as a
5 vendor.

6 And so when we talk about usability,
7 but it may place significant limits on usability.

8 DR. SCANLON: Well, as a self-avowed
9 cynic I can tell you that the organizations are
10 blinded. But I think that there would be -- to
11 each other in the software because of the legal
12 implications of sharing and whatnot at the
13 present.

14 I think that it is entirely feasible
15 for us to publish the range of SMRs on the
16 website at a site level but it's not within our
17 current ability without rewriting a bunch of
18 contracts. Which, again, I'm not saying we're
19 not opposed -- or we're opposed to, to identify
20 those organizations.

21 But that doesn't address the issue of
22 what happens if someone is a poor performer, and

1 why would they be incentivized to pay to report
2 poorly. And so while you, you know, you can say
3 that we are not being good stewards by keeping
4 this data in a lockbox, that's not the spirit of
5 what this is for.

6 And again, I'm not trying to sound
7 Pollyannaish here but our goal is to get the data
8 out there. But in the absence of an audience for
9 it, or some external pressure, we're not -- we
10 are currently not able to publish un-blinded
11 results in a public fashion. Maybe that's a
12 fatal flaw in the mechanism, but that result was
13 necessary to get programs up and running in this
14 in the first place.

15 And this has been an iterative
16 process. As I said, the software has been
17 existence since before 2004. Certainly we can
18 push for that.

19 I think the pediatric community at
20 large has been in the forefront of transparency.
21 And so we can push that envelope. But, again,
22 you may just drive poor performers, if it's at

1 the level of the VPS we may just drive poor
2 performers to drop out and hide their problems.

3 CO-CHAIR BRATZLER: So I'm going to let
4 Todd have the last word here on this before we
5 vote on usability.

6 DR. DORMAN: Well, I was just going to
7 add a comment that's maybe an academic comment
8 and sounds a little bit strange when you first
9 hear it. But there is -- I'm not aware of data
10 that says that you can use such a measure to
11 compare ICU to ICU. They're internal quality
12 measures. So publicly reporting would create the
13 impression that a unit that is at 1.5 is somehow
14 worse than a unit that is at .7. And I don't
15 believe that there is data that has actually
16 supported that fact. They are different and
17 there are many reasons why they may be different.

18 And so I think there is an unintended
19 consequence that has led people to be concerned
20 about transparency with these numbers because
21 then the utilization of the number becomes
22 potentially misused based upon our understanding.

1 And I know that sounds crazy because
2 it's compared to predicted and so, but.

3 CO-CHAIR BRATZLER: Steve, one last.

4 DR. GROSSBART: But isn't the ability
5 to create consensus measures that allow for
6 comparisons across different users, different
7 facilities, different populations, I mean isn't
8 that an expectation of NQF consensus measurement
9 development?

10 DR. NISHIMI: Yes.

11 CO-CHAIR BRATZLER: So that all goes
12 into your decision about how you vote on
13 usability and use. So any other conversations
14 there?

15 (No response.)

16 CO-CHAIR BRATZLER: We'll go ahead and
17 vote on usability.

18 MS. AMIRAULT: Usability and use for
19 0343; 1 being high, 2 moderate, 3 low, or 4
20 insufficient.

21 (Voting.)

22 MS. AMIRAULT: Zero high, 8 moderate,

1 12 low, and 0 insufficient. So based on the
2 percentage this is in the gray zone.

3 CO-CHAIR BRATZLER: All right. The
4 last one is overall suitability for endorsement.
5 Any other comments or questions?

6 (No response.)

7 CO-CHAIR BRATZLER: If you would call
8 the vote.

9 MS. AMIRAULT: Overall suitability for
10 0343; 1 being yes and 2 being no.

11 (Voting.)

12 MS. AMIRAULT: Nine yes and 11 no.
13 This is in the gray zone.

14 CO-CHAIR BRATZLER: All right, thank
15 you. Thanks, Matt, for your conversations today.

16 DR. SCANLON: Yes, thank you.

17 CO-CHAIR BRATZLER: So we're a little
18 behind schedule. We have one more measure that
19 we were supposed to do before lunch but it's
20 almost time for public comment.

21 So I think the suggestion up here is
22 to get the pulse of the committee to let's go

1 ahead and do public comment. And then, as we did
2 yesterday, get our lunch and then do a working
3 lunch to keep moving so that we can do the best
4 we can to get all the measures done today before
5 we leave.

6 Does that seem reasonable?

7 MS. BAL: Operators, any public
8 comment?

9 THE OPERATOR: At this time if you
10 would like to make a comment, please press star
11 then the number one.

12 (No response.)

13 THE OPERATOR: There are no public
14 comments at this time.

15 CO-CHAIR LANG: Also, we're going to
16 draw straws to determine whether the term that
17 each of us will serve on the Standing Committee
18 will be two years or three years; is that
19 correct?

20 MS. BAL: That's correct.

21 CO-CHAIR LANG: So it's either two or
22 three. I don't think there are any other

1 possibilities, are there?

2 CO-CHAIR BRATZLER: Two.

3 MS. BAL: Oh, sorry. Your name and the
4 years.

5 CO-CHAIR BRATZLER: Dale Bratzler, two.

6 CO-CHAIR LANG: David Lang, three.

7 DR. NISHIMI: Into the mike you need to
8 announce it.

9 MR. BENSON: Ken Benson, three.

10 DR. DORMAN: Todd Dorman, two.

11 DR. GLOMB: William Glomb, three.

12 MS. WEST: Chana West, two.

13 DR. OHTAKE: Patricia Ohtake, three.

14 DR. ELLIOTT: Kim Elliott, two.

15 DR. RILEY: Crystal Riley, three.

16 DR. YEALY: Don Yealy, two.

17 DR. LAMPONE: Thomas Lampone, two.

18 DR. COLLINS: Curtis Collins, three.

19 DR. DiGIOVINE: Bruno DiGiovine, two.

20 DR. BAULDOFF: Gerene Bauldoff, three.

21 DR. JIMENEZ: Edgar Jimenez, two.

22 DR. GROSSBART: Stephen Grossbart,

1 three.

2 DR. O'BRIEN: Jim O'Brien, three.

3 DR. MURRAY: Richard Murray, three.

4 DR. SCHINDLER: Christine Schindler,
5 three.

6 MS. BAL: So for the people on the
7 phone, for Mitch Harris is two; Susan Pollart is
8 two; David Stockwell is three; and Ella is two.

9 DR. NISHIMI: Thank you. Lunch is
10 ready.

11 CO-CHAIR BRATZLER: So let's take about
12 10 minutes, 10-15 minutes max and then by 12:30
13 we'll get back and get started again.

14 MS. BAL: Adam, we'll be back at 12:30
15 and we'll go over your measures. Thank you.

16 (Whereupon, the above-entitled matter
17 went off the record at 12:15 p.m. and resumed at
18 12:30 p.m.)

19 CO-CHAIR BRATZLER: All right. Is
20 everybody ready to get started again? And,
21 Adams, are you on the line?

22 (Pause.)

1 DR. NISHIMI: Operator, is Adams
2 Dudley on the line?

3 THE OPERATOR: No, they haven't joined
4 yet.

5 (Pause.)

6 CO-CHAIR BRATZLER: So, we're waiting
7 on our developer to get on the line. If it's
8 okay, I guess we can go ahead and start.

9 Okay. So, this is a maintenance
10 measure. So, our two discussants are Edgar and
11 Patricia and we'll go ahead and do the
12 conversation about evidence. And then once Adams
13 rejoins the call, we'll ask him to give an
14 overview of the measure.

15 DR. OHTAKE: Thank you. So, this is
16 Measure 0703, Intensive Care In-Hospital
17 Mortality Rate. And it's for all adult patients
18 admitted to the ICU and the percentage of
19 patients whose hospital outcome is death, both
20 observed and risk-adjusted mortality rates are
21 reported with predicted rates based on the
22 Intensive Care Outcomes Model-Mortality.

1 And so, the rationale is that death is
2 the reason -- preventing death is the reason why
3 people are admitted to the ICU. This is an \$81
4 billion enterprise to care for our patients in
5 the ICU and we certainly want to be sure we're
6 doing the best -- providing the best care
7 possible.

8 The numerator is all of -- the total
9 number of eligible patients whose hospital
10 outcome is death. And the denominator is the
11 total number of eligible patients who are
12 discharged, and this includes both deaths and
13 transfers out to other hospitals. And this is an
14 adult measure. So, individuals less than 18
15 years of age at the time of ICU admission are
16 excluded.

17 ICU readmissions are excluded. Short
18 stays in the ICU are excluded, less than four
19 hours, or primary admission for trauma burns or
20 immediately post-coronary artery bypass grafting,
21 or admitted with a diagnosis of rule-out MI.

22 It's an outcome measure and currently

1 it's being -- the data is being abstracted from
2 paper medical records, although the developer
3 indicated that an eMeasure is in development and
4 they hope to have that available in 2016. And
5 the level of analysis is at the level of
6 facility. It was first endorsed in 2001.

7 As far as the evidence goes, the
8 developers have indicated that there was some new
9 evidence. But when the NQF staff reviewed that,
10 there didn't seem to be a lot of updated
11 literature available.

12 And when we discuss this in our
13 workgroup, our workgroup agreed with that that
14 the evidence seems to be consistent with what was
15 available at the previous endorsement.

16 DR. JIMENEZ: Nothing to add, except
17 that it is paired with 0702, right? Just to keep
18 in mind as we go through that this is a paired
19 measure.

20 DR. OHTAKE: Thank you.

21 CO-CHAIR BRATZLER: Todd.

22 DR. DORMAN: So, really a point of

1 clarification. So, it's not really an evidence
2 question, but this point of it moving to an
3 eMeasure, does that impact our discussion?

4 And if we -- will they then dovetail
5 that under this and be allowed to continue with
6 if we approve this as an eMeasure, or does that
7 have to come back?

8 DR. NISHIMI: You aren't approving it
9 as an eMeasure. You're approving what's before
10 you.

11 They would have to bring an eMeasure,
12 because there are some very specific criteria.

13 DR. DORMAN: Okay. Thank you.

14 CO-CHAIR BRATZLER: So, Operator, can
15 you tell us -- oh, I'm sorry. James, go ahead.

16 DR. O'BRIEN: So, the one evidence
17 that I might suggest that has some relevance is a
18 paper from Jack Iwashyna in Michigan, which looks
19 at confounded by indication risk adjustment.

20 The foundation of that is based around
21 observational studies, but I think has
22 applicability when it comes to benchmarking, but

1 suggests that when there is -- is truly
2 confounded by indication, which may be the case
3 in ICUs that sicker patients may be transferred
4 or present to different hospital.

5 Risk adjustment really doesn't help
6 you to overcome that and you still wind up with
7 misclassification as far as the actual underlying
8 effect.

9 CO-CHAIR LANG: I just wanted to
10 clarify since Edgar mentioned this, that the next
11 measure that we're going to be considering
12 concerning length of stay in the ICU, it was
13 stated on our phone call by Adams Dudley that
14 that measure, the length of stay measure, is only
15 to be used if you're also doing mortality
16 reporting. So, that clearly is not a standalone
17 measure.

18 DR. DIGIOVINE: And I just want to
19 make a comment to James' point. I just want to
20 make sure I understand it.

21 I think Jack Iwashyna's research is
22 around transfers from another hospital, which I

1 understand is an exclusionary criteria for this
2 measure. I just wanted to be sure that was
3 correct.

4 DR. JIMENEZ: That's correct.

5 DR. O'BRIEN: So, I think the other
6 applicability, though, I can certainly see with a
7 tertiary care hospital in urban environment,
8 there may be a different indication for patients
9 who are admitted to ICUs there relative to a
10 hundred-bed hospital in a rural area.

11 DR. NISHIMI: Adams, have you
12 rejoined?

13 THE OPERATOR: Adams has not rejoined
14 yet.

15 DR. NISHIMI: I think we just have to
16 go ahead with the --

17 CO-CHAIR BRATZLER: So, at this point
18 we have to decide whether we're going to vote on
19 evidence. The subcommittee actually recommended
20 that we didn't need to vote on evidence, but I'll
21 leave it up to the group. So, raise your hand if
22 you think we should go ahead and vote on evidence

1 or move forward.

2 Do you think we should vote on
3 evidence? So, we have two votes. So, are we
4 doing this as a majority or -- majority, okay.

5 So, I guess we will not vote on
6 evidence at this point and go on and discuss gap.

7 DR. OHTAKE: Okay. So, the developers
8 provided information of performance scores from
9 data collected between 2010 and 2011. And it
10 looked at almost 70,000 patients and there were
11 just over 8,000 deaths for an overall ingested
12 mean mortality rate of 11.67 percent.

13 This is down 2.18 percent from the
14 previous data period. So, there has been some
15 movement in performance. However, there still is
16 felt in our discussion that there's definitely a
17 gap that -- a performance gap that can be
18 addressed by continuing to use this measure.

19 As far as disparities, there is --
20 were not disparities of actual patient
21 measurements reported. However, the literature
22 information identified -- that was presented

1 identified that there is disease-specific racial
2 variation among African-Americans.

3 There's also disparities for the
4 elderly. Particularly, the older women seem to
5 fare worse than men. And also based on insurance
6 status as well.

7 Edgar, is there anything else you want
8 to add?

9 DR. JIMENEZ: Nothing to add.

10 DR. DUDLEY: Hi. I just wanted to let
11 you know I'm here. This is Adams Dudley.

12 CO-CHAIR BRATZLER: Yes, Adams, this
13 is Dale Bratzler. So, we're going to in just a
14 moment have you give a brief overview of the
15 measure.

16 DR. DUDLEY: Okay.

17 CO-CHAIR BRATZLER: Don, can you --

18 DR. YEALY: Just one question for the
19 developer. The most recent data we have are four
20 plus years old. There's nothing more recent that
21 we can sink our teeth into regarding the gap?

22 DR. DUDLEY: No, we do not have more

1 recent data.

2 DR. YEALY: Any particular reason why
3 that is?

4 DR. DUDLEY: We have not -- right now
5 we are not collecting this data. We're waiting
6 for CMS evaluation for the possibility of
7 national adoption. So, there isn't a current
8 dataset.

9 CO-CHAIR BRATZLER: Bruno.

10 DR. DIGIOVINE: Yes, just sort of
11 relative to what we talked about last time, your
12 -- what is being shown here is crude mortalities
13 and you talked a little -- we talked a little bit
14 about a prediction score.

15 So, is the measure a raw mortality
16 score, or a standardized mortality score?

17 DR. DUDLEY: It's a risk-adjusted
18 mortality score.

19 DR. DIGIOVINE: Can you elaborate on
20 what you mean by that?

21 DR. DUDLEY: We use the measures that
22 were originally reported in what's called the MPM

1 Model, Mortality Prediction Model. It's one of
2 three major models used in ICU risk adjustment.

3 There are hundreds of published papers
4 with the three models. And what we did in
5 developing the model that was used for public
6 reporting is to compare the work required to
7 collect the data for each of the three models and
8 also to compare the performance assessments one
9 would generate using each of the three models.

10 We found very high correlation between
11 the performance assessment for the three models
12 above 0.9. And found that the model we're
13 currently using required much less work to get
14 the data collected than other models, less than
15 15 minutes a patient.

16 So, in the balance of the burden of
17 data collection and the benefits in terms of
18 prediction, it seemed like it fell towards the
19 model that we're currently using.

20 DR. DIGIOVINE: I'm sorry, Adams.
21 Maybe I didn't ask my question clearly. So, if
22 you're MPM and you have a predicted mortality for

1 every patient, why don't you report for our
2 review standardized mortality ratios rather than
3 just crude mortality rates?

4 DR. DUDLEY: Report to you for your
5 review, or report to the -- we report both to the
6 -- to the hospitals that are part of the program,
7 and we'll report to you anything you would like.

8 DR. DIGIOVINE: So, the numerator is
9 the number of deaths. The denominator is the
10 number of patients.

11 DR. DUDLEY: Right.

12 DR. DIGIOVINE: So, the score would be
13 a percentage. How does that percentage then
14 become risk-adjusted?

15 DR. DUDLEY: So, we calculate -- so,
16 that's the raw data. And then for each patient
17 we have all the variables that go into the risk-
18 adjustment model we calculated and expected
19 mortality rate. And we also report and observe
20 to expected mortality rate.

21 CO-CHAIR BRATZLER: So, other
22 questions about performance gap?

1 (No response.)

2 CO-CHAIR BRATZLER: So, before we vote
3 on performance gap, Adams, I was wondering if you
4 wanted to just give a brief -- we kind of jumped
5 into the measure without you, but if you wanted
6 to give any brief introduction to the measure?

7 DR. DUDLEY: And I apologize for not
8 being here at the beginning. I didn't catch the
9 schedule change.

10 So, the -- obviously mortality in the
11 ICU is extremely important. And we decided in --
12 a group of volunteer hospitals in California
13 started measuring this in 2006 and publicly
14 reporting it in 2007.

15 And along with the public reporting,
16 developed some performance improvement
17 collaboratives. And that is -- it's from those
18 groups that this data comes.

19 It eventually expanded to every
20 hospital with at least 200 beds in California.

21 CO-CHAIR BRATZLER: Is it being used
22 outside of California, Adams?

1 DR. DUDLEY: It is not being used
2 outside of California.

3 CO-CHAIR BRATZLER: Okay. All right.
4 So, we've had a conversation about performance
5 gap.

6 Any other conversations about
7 performance gap? And if not, we'll go ahead and
8 vote on performance gap.

9 MS. AMIRAULT: Performance gap for
10 0703. One being high; two, moderate; three, low
11 and four, insufficient.

12 (Voting.)

13 MS. AMIRAULT: If everyone could just
14 do it one more time? Sorry about that.

15 (Voting.)

16 MS. AMIRAULT: Five high, 13 moderate,
17 two low and two insufficient. Based on the
18 percentage, we'll move along.

19 CO-CHAIR BRATZLER: Okay. And so,
20 we'll move to a discussion of reliability.

21 DR. JIMENEZ: With reliability, there
22 was about 94 percent with a range of 85 to 97

1 percent.

2 The difference in performance can be
3 identified and requires quality data collection,
4 though. I mean, it is an intensive, manual, at
5 this point in time, operation.

6 And then at the level it performs, it
7 can be varying in quality outcome. So, based on
8 our algorithm, it can be rated as high in
9 quality.

10 DR. OHTAKE: I just add that they
11 looked at inter-rater reliability, as Edgar said,
12 with trained auditors compared to the hospital's
13 data abstracters.

14 CO-CHAIR BRATZLER: And did -- as
15 we've discussed with previous measures, is there
16 any ongoing periodic reliability testing to
17 participate in the database?

18 DR. OH TAKE: I think we'd have to ask
19 the developer that. But from the measure, they
20 indicated that this was a critical point, as you
21 bring up. So, perhaps the developer could tell
22 us about any ongoing quality checks on the

1 particular hospital abstracters or data
2 collectors.

3 DR. DUDLEY: It is important. And,
4 actually, even when someone new comes on to learn
5 to collect the data, I would -- we strongly
6 recommend training beforehand.

7 The training isn't terribly onerous,
8 but it is important. And then we would recommend
9 approximately every year or two, we found with
10 every two-year auditing that the data stay pretty
11 well on track.

12 CO-CHAIR BRATZLER: James.

13 DR. O'BRIEN: Can the developer just
14 clarify -- I saw that transfers into a hospital
15 are excluded from the denominator. Transfers out
16 of the hospital, though, look like remain and are
17 considered a patient who survived the
18 hospitalization; is that accurate?

19 DR. DUDLEY: That is correct.

20 CO-CHAIR BRATZLER: Any other
21 questions/comments about reliability?

22 (No response.)

1 CO-CHAIR BRATZLER: Okay. All right.
2 So, we'll go ahead and vote on reliability.

3 MS. AMIRAUULT: Reliability for 0703.
4 One being high; two being moderate; three, low or
5 four, insufficient.

6 (Voting.)

7 MS. AMIRAUULT: Four high, 15 moderate,
8 three low and zero insufficient. Based on the
9 percentage, we'll move along.

10 CO-CHAIR BRATZLER: All right.
11 Validity testing.

12 DR. JIMENEZ: To validity. Great.
13 The risk adjustment follows a Bayesian
14 statistical model. The areas under the curve are
15 0.81. And if you correlate with others, the
16 system measure as 0.92. And they allow
17 differentiation across the measured entities.

18 The exclusion criteria are appropriate
19 through SDS parameters. And the usual groups
20 that have been excluded also like burns, trauma,
21 cardiothoracic are included in the database and
22 usually are seen by more specialized hospitals,

1 too. So, it qualifies for moderate validity.

2 I don't know, Patricia, if you have
3 anything else.

4 DR. OHTAKE: I have nothing further to
5 add other than the risk adjustment variables.
6 There are 15 of them that are pretty commonly
7 used in risk adjustment with this particular
8 patient group.

9 CO-CHAIR BRATZLER: So, any committee
10 conversation or --

11 DR. O'BRIEN: Does the developer have
12 any information on the number of patients who are
13 excluded due to transfer and then also the number
14 of patients who are transferred out and
15 considered alive that are included in the
16 dataset?

17 DR. DUDLEY: Both are quite small. We
18 actually -- in the -- the issue of transfers came
19 up when this was first endorsed. And the
20 particular concern was raised by the American
21 Thoracic Society that academic medical centers
22 would be penalized by accepting in transfer

1 patients who were particularly ill.

2 The -- we analyzed at that time, we
3 have not reanalyzed since, the impact of
4 excluding all transfers, or just transfers in
5 each direction, and the performance score
6 correlations were about 0.95 with -- comparing
7 with transfers versus without transfers.

8 And so, the decision was made since
9 the area of particular sensitivity was transfers
10 into centers that were accepting high-risk
11 patients, that was the part that we decided to
12 exclude.

13 But as of the analyses when we went
14 through the initial endorsement, there is
15 essentially no impact on performance ratings.

16 Would this be an opportunity for me to
17 add another piece of information back on
18 performance gap? Is that okay?

19 CO-CHAIR BRATZLER: You can. It's
20 already passed on that criterion.

21 DR. DUDLEY: Sure. I just wanted to
22 get out there for future consideration, because I

1 know there will be more levels, I think perhaps -
2 - I was surprised by the low number of people who
3 thought the performance gap was high.

4 And then I thought about the context
5 and in reality it might look that way because
6 we've been measuring this and reporting it for
7 six years, but when we started, there were large
8 groups of hospitals that were three-fold
9 difference in risk-adjusted mortality.

10 So, I think that in thinking about the
11 performance gap, it might be worth considering
12 we're assessing that in a group of hospitals that
13 have been working on this for a long time, but
14 where talking about application of it almost all
15 the hospitals in the country haven't yet had this
16 applied. And so, the performance gap will be
17 much larger in that as it were a naive
18 population.

19 CO-CHAIR BRATZLER: And that will be
20 relevant to our conversation about use.

21 Todd, I know you had --

22 DR. DORMAN: Yes, I'm not sure if you

1 -- if you stated this earlier or if I missed it
2 in the paperwork. Which version of MPM are you
3 using for the -- Three? 3-0?

4 DR. DUDLEY: Actually, what we
5 recommend is using the variables and then
6 recalibrating the coefficients to the new
7 population frequently.

8 So, we actually recalibrate quarterly,
9 because treatment changes and sort of the essence
10 of what puts someone at risk doesn't change, but
11 the relative contributions of particular risks do
12 change over time.

13 And so, we actually recommend that you
14 recalibrate to the new population and the new
15 data frequently.

16 CO-CHAIR LANG: Yes, for your
17 calculation algorithm you stipulate on S-18 that
18 the death rate for each hospital is adjusted
19 according to average case mix.

20 Could you elaborate on that for us so
21 it can help me understand better how that's done?

22 DR. DUDLEY: Sure.

1 CO-CHAIR LANG: That would seem to be
2 a critical element of this measure.

3 DR. DUDLEY: Sure. So, I'll explain
4 the -- I'll start back with the last comment
5 about the recalibration.

6 So, what we do is we take all the data
7 from all the patients across all the hospitals
8 and calculate the impact of each risk factor
9 across all of the hospitals.

10 And then each of those variables
11 contributes to for an individual patient,
12 calculated risk of mortality.

13 And then looking at a particular
14 hospital you add up the predicted risk for each
15 of its patients. And that gets you an estimate
16 of what the predicted mortality should be.

17 And then you look at the number of
18 observed deaths and compare the observed to
19 expected.

20 So, for hospitals that have more risk
21 factors, you're applying to each of the
22 individual risk factors the average weight of

1 that across the state as recalibrated each
2 quarter. And then, therefore, they're getting a
3 higher predicted death rate per hundred patients
4 that they have and capturing their severity of
5 illness in that way.

6 Is that clear?

7 CO-CHAIR LANG: Yes.

8 CO-CHAIR BRATZLER: Any other
9 questions or comments about validity?

10 (No response.)

11 CO-CHAIR BRATZLER: Okay. Seeing
12 none, Janine, go ahead and vote.

13 MS. AMIRAULT: Just a note that the
14 highest eligibility for validity for 0703 is
15 moderate. So, options are two, moderate; three,
16 low and four, insufficient.

17 (Voting.)

18 MS. AMIRAULT: If you could just do it
19 one more time? Thank you.

20 (Voting.)

21 MS. AMIRAULT: Zero high, 13 moderate,
22 nine low and zero insufficient. And based on the

1 percentage, it's grey zone.

2 CO-CHAIR BRATZLER: Okay. We'll go
3 ahead and discuss feasibility.

4 DR. JIMENEZ: Okay. With the
5 feasibility, this is pretty much basically chart
6 abstraction and manual. So, that's a burden in
7 the collection, but the usefulness has been
8 referred to as outweighs the burden of the
9 collection.

10 And that's pretty much what I have.
11 I mean, it's the, you know, it's the, I mean, it
12 has been used in California extensively with no
13 problems at all reporting, except for the manual
14 collection.

15 DR. OHTAKE: I'd just like to add to
16 bring attention to the fact that there's no costs
17 or licensing requirements with this particular
18 measure. So, it's freely available.

19 CO-CHAIR BRATZLER: Is there any
20 sampling in cases, or is this a hundred percent
21 of the population at the ICU?

22 DR. DUDLEY: We request the first 400

1 consecutive -- sorry -- 100 consecutive patients
2 per quarter for a rolling annual sample of 400
3 patients.

4 CO-CHAIR BRATZLER: Thanks. Any other
5 conversation/questions about feasibility?

6 (No response.)

7 CO-CHAIR BRATZLER: Okay. Janine.

8 MS. AMIRAULT: Feasibility for 0703.
9 One being high; two, moderate; three, low and
10 four insufficient.

11 (Voting.)

12 MS. AMIRAULT: Two high, 14 moderate,
13 six low and zero insufficient. And based on the
14 percentage, we will move forward.

15 CO-CHAIR BRATZLER: All right. Then
16 usability and use.

17 DR. JIMENEZ: The measure has, like we
18 said, has only been used in California. It is
19 expected to have some acceptability from CMS as
20 it moves to an electronic format, but it's not
21 there yet.

22 So, besides the California

1 participating hospitals, there hasn't been any
2 other usability.

3 Now, I know from discussions that I've
4 had with the Leapfrog Group, that they are
5 looking for some measures that would eventually -
6 - would -- in the public format of reporting
7 would supply information on ICUs for the
8 intensivist physician standard, but -- and this
9 has been looked at by the -- will probably have
10 to be in electronic format before that.

11 DR. OHTAKE: I just add that the
12 developer stated that it was -- the measure was
13 discontinued use in 2013 because there are other
14 measures -- or in favor of measures required by
15 CMS.

16 So, I guess my question for the
17 developer is, is this measure currently available
18 for use as paper-abstracted literature should --

19 DR. DUDLEY: Yes. All of the
20 requirements to collect the measure are available
21 for free.

22 DR. OHTAKE: Thank you.

1 CO-CHAIR BRATZLER: So, I just want to
2 make sure I understand. So, in 2013 because of
3 competing priorities, it's just not being -- I
4 think, Adams, you said it was being voluntarily
5 collected by a number of California hospitals and
6 actually publicly reported by some.

7 DR. DUDLEY: Right.

8 CO-CHAIR BRATZLER: That's not
9 happening anymore?

10 DR. DUDLEY: The concern was that the
11 CMS data collection burden was increasing and
12 would push hospitals on their resources and they
13 were going to focus on those things, but we want
14 to move this over to a CMS-preferred format.

15 CO-CHAIR BRATZLER: Any other
16 questions/comments about use or usability?

17 (No response.)

18 CO-CHAIR BRATZLER: All right, Janine.

19 MS. AMIRAULT: Usability and use for
20 0703. One being high; two, moderate; three, low
21 and four insufficient.

22 (Voting.)

1 MS. AMIRAULT: One high, 11 moderate,
2 10 low and zero insufficient. And based on the
3 percentage, this is in the grey zone.

4 CO-CHAIR BRATZLER: All right. Our
5 last question is overall suitability for
6 endorsement.

7 Any other -- yes, Bruno.

8 DR. DiGIOVINE: So, I'll make my --
9 Todd made the comment earlier about using
10 mortality ratios as quality. And I just happened
11 to come across a quote from Dr. Hofer at the
12 University of Michigan who said that publication
13 of hospital mortality rates misinforms the public
14 about hospital quality and described them as
15 seriously inaccurate.

16 So, I just thought it would be -- I
17 think that's weighing on -- certainly weighing on
18 how I vote and thought the developer at least
19 should have an opportunity to respond to that.

20 DR. DUDLEY: Sure. I think -- so, I
21 publish with Tim on that topic and I do think
22 it's hospital to do hospital mortality reporting

1 wrong.

2 That's why you see us; A, having
3 tested the various available risk adjustments
4 very carefully to -- risk adjustments allow us
5 very carefully to be sure that we -- the one we
6 used performs adequately, and; B, using a
7 relatively largish sample size.

8 So, when you end up with 400 patients
9 per hospital, that's a much larger sample size
10 than what you're getting with most of the
11 currently publicly reported measures. So, most
12 hospitals that have MI reports and so forth from
13 CMS don't have 400 patients in the measure.

14 So that we reduce the risk of
15 misclassification both by having better risk
16 adjustment by far than the currently used CMS
17 models and by having large enough sample sizes
18 that the probability of risk adjustment is -- I'm
19 sorry -- of misclassification is much lower than
20 would be expected.

21 CO-CHAIR BRATZLER: James.

22 DR. O'BRIEN: I think probably in a

1 similar vein working in a health system that has
2 12 hospitals that are connected by an eICU in
3 which we're collecting APACHE IV measures, we see
4 that in our lowest acuity hospitals despite
5 adjustment, those have the lowest also observed
6 to expected mortality rates.

7 Part of that is due to the fact of
8 them being extreme outliers and the indication
9 bias for where they wind up being. And then the
10 performance of the risk adjusting focusing on the
11 middle part. And so, these extreme outliers of
12 hospitals even within, again, a 12-hospital
13 system, it just doesn't perform well. And so, it
14 doesn't even have face validity within our
15 system.

16 DR. DUDLEY: We -- again, we're
17 publicly reporting with this measure and we
18 didn't have an instance of the hospitals
19 complaining to the media that we were being
20 unfair to them or that we had misrepresented
21 their patient population.

22 I think it's possible that within a

1 system you get even more dramatic shifts in where
2 the patients go because it's within system issues
3 and that could be perhaps dealt with by transfer
4 rules.

5 But overall despite public scrutiny,
6 we did not actually have a problem with hospitals
7 complaining about the data, the accuracy of the
8 data, the accuracy of other people's data or how
9 they were rated.

10 Again, I think a lot of that comes
11 down to making sure people are carefully trained
12 to collect the data correctly and that you're
13 auditing them to make sure they're doing that as
14 well.

15 CO-CHAIR BRATZLER: And you have a big
16 sample size per hospital.

17 DR. DUDLEY: That does help.

18 CO-CHAIR BRATZLER: Yes. Any other
19 conversations before we vote on suitability?

20 (No response.)

21 CO-CHAIR BRATZLER: All right, Janine.

22 MS. AMIRAULT: Overall suitability of

1 0703. One being yes, and two being no.

2 (Voting.)

3 MS. AMIRAULT: Would you mind just one
4 more time? Thank you.

5 (Voting.)

6 MS. AMIRAULT: 13 yes, nine no. And
7 based on the percentage, this is also a grey
8 zone.

9 CO-CHAIR BRATZLER: All right. Thank
10 you guys very much. So, we'll move on. We're
11 about back on schedule, and go to Measure 0702,
12 Intensive Care Unit Length-of-Stay.

13 Adams, we'll let you introduce the
14 measure and then our two discussants will be Todd
15 and David.

16 DR. DUDLEY: Sure. So, first thing,
17 this measure comes from the exact same variables
18 and the exact same data collection as the prior
19 measure so that one ends up with both an outcome
20 -- a clinical outcome and an efficiency measure
21 from the same data collection.

22 We do not recommend that this measure

1 be used without the mortality measure, because we
2 wouldn't want people to focus only on length of
3 stay without having the clinical outcome also on
4 the dashboard because of potential unintended
5 consequences.

6 The approach to risk adjustment is
7 similar in that the exact same variables are
8 used. The modeling is slightly different because
9 it's a continuous variable that's skewed instead
10 of a binary outcome variable.

11 Because it's the same data, it's the
12 same training and it's the same auditing that we
13 recommend. And I think that's all I have to say
14 unless there are other questions.

15 CO-CHAIR BRATZLER: All right. Todd.

16 DR. DORMAN: I'm going to start. So,
17 Intensive Care Unit Length-of-Stay is the measure
18 title. It's an outcome measure. Paper medical
19 records. Level of analysis is at the facility
20 level.

21 It is a maintenance measure that was
22 previously endorsed in 2011. It is, I guess,

1 technically a paired -- or at least it's
2 recommended to be paired with the previous
3 measure that we just finished discussing.

4 Under evidence, which is where we're
5 starting, the developer tested that there is new
6 evidence since the last NQF review in 2011, but
7 only really provided explanatory information and
8 we'd like to hear a little bit more about that.

9 It should be pointed out that I guess
10 the phrase was used, "efficiency." This is
11 really connected to a contributor to cost, not
12 patient outcome at least as presented here.

13 And I think I'll stop there. I don't
14 think we saw any -- other than the comment from
15 the developer that there's new evidence that they
16 didn't provide a lot of information, I don't
17 think we were aware of any new evidence.

18 CO-CHAIR BRATZLER: Adams.

19 DR. DUDLEY: New evidence about -- I'm
20 sorry.

21 DR. DORMAN: The evidence.

22 DR. NISHIMI: New evidence for the

1 underlying rationale.

2 DR. DUDLEY: So, we -- the new
3 evidence -- perhaps I misunderstood the form.
4 The new evidence is just their updated validity
5 and reliability reports that we discussed with
6 the last variable -- the last measure, I mean.

7 CO-CHAIR BRATZLER: All right. Since
8 this is a measure that's for maintenance, does
9 the committee want to vote on evidence, or not?

10 If you do, raise your hand. Okay.
11 We'll go ahead then and discuss gap.

12 CO-CHAIR LANG: Data were collected
13 between 2010-2011. 224 hospitals contributing,
14 about 70,000 patients and more than a quarter
15 million ICU days.

16 The overall unadjusted mean length of
17 stay was 3.4 days with the standard deviation of
18 0.8 days.

19 The developer does indicate that
20 disparities exist among different population
21 groups, diagnosis, level of care and reported
22 racial disparities such that African-Americans

1 have an adjusted ICU length of stay that was
2 significantly shorter than that of Caucasians.

3 CO-CHAIR BRATZLER: Anything else,
4 Todd?

5 DR. DORMAN: I'd like to hear the
6 developer comment a little bit on the size of the
7 gap here and the difference in interquartile
8 ranges is 2.8 to 3.9, which is quite small.

9 DR. DUDLEY: Again, so this gets at
10 the gaps that you see in data that's been
11 reported to hospitals for six years.

12 In the beginning, the gaps were quite
13 a bit larger, but I think overall we found that
14 the length of stay gaps were less than the
15 mortality gaps.

16 So, in the original mortality pilot
17 study that we did back in 2006 -- 2005 and '06,
18 there were threefold differences between stable
19 groups of hospitals, you know, ten hospitals --
20 compared the top ten hospitals with the bottom
21 ten hospitals. There was threefold difference in
22 observed-to-expected mortality ratios. There

1 were not gaps that large in the length of stay.

2 Nonetheless from a payer perspective
3 the gap that is present even now is very
4 important. It's a very big difference to pay for
5 an extra -- even an extra half day on average of
6 ICU stay versus ward stay is very large.

7 DR. O'BRIEN: If the developer maybe
8 can just comment on that in the world of DRGs how
9 the payer winds up being on the hook, and then
10 also maybe considering Jeremy Kahn's work looking
11 at the effect of reducing ICU length of stay and
12 whether that actually impacts total cost.

13 DR. DUDLEY: The -- taking the second
14 one last, of course it's all part of a, you know,
15 it's ICU days are one input into a total cost of
16 care, but I think they're a very expensive input.

17 And so, to the extent that one can
18 optimize the use of that input, one is better
19 off.

20 Sometimes payment is based on a DRG.
21 That is true. In that case in the short term,
22 the savings don't accrue to the payer. But in

1 the long term, they recalibrate DRG rates based
2 on cost reports.

3 In addition, there are many payers,
4 for instance, many Medicaid programs that are
5 paying still on a per diem basis where the per
6 diem is higher if it's an ICU day than if it's
7 not.

8 So, we have a very eclectic approach
9 to payment, but in the long term it all comes out
10 in the end. We want to optimally use our
11 resources and if there's a way to use less and
12 get the same clinical outcomes, which is why we
13 always would use this with the mortality measure,
14 then that ought to be sought.

15 So, we manage to reduce statewide
16 risk-adjusted mortality substantially over the
17 reporting period while reducing the variation of
18 length of stay.

19 DR. DORMAN: Thank you. So, the
20 question I'm going to ask really I was going to
21 deal with under one of the other sections. But
22 since you brought up that the gap is growing, I

1 feel like I have to ask it now.

2 I'm trying to get at a better
3 understanding of what's being tracked and how
4 chart reviewers are figuring out whether a
5 patient in the ICU is actually an ICU patient or
6 a patient in the ICU.

7 And I don't think that that's
8 something that's commonly documented in a note.
9 I don't know how they would abstract that. And
10 so, it would not surprise me that ICU length of
11 stay is growing, but with patients who are
12 actually floor status patients who are staying in
13 the ICU.

14 So, since you brought it up under gap
15 even though it's probably closer to validity, I'm
16 trying to understand how you know these patients
17 are actually ICU patients and not step-down
18 patients, telemetry patients or floor patients
19 who happen to be physically located in an ICU.

20 DR. DUDLEY: So, it's part of the
21 training. It's something that we strongly
22 recommend is a matter of ongoing discussion among

1 the hospitals participating in any system.

2 We -- actually, let me go back for a
3 second. I don't think I said that the gap is
4 increasing. In fact, the gap isn't increasing.
5 It's actually decreasing because we've been
6 reporting it for a long time. What I meant was
7 that the mortality gap was greater than the
8 length of stay gap.

9 But at any rate, who meets criteria
10 for being an ICU patient is a very important
11 issue. And we discuss with the hospitals what
12 constitutes telemetry, how they've renamed their
13 units. We try not to just use walls and instead
14 talk about the intent of the care.

15 And the -- part of the rationale for
16 doing it a hundred consecutive patients at the
17 start of each quarter is to get the data capture
18 in real-time so that you don't have to go back
19 and figure out from the chart backwards was the
20 patient in the ICU.

21 eMeasures are also bad in this respect
22 in that it can be difficult to tell when the

1 patient officially left ICU-type care.

2 So, this will be an ongoing issue that
3 applies to any kind of ICU measure, but, again,
4 was something that the hospitals reporting this
5 were not as concerned about. Certainly didn't
6 complain to the media about any of this or
7 anything.

8 CO-CHAIR BRATZLER: Bill.

9 DR. GLOMB: I was going to ask whether
10 you'd consider using one of the commercially
11 available authorization and claims programs like
12 InterQual or Milliman to help you make those
13 determinations.

14 Those are used by everybody from
15 payers to hospital claims departments now.
16 They're universally reproducible in their
17 results. It's not geared toward the payer base
18 or the provider base and it seems like that might
19 solve part of that problem.

20 I'm frequently having to tell folks
21 who are unhappy with their claims resolution that
22 geography, where the patient is located in a

1 hospital, is not what constitutes level of care.
2 It's level of care that constitutes level of
3 care.

4 And so, that would avoid this question
5 about whether someone truly meets the ICU level
6 of care or not.

7 DR. DUDLEY: Right. So, the issue
8 there is that NQF measures can't have any
9 proprietary component to them or aren't supposed
10 to have any proprietary component to them. And
11 CMS isn't supposed to adopt things that have a
12 proprietary component to them.

13 So, we have tried to mimic those
14 without using official intellectual property of
15 someone else.

16 DR. NISHIMI: I just wanted to clarify
17 for you, Adams, actually NQF has for quite a
18 while now accepted measures that have proprietary
19 components.

20 DR. DUDLEY: Okay.

21 DR. GLOMB: And CMS does endorse, I
22 think, both -- I know InterQual, but I think they

1 also endorse Milliman.

2 CO-CHAIR BRATZLER: All right. So,
3 I'm going --

4 DR. DUDLEY: Well, that could be here.

5 CO-CHAIR BRATZLER: I'm going to bring
6 our conversation and make sure we're focused on
7 gap before we go on to some of these issues that
8 I think are around validity.

9 Any other issues around gap?

10 (No response.)

11 CO-CHAIR BRATZLER: Then let's go
12 ahead and vote. Janine.

13 MS. AMIRAULT: Performance gap for
14 0702. One being high; two, moderate; three, low
15 and four insufficient.

16 (Voting.)

17 MS. AMIRAULT: Two high, ten moderate,
18 ten low and zero insufficient. And based on the
19 percentage, this is grey zone.

20 CO-CHAIR BRATZLER: Reliability.

21 DR. DORMAN: So, the developer attest
22 that there's been no change in the

1 specifications. The measure is risk-adjusted.

2 The developer used data element reliability
3 testing that's been published with about 11,000
4 patients out of 35 California hospitals.

5 Inter-rater reliability was assessed
6 and was 91 and a half to 98.8 percent.
7 Reliability testing was both at the measure
8 squared and the data element, as I mentioned.

9 I'm not sure that that's -- let's see.
10 I think I'm going to leave it at that. And the
11 algorithm comes out to being eligible rating as
12 moderate.

13 CO-CHAIR BRATZLER: Bill, did you have
14 a comment?

15 (Off microphone comment.)

16 CO-CHAIR BRATZLER: So, I assume
17 reliability here is largely the same as the
18 measure we discussed previously, same data
19 elements.

20 Any other questions/comments about
21 reliability?

22 (No response.)

1 CO-CHAIR BRATZLER: Okay, Janine.

2 MS. AMIRAUULT: So, reliability for
3 0702. Two, moderate; three, low or four,
4 insufficient.

5 CO-CHAIR BRATZLER: Remember you can
6 only vote two, three or four here.

7 MS. BAL: I'm sorry. Before we
8 continue, I just want to make an announcement
9 that Mitch Harris is actually conflicted with
10 this measure. So, he won't be voting. Thank
11 you.

12 (Voting.)

13 MS. AMIRAUULT: One high, 14 moderate,
14 seven low and zero insufficient. And based on
15 the percentage, we can move along.

16 CO-CHAIR BRATZLER: So, we'll discuss
17 validity.

18 CO-CHAIR LANG: Validity. So, again,
19 this is not an eMeasure, but the data are
20 obtained from paper records.

21 The developer stipulates that
22 agreement was assessed between trained auditors,

1 the authoritative source and hospital data
2 collectors for all individual risk model elements
3 and the percent agreement was 94 percent.

4 There are a number of potential
5 threats to validity, including a handling of
6 transfers, which was mentioned, and appropriate
7 case mix and risk adjustment.

8 And there are a number of individuals
9 who I should preface my comment by stating have
10 more content expertise than me, but -- or than I
11 do, but my understanding is that APACHE has some
12 limitations for risk adjustments as reflected on
13 Page 27 where there's -- or 28, rather, where
14 there's an r-square of 0.42.

15 The argument here that there's a
16 strong correlation coefficient r of 0.89 between
17 a simplified method and APACHE and I guess if the
18 developer could help me understand the -- whether
19 this fully addresses the lower independent r -
20 square of 0.28 for the simpler model.

21 DR. DUDLEY: So, our focus is on the
22 public reporting of this. And so, if your -- and

1 where it's the r-squared -- and that -- sorry.

2 Our focus is on the public reporting
3 and that focus then is what's the score for a
4 hospital?

5 R-squared is a measure of the
6 explanation of variation in predicted scores for
7 a patient.

8 So, if there is noise at the patient
9 level that cancels out when you get up to the
10 hospital level, it's possible to have a lower r-
11 squared at the patient level and still have good
12 correlation between two different methods of
13 assessing risk and performance.

14 And so, the r of 0.89 is between the
15 simpler model and the APACHE model and is an
16 indication of very high correlation for the
17 hospital-level score between the two models.

18 And since our focus is on what in the
19 end do we say about the hospital's performance,
20 we find that helpful.

21 CO-CHAIR BRATZLER: Other comments
22 about validity?

1 DR. LAMPONE: I just had one comment,
2 and this was brought up earlier about the actual
3 length of stay.

4 I think we're talking about the
5 validity and reliability of the risk adjustment.
6 So, whether you have a patient that is admitted
7 to the ICU, continues to need to be at -- is
8 appropriate for that care setting.

9 Moving forward, how do you know to
10 your point that you have patients in the ICU that
11 weren't continued ICU stay, which seems to be the
12 driver of the -- of the basic question that the
13 measure is supposed to be answering.

14 And without having some structured
15 criteria, I think you get a lot of noise in the
16 measure, because there may be patients waiting
17 for a bed to open in the step-down unit, patients
18 where they're waiting on care decisions or things
19 aren't being delivered -- care isn't being
20 delivered efficiently that may skew this.

21 So, I wonder not only the committee's
22 ideas about that, but also the developer and

1 whether that is felt to be relevant enough to
2 play into this measure.

3 DR. DUDLEY: So, if the patient -- so,
4 there are two types of I'm in the ICU, but in the
5 heads of the ICU doc, for instance, I'm not an
6 ICU patient. There are two types of situations
7 you just described.

8 If the patient has been -- it has been
9 agreed that the patient should be discharged and
10 go to another floor and it's just that the bed
11 isn't there, then those orders are written and
12 our data collectors would not count the patient
13 as in the ICU.

14 If some care decisions have not been
15 made or other things have occurred that are --
16 potentially reflect inefficiency and it is not
17 clear that the patient is to leave, then we count
18 them and I think the perspective -- so, these
19 measures were developed and vetted by a group, a
20 multi-stakeholder board that oversees the whole
21 thing and it includes consumer and payer groups
22 as well.

1 And I think their perspective would be
2 if you haven't made the care decisions that
3 another hospital would have, then we want to hold
4 you responsible for that, because we're paying
5 for the lower efficiency and getting people to
6 talk to each other or whatever it is that it
7 takes to get to the care decision.

8 DR. LAMPONE: Yeah, the only thing I
9 would add is that I think you see many times
10 those patients who have had complex issues and
11 they're in the ICU still getting some treatment,
12 but basically being monitored. And there's a
13 subjective decision made that that level of
14 monitoring could not occur in another portion of
15 the hospital in another setting. So, I think
16 that's where it gets a little grey.

17 DR. DUDLEY: Right. And I've heard
18 preference for some of the proprietary methods of
19 assessing a patient's level of care, but I think
20 there's no way in the end that there isn't some
21 subjectiveness left in these decisions.

22 But I think that from a management

1 standpoint we have to pick a decision and -- or a
2 point at which we implement the idea that the
3 length of stay is ended.

4 And the orders are a clearer thing
5 that someone can abstract and be confident about.
6 And much of the other stuff that's uncertain and
7 varies and is subjective isn't stuff that we
8 would necessarily want to take account for and we
9 might even want to hold the hospital responsible
10 for that.

11 CO-CHAIR BRATZLER: James.

12 DR. O'BRIEN: So, just a -- it may be
13 -- I'm not sure if it's an error related to what
14 we have as far as the data dictionary, but what's
15 included on the NQF website says that the date of
16 discharge from the ICU is that latest documented
17 data of the patient being physically in the unit,
18 not when there's an order for discharge or
19 transfer.

20 DR. DUDLEY: I will look into the data
21 dictionary, but it -- they have to physically be
22 in the unit and -- I'm trying to think of how

1 that plays out differently. I'm not -- I'm not
2 sure about that.

3 CO-CHAIR BRATZLER: Bruno.

4 DR. DIGIOVINE: We just finished
5 reviewing a similar measure for pediatric ICUs
6 where they felt it was important to have
7 readmission data as a balancing measure when
8 looking at length of stay.

9 Do you think that is a threat to
10 validity in your -- in looking at it as an adult
11 ICU without knowing whether there may be
12 premature discharges that are leading to
13 readmissions?

14 DR. DUDLEY: Yeah, I thought that was
15 interesting. I think there's a big difference in
16 the importance of that in the pediatric arena
17 where mortality often is lower and -- but even
18 so, I wondered about that. I mean, what we care
19 about in the end is the clinical outcome, most
20 important clinical outcome, and then efficiency
21 in getting to that clinical outcome.

22 So, I think that at least from the

1 perspective of participants in our group, it was
2 not thought that going to the effort of
3 collecting readmission data was worth it and that
4 it was most important to have the clinical
5 outcome and then some efficiency measure.

6 CO-CHAIR BRATZLER: Other comments?

7 (No comments.)

8 CO-CHAIR BRATZLER: So, hearing none,
9 we'll go ahead and vote on validity.

10 MS. AMIRAULT: Validity for 0702.

11 One, being high; two, moderate; three, low and
12 four, insufficient.

13 (Voting.)

14 MS. BAL: Ella, can you please resend
15 your vote?

16 (Voting.)

17 MS. AMIRAULT: Zero high, 12 moderate,
18 10 low and zero insufficient. And based on the
19 percentage, it's in the grey zone.

20 CO-CHAIR BRATZLER: All right.
21 Feasibility.

22 DR. DORMAN: So, feasibility, I think

1 is -- gets us back into the same discussion to
2 some extent we've had. It's chart abstraction
3 and the primary concern really exists around that
4 concept. It was discussed -- or concerns were
5 raised around the statement that chart
6 abstractors took between 11 and 15 minutes. And
7 we've just spent a lot of time talking about the
8 complexity of figuring out whether the patient
9 was critically ill and required a critical care
10 service.

11 And I think the developer said earlier
12 that the people are trained to look for the
13 intent. Seems like it would take longer than 10
14 to 15 minutes to do that. So, there was
15 significant concern about that aspect.

16 CO-CHAIR BRATZLER: Any other --

17 DR. DUDLEY: I may have been unclear.
18 So, obviously looking for an intent is impossible
19 to do from a chart. I -- so, the -- I'm not
20 certain right now because I haven't gone through
21 an auditing process in a while, about the use of
22 orders versus use of the physically in the ICU,

1 but both of those are relatively easy to
2 implement.

3 CO-CHAIR BRATZLER: Yes, Chana.

4 MS. WEST: I was trying to be quiet
5 here, but in the -- in my past life I actually
6 was responsible for the people that were
7 collecting the data on this measure and the
8 previous measure. And it did take a significant
9 amount of time for them to pull the data from the
10 records. And it was an electronic measure -- I'm
11 sorry -- an electronic record. So, it wasn't
12 paper where they're having to flip every single
13 page in the chart. It was electronic, which is
14 easier to navigate and it did take a significant
15 amount of time to extract.

16 CO-CHAIR BRATZLER: Other comments?
17 Feasibility.

18 (No comments.)

19 CO-CHAIR BRATZLER: Okay. Hearing
20 none, Janine.

21 MS. AMIRAULT: Feasibility for 0702.
22 One, high; two, moderate; three, low and four,

1 insufficient.

2 (Voting.)

3 MS. AMIRAULT: Zero high, 11 moderate,
4 11 low and zero insufficient. Based on the
5 percentage, this is in the grey zone.

6 CO-CHAIR BRATZLER: And use and
7 usability.

8 CO-CHAIR LANG: Usability. Until
9 2013, the measure was used for internal QI in
10 California. In 2013, the developer transformed -
11 - began transforming the measure into an eMeasure
12 for consideration by CMS. Currently, a model
13 using data from two hospital EMRs is in progress.

14 Among the potential unintended
15 consequences from this measure, one was mentioned
16 previously, a premature discharge from ICUs.
17 Another potentially could be that hospitals may
18 seek to avoid high-risk patients who due to their
19 severity of illness may require longer ICU stays.

20 CO-CHAIR BRATZLER: Do you have
21 anything else, Todd, or anything?

22 (No response.)

1 CO-CHAIR BRATZLER: Any other
2 questions/comments about use or usability?

3 (No comments.)

4 CO-CHAIR BRATZLER: Okay, Janine.

5 MS. AMIRAULT: Usability and use for
6 0702. One, high; two, moderate; three, low and
7 four, insufficient.

8 (Voting.)

9 MS. AMIRAULT: Zero high, 10 moderate,
10 12 low and zero insufficient. So, this is also a
11 grey zone.

12 CO-CHAIR BRATZLER: And then our last
13 question about overall suitability for
14 endorsement.

15 Any other comments? I think we've
16 chatted with the developer quite a bit about
17 suggestions, concerns particularly about level of
18 care versus location of care, particularly about
19 whether there needs to be a balancing measure on
20 readmission or not. So, I think we've covered
21 all those points.

22 Any other comments, and then we'll go

1 ahead and vote on overall suitability?

2 (No comments.)

3 MS. AMIRAULT: Overall suitability for
4 measure 0702. One yes, two no.

5 (Voting.)

6 MS. AMIRAULT: Six yes, and 16 no.
7 So, this fails.

8 DR. NISHIMI: So, measure 0702 is not
9 recommended for endorsement.

10 CO-CHAIR LANG: We will be proceeding
11 with Measure 0468, Hospital 30-day, all-cause,
12 risk-standardized mortality rate following
13 pneumonia hospitalization.

14 Please.

15 DR. OHTAKE: I just have a quick
16 question. Since 0702 is meant to be paired with
17 0703 that failed, I'm just curious how that's
18 handled from a procedural, like --

19 DR. DUDLEY: No, 070 -- the mortality
20 measure is fine on its own. The length of stay
21 measure is the one we would not recommend being
22 used by itself.

1 CO-CHAIR LANG: So, we will readdress
2 the mortality measure on our phone call since
3 it's in the grey zone.

4 So, we're proceeding with Measure
5 0468. Are there developer representatives on the
6 phone who wish to comment or describe?

7 Wow. All day we've had people on the
8 phone and you're here. Thank you for being here.
9 Wow. You're right here.

10 Please, would you like to describe or
11 discuss the measure for two to three minutes to
12 introduce it to us?

13 DR. BERNHEIM: I'm going to let Karen
14 do that. This is Susannah Bernheim. I'm the
15 project director.

16 DR. DORSEY: I'm Karen Dorsey and so
17 I'll start by saying that this measure we are
18 sending back with some changes since the last
19 endorsement.

20 Specifically, we've expanded this
21 measure's cohort to include patients with sepsis
22 who have a diagnosis of pneumonia that's present

1 on admission and to include patients with
2 aspiration pneumonia. Those two sets of patients
3 were not included last time we came before the
4 committee.

5 This measure is an outcomes measure
6 measuring 30-day mortality. It has been in the
7 IQR program for several years. We present new
8 information about measure reliability, new
9 testing for the risk adjustment model because
10 we've expanded the cohort. So, there's quite a
11 bit of new testing in this endorsement
12 maintenance application.

13 The -- I think that we're sort of
14 prepared with questions that came up from the
15 working group to talk a little bit about
16 rationale for expansion of the measure cohort.
17 And so, we're eager to get into that discussion
18 with you all.

19 CO-CHAIR LANG: Great. Thank you very
20 much. I want to mention that we have two
21 individuals on our committee who are conflicted
22 and will not be participating. That's Mitch

1 Harris and Dale Bratzler.

2 And the measure will be reviewed for
3 us by Chana and Rich. Take it away. Benson,
4 please speak closer to the mic.

5 DR. MURRAY: Not the work, but that
6 should be a winning strategy. Okay. So, this is
7 hospital 30-day, all-cause, risk-standardized
8 mortality rate following pneumonia
9 hospitalization.

10 The steward is CMS. And so, mortality
11 is defined as death for any cause within 30 days
12 after the date of admission for the index
13 admission discharged from the hospital with a
14 principal discharge diagnosis of pneumonia.

15 And as was said, some of the
16 subcategories here we can get to in more detail
17 probably during validity. And CMS annually
18 reports this measure for patients who are 65 and
19 older although this, as I understand it, this can
20 be used to present data for over 18 or older than
21 65.

22 The level of analysis is the hospital

1 or acute care setting. And the data source for
2 the measure is administrative claims.

3 There is quite a bit of information
4 that has been reviewed for previous documentation
5 of the evidence and I don't think a huge amount
6 has been added since. Although, there have been
7 a couple of papers that are more recent that have
8 been cited and they are said to support some of
9 the changes in the numerator.

10 So, basically the rationale for this
11 is that the healthcare -- this healthcare outcome
12 developer states hospitals are able to influence
13 mortality rates through a broad range of clinical
14 activities, including preventing complications,
15 provision evidence-based care, discharge
16 planning, management of care, transitions,
17 medication reconciliation and patient education.

18 So, this is eligible for a pass
19 rating. So, I guess we're asked at this point
20 whether you want to actually review the
21 incremental evidence.

22 I think the question is, is how

1 important is the incremental evidence to the
2 decision to change the numerator?

3 I know it helps justify it, but the
4 change in the numerator was actually driven by, I
5 think, expert input.

6 DR. DORSEY: And so, there was some
7 evidence that we allude to in the materials of
8 changes in coding practices or increased use of
9 sepsis coding for patients who also have
10 pneumonia when they present to the hospital.

11 And that was -- well, I describe that
12 as sort of the starting point, what brought our
13 interest to looking into this in the fee-for-
14 service population specifically related to this
15 measure.

16 So, then we conducted a great deal of
17 analysis to look at whether or not this expansion
18 was good and whether the validity of the measure
19 would be enhanced. And so, it was that kind of
20 coupling of the evidence and our own
21 investigation.

22 CO-CHAIR LANG: So, unless --

1 DR. LAMPONE: I just had a
2 clarification on that. When you included sepsis
3 you said "not severe." Did that include hard
4 clinical evidence, or was that based upon
5 presentation evidence of hypotension,
6 tachycardia, etcetera, etcetera?

7 Do they have to have a bacterial or
8 culture positive data?

9 DR. DORSEY: So, this is all claims-
10 based. So, when we refer to severe sepsis, we're
11 referring to having received a principal
12 discharge diagnosis of severe sepsis according to
13 the current kind of coding guidelines.

14 DR. MURRAY: So, you don't know what's
15 behind that in any individual case, right?

16 DR. DORSEY: Only what the coding
17 guidelines instruct.

18 DR. MURRAY: And since we're talking
19 about sepsis, I understand there's been a recent
20 change sepsis-3 to the definition.

21 Is that something that we should be
22 discussing at some point? Are there any threats

1 to validity or now or --

2 DR. DORSEY: At some point I think for
3 certain that I think is not two weeks old yet --

4 DR. MURRAY: Right.

5 DR. DORSEY: -- that change to
6 guidance. So, it wouldn't change our sort of
7 conclusions about the appropriateness of this
8 cohort expansion right now, but it's certainly
9 something that we would have to revisit and come
10 back to the committee as hospitals begin to
11 uptake the new guidelines and if that requires
12 changes to what we're proposing today.

13 DR. YEALY: Maybe that's something I
14 could comment on. I just wrote an editorial on
15 this.

16 I'm not certain how broad the uptake
17 will be on the new sepsis-3 definitions. And
18 essentially all that happened in them was getting
19 rid of the term "severe sepsis."

20 DR. MURRAY: Right.

21 DR. YEALY: You're either septic or
22 septic shock. And I think there will be some

1 coding changes, but I don't think fundamentally
2 it will change it.

3 May I ask one question? How do you
4 restratify here? It says that they're risk
5 adjusted.

6 DR. DORSEY: We risk adjust for a
7 series of patient co-morbidities -- I'm sorry.

8 DR. YEALY: Okay. So, how exactly do
9 you do it?

10 DR. DORSEY: Well, we select variables
11 using the hierarchical condition categories which
12 group similar ICD-9 codes according to their,
13 sort of, likeness and condition.

14 So, we use the -- for this version of
15 the measure, the ICD-9 compatible map, which is
16 Version 12. And that's what makes up the
17 candidate risk variables.

18 And then we select which of those
19 variables are sort of the best predictors in our
20 models.

21 We use a hierarchical model that
22 adjusts for clustering of similar patients in

1 individual facilities.

2 DR. YEALY: So, I guess my concern is
3 two things would -- all right.

4 MR. SPEAKER: Get back to threats to
5 validity, I guess.

6 CO-CHAIR LANG: Focusing on evidence.
7 So, unless there is sentiment among the group
8 that we should vote, we'll pass and move to
9 performance gap.

10 MS. WEST: So, the developer ran four
11 years of data in order to calculate and see if
12 there were any discernible differences in
13 performance. And when they ran the data, it
14 seemed that there were some discernible gaps.

15 It seemed that African-Americans were
16 disproportionate in terms of -- in terms of
17 performance and -- but I think one of the things
18 that we talked about and we only discussed this
19 very briefly, this entire measure at the end of
20 the workgroup call due to timing constraints, but
21 the question was whether or not the measure was
22 actually having any impact, because the mortality

1 rates were actually increasing.

2 It went from with the initial -- or,
3 I'm sorry -- with the last evaluation in 2012 it
4 went from 11.7. And then with the most recent
5 data run it went to 16.4 percent. So, that was
6 one of the discussion points.

7 CO-CHAIR LANG: Please go ahead.

8 DR. DORSEY: So, the increase that
9 you're speaking of is directly and wholly related
10 to the expansion of the cohort.

11 So, the patients who have a principal
12 discharge diagnosis of sepsis or aspiration
13 pneumonia carry a higher mortality risk.

14 And so, when we brought them into the
15 cohort, it increased the average mortality rate
16 for the entire cohort, but we also present the
17 trend in mortality rates over three years.

18 And with the expanded cohort, you do
19 see a decrease in the mortality rates in the
20 national sample over the three-year period.

21 So, it decreased, but it -- the whole
22 thing increased because we included sicker

1 patients in the cohort.

2 CO-CHAIR LANG: Additional discussion
3 or questions for the developers? Yes, Bruno.

4 DR. DIGIOVINE: Yeah, so I'm trying to
5 understand the disparity issue. And this will
6 come up for the next one as well.

7 So, I'm reading this as every group
8 you point out has the same median rate of
9 mortality. So, that would strike me as a lack of
10 disparity.

11 And so, on what data are we using to
12 say there's a gap in performance? I don't know
13 what we would say would be the appropriate
14 mortality for patients admitted with pneumonia
15 for over 30 days.

16 DR. BERNHEIM: So, this has been
17 something that's actually always confused me
18 about this NQF form as well. So, I'll just admit
19 that.

20 So, there's two things about
21 performance gap. One is just as this measure is
22 used, do we think there's evidence that there's

1 still room to improve, that it's useful to report
2 this because we think there's evidence that
3 hospitals can improve and we're seeing that in
4 two ways.

5 One, there's still a substantial
6 distribution among all hospitals in mortality
7 rates. That is a hint that there's some room to
8 improve. And we're seeing some decreases over
9 the last three years and we think there's
10 probably still room to move.

11 The disparities piece is kind of stuck
12 in that same section of the application, but
13 you're right in this case. We're not seeing huge
14 disparities among hospitals based on their mix of
15 patients.

16 There's still a performance gap
17 nationally on this measure, but we don't see a
18 huge disparities gap.

19 Does that help?

20 DR. DIGIOVINE: So, just that last --
21 you said there's a performance gap on this
22 measure nationally based on what?

1 DR. BERNHEIM: So, based on the two
2 things I noted before that what -- how I
3 interpret the question of performance gap is, do
4 we think that there's evidence that there is room
5 for our nation's hospitals to do better?

6 And so, the fact that they have been
7 improving in recent years and that there's a wide
8 distribution across all hospitals suggests that
9 there is a gap in performance nationally, but
10 it's sort of distinct from the disparities
11 question even though those are lumped in the
12 form, which I think often confuses committees
13 and, quite honestly, developers.

14 DR. NISHIMI: Just as a point of
15 clarification why they're together. We have seen
16 measures for which if you were just to look at
17 the performance overall, one might conclude that
18 there's no longer a gap and no room for
19 improvement. But when you drill down and look at
20 disparities by race and ethnicity, there's a
21 clear breakdown.

22 So, in other words, there is room for

1 improvement. That's actually why it's very
2 important to look at those together.

3 DR. DORSEY: Thank you.

4 DR. YEALY: So, I'm -- again, it's
5 hard to know about a gap or disparities based on
6 care if we can't be certain that the illness
7 burden at presentation is the same, not illness
8 burden that eventually develops. That's a whole
9 separate -- that's actually what you're trying to
10 measure is the care quality.

11 So, absent using a pneumonia-specific
12 tool, which is virtually impossible to do from an
13 administrative dataset, how do we know that these
14 all -- that different collections of patient have
15 the same illness burden to start off with? I
16 don't -- that's why I was asking other questions
17 about how do you risk adjust.

18 What I'm hearing I don't think would
19 fully embrace all these and disparities could
20 just be different groups of people with different
21 initial illness burdens.

22 DR. BERNHEIM: All right. So, I think

1 you're asking -- and I'll just build off of what
2 Karen said, you know, how do we handle the fact
3 that either individual patients, subgroups of
4 patients or hospitals are going to have different
5 case mix of patients when they come in.

6 And so, you know, we have a model that
7 takes for each patient that links back to the
8 prior 12 months and collects all diagnoses from
9 their both inpatient and outpatient settings.

10 We have a fair amount of information
11 about patients, it's claims-based information,
12 but we have a fairly good sense for patients
13 about how sick they are and that is -- that risk
14 of adjustment is built in.

15 And in the original measure, we were
16 able to then validate it against the model using
17 clinical data for severity and show that the
18 hospital profiling was the same if you use the
19 claims data for the risk adjustment or the
20 clinical data.

21 Does that answer your question? I'm
22 not sure that I understood the question. So, I

1 just want to make sure I answered it.

2 DR. YEALY: It still doesn't sound
3 pneumonia-specific to me. I mean, so some of the
4 things you'd never be able to know.

5 For example, the respiratory rate is
6 a big driver of initial illness burden. You'd
7 never pick that up in a million years.

8 Minor alteration in sensorium you
9 would never -- is the single biggest driver.
10 Beyond that, you'd never pick that up.

11 DR. BERNHEIM: Right. So, very
12 important point. So, what we don't have is
13 exactly what you said, is we do not in this
14 measure have, you know, minute clinical data on -
15 - we don't have respiratory rate, we don't have
16 oxygen saturation. And that's why the original
17 chart validation was so critical.

18 So, in that case, what we did was we
19 took the exact same set of patients from the same
20 hospitals and we ran a model that used the claims
21 data for risk adjustment, and we ran a model that
22 did have that clinical data, and we asked the

1 question whether or not it profiled hospitals
2 similarly.

3 So, even if it doesn't get each exact
4 patient identical when you're at the aggregated
5 level of trying to understand the risk burden of
6 the patients even though it's a little bit
7 counterintuitive, we've done this with many of
8 our measures, we find that at the aggregate level
9 of the hospital the claims data does equate the
10 job at the risk adjustment. And so, we get very,
11 very similar outputs in the model as if we had
12 clinical data.

13 Not that we aren't eager to move
14 towards clinical data, but that's what we can do
15 with these measures.

16 DR. LAMPONE: I'm sorry, can I just --
17 I was just going to ask and I saw it in some of
18 the data provided in one document I couldn't
19 open, what are your age bands for risk
20 adjustment?

21 And the reason why I ask, I think, you
22 know, and this is a CMS measure, as you get

1 higher in age with co-morbidities, chronic renal
2 failure, even Stage 2 or 3 is not the same as
3 chronic renal failure, you know, in a younger
4 patient, because that's often coupled with other
5 co-morbidities such as congestive heart failure,
6 diabetes and other things that have been
7 longstanding.

8 So, how does your model adjust for
9 that? Because my experience with that age band
10 of over 65, they tend to bounce back to the
11 hospital much more frequently mainly in many
12 instances not because of the initial diagnosis,
13 but because the initial diagnosis exacerbated an
14 existing co-morbidity that wasn't really evident
15 at the time of discharge.

16 DR. DORSEY: Yeah, we do include age
17 as a continuous variable in our risk model.

18 DR. LAMPONE: And so, what is that?
19 What are those age bands? That's what I was
20 interested in.

21 DR. DORSEY: I don't -- I don't think
22 I understand your question, what are the age

1 bands?

2 DR. LAMPONE: What were the age
3 cutoffs? What are the different individual age -
4 -

5 DR. DORSEY: So, we use it as a
6 continuous variable for --

7 DR. LAMPONE: Okay.

8 DR. DORSEY: -- all fee-for-service
9 patients over 65.

10 DR. LAMPONE: Okay.

11 DR. DORSEY: That's who's in the
12 measure.

13 DR. LAMPONE: Does your risk model
14 take into account age into those -- into the risk
15 model?

16 DR. DORSEY: Yes.

17 DR. LAMPONE: Okay.

18 DR. DIGIOVINE: So, just because I
19 just want to make sure I understand this, your
20 data is again showing us no difference in
21 mortality rates over the period of time that
22 you're reporting. I thought I heard you say

1 that's because the definition changed.

2 I thought the definition change was
3 from here forward -- if the definition changed in
4 the past, when did it change? And can you show -
5 - do you have data using the same definition over
6 a period of time that is in our packet somewhere?

7 DR. DORSEY: So, the way that we
8 report the measures is that we use claims from
9 previous years. Right? So, we use claims for
10 three years previous to whatever year it's
11 reported in.

12 So, when we did the retesting of this
13 measure, we're actually using data from 2012
14 through 2015. So, that's why we're talking about
15 what's happened over the past few years.

16 So, we can change the definition of
17 the cohort, look at those years in the past, and
18 we can see the trends in the mortality rate in
19 2012, 2013, 2014.

20 And so, that's what we mean by a
21 decline over those past years even in the -- with
22 the expanded cohort definition.

1 Does that answer your question? So,
2 overall the mortality went up over that same
3 period of time from 2012 to 2015, because we
4 expanded the cohort and brought sicker patients
5 or patients with a higher risk of mortality into
6 the cohort over the -- compared to our old
7 definition that did not include sepsis or
8 aspiration pneumonia.

9 DR. DIGIOVINE: But it is true that
10 between 2011 and 2015 there's been no improvement
11 in --

12 DR. DORSEY: No, there has been, or
13 improvement in the outcome --

14 DR. DIGIOVINE: But the data you have
15 in front of us have a mean of 17, 17, 16 and 16.

16 DR. DORSEY: So, that's the -- that's
17 actually the between group of comparison. When
18 you look at the table right above that in the
19 summary document here, you can see the rates over
20 each year of measurement.

21 DR. DIGIOVINE: Right. And they go
22 16.8, 16.7, 15.5, 16.4.

1 DR. DORSEY: Right.

2 DR. DIGIOVINE: You're interpreting
3 that as an improvement?

4 DR. DORSEY: Yes.

5 DR. DIGIOVINE: Okay.

6 DR. BERNHEIM: The 16.8, 16.7, 15.5,
7 the 16.4 is mislabeled. That's the three-year
8 combined.

9 DR. DIGIOVINE: I see.

10 DR. BERNHEIM: So, just look at those
11 first three columns. That's the trend, that's --
12 those first three columns.

13 DR. DIGIOVINE: I see.

14 DR. BERNHEIM: The fourth column is
15 the three-year --

16 DR. DIGIOVINE: Okay. Thank you.

17 DR. BERNHEIM: -- combined.

18 CO-CHAIR LANG: Is there additional --
19 oh, go ahead. I'm sorry.

20 DR. GLOMB: Just for clarification,
21 that's a statistically significant improvement?

22 DR. DORSEY: We actually don't test

1 the statistical significance of it.

2 DR. GLOMB: Okay.

3 CO-CHAIR LANG: Are there additional
4 comments or questions for the developers
5 pertaining to performance gap?

6 (No response.)

7 CO-CHAIR LANG: As I see no further
8 comments/questions indicated, we'll proceed to
9 vote on performance gap.

10 Janine.

11 MS. AMIRAUT: Performance gap for
12 0468. One, being high; two, moderate; three, low
13 and four, insufficient.

14 (Voting.)

15 MS. AMIRAUT: One high, 11 moderate,
16 eight low and one insufficient. Based on the
17 percentage, it's grey zone.

18 CO-CHAIR LANG: Reliability.

19 DR. MURRAY: Do you want to continue,
20 or do you want me to go? I can go. So,
21 reliability has been tested. And the testing
22 shows that the measure data elements are

1 repeatable producing the same results a high
2 proportion of the time when assessed in the same
3 population and same time period.

4 The developer has conducted
5 reliability testing at the measure score level.
6 And as mentioned, there have been updates to
7 testing.

8 And the data being used include a more
9 recent cohort from 2011 to 2014 Medicare fee-for-
10 service in 4600 hospitals or so.

11 They used a split sample methodology
12 and reported the statistic of the intraclass
13 correlation coefficient which had a numerical
14 value of 0.79 which we're told is a strong
15 number, but perhaps you can speak to that. And
16 given the algorithm, it is potentially eligible
17 for a high rating.

18 So, could we ask the developers to say
19 a little bit more about the statistical method
20 and reliability testing?

21 DR. DORSEY: Sure. We actually have
22 one of our analysts on the phone and maybe she

1 can weigh in if the operator could open up her
2 line, but I'll say that we take the full three-
3 year measurement period and we randomly split it
4 into two equal -- two equal parts, two equal
5 samples, and then we look at the characterization
6 of hospitals in each sample and compare them.

7 And we calculate the intraclass
8 correlation coefficient in the hospital
9 performance.

10 DR. MURRAY: And this is on the raw
11 data, or is this on the risk --

12 DR. DORSEY: No, this is adjusted.

13 DR. MURRAY: This is adjusted. Okay.

14 Thank you.

15 Any other questions on this?

16 DR. NISHIMI: Operator, can you open
17 Jackie's line?

18 THE OPERATOR: I did not see that
19 Jackie is on the line.

20 CO-CHAIR LANG: Okay.

21 DR. NISHIMI: Only if the committee
22 has more questions about it.

1 DR. MURRAY: So, the question is, do
2 the results demonstrate sufficient reliability so
3 the differences in performance can be identified?

4 CO-CHAIR LANG: Are there additional
5 comments/questions for our developers?

6 (No response.)

7 CO-CHAIR LANG: Going once. Going
8 twice. We will proceed to you, Janine.

9 MS. AMIRAULT: Reliability for 0468.
10 One, being high; two, moderate; three, low and
11 four insufficient.

12 (Voting.)

13 MS. AMIRAULT: Five high, 13 moderate,
14 three low and zero insufficient. Based on the
15 percentage, we'll move along.

16 CO-CHAIR LANG: Proceeding to
17 validity.

18 DR. MURRAY: Do you want to take that
19 one? No? Go ahead.

20 MS. WEST: Okay. I'll take this, but
21 I will say that I'm not a methodologist or a
22 statistician. So --

1 MR. SPEAKER: That's okay. That makes
2 two of us.

3 MS. WEST: -- I'll definitely need
4 some other people to jump in here. So, with the
5 specifications as I noted earlier, several
6 changes were made.

7 They expanded the definition in terms
8 of the cohort, added "aspiration pneumonia," as
9 well as "severe sepsis."

10 They document inside of -- inside of
11 the measure information form where the literature
12 supports the increase in -- or the broadening of
13 the definition in adding severe sepsis in there.

14 And I know that we discussed on the
15 workgroup that there was some earlier reasons for
16 why they added aspiration pneumonia in there as
17 well.

18 In terms of the actual testing, the --
19 they conducted additional testing of the risk
20 adjustment model and the broadened definition --
21 I'm sorry -- they -- excuse me -- they conducted
22 additional tests of the risk adjustment model,

1 but did not conduct additional testing on the
2 respecified measure itself.

3 In terms of threats to validity, they
4 examined frequencies and proportions of the total
5 cohort use for each exclusion criterion and
6 provided percentiles for each of those used
7 there.

8 I'm not sure if anybody else wants to
9 jump in and be able to explain some of the
10 numbers that we're actually seeing in there, but
11 that was on page 7 of the actual document if we
12 wanted to post it for everyone to take a look at
13 it.

14 DR. MURRAY: So, I guess a couple
15 questions for the developers. The validity
16 testing results, are these -- they're not a
17 testing of the validity, they're a testing of the
18 risk stratification scheme, is that -- are they a
19 testing of just the risk stratification, really?

20 DR. DORSEY: So, we describe what we
21 do for measure validity. We describe the risk
22 model validation that was done as part of

1 original measure development and that we've
2 replicated from many of our claims-based measures
3 around other conditions.

4 And we talk about sort of our vigorous
5 adherence to the methodology around the
6 development of the measure itself. So, yeah,
7 it's mostly focused around the validity of the
8 risk model.

9 DR. MURRAY: So, I guess the question
10 stands as to whether the validity construct is
11 different now because the numerator has changed
12 so much and you've seen such a change actually in
13 the actual numerical value that comes from that
14 computation.

15 DR. BERNHEIM: And so, I think the key
16 thing there is that we felt like the expansion of
17 the cohort was largely a response to a threat to
18 validity.

19 So, the literature was indicating that
20 as hospitals were increasingly coding pneumonia
21 patients as septic and they were doing this at
22 very different rates at different hospitals, we

1 were losing many pneumonia patients in the
2 measure and we were losing different proportions
3 of them across hospitals.

4 And so, there was a threat to the
5 validity of the measure without these patients.
6 And so --

7 DR. MURRAY: Right.

8 DR. BERNHEIM: -- the other thing we
9 think is that it makes the measure a lot more
10 valid to bring these sepsis patients in who based
11 on the coding guidance before two weeks ago,
12 really anyone who was sick enough to be
13 hospitalized with pneumonia would meet criteria
14 for sepsis.

15 So, it was sort of just a choice for
16 hospitals whether to call these exact same
17 patients sepsis or not. So, we really needed to
18 bring them into the measure to keep the measure
19 valid.

20 The one other test we did, which isn't
21 sort of typical measure of validity, but I think
22 helped us feel very sure we were moving in the

1 right direction, is that we did an examination of
2 the relationship between a hospital's proportion
3 of pneumonia patients that were coded as sepsis
4 and how they did on this measure.

5 And what we saw in the old measure was
6 that hospitals that had a very high proportion of
7 their seeming pneumonia patients coming in with a
8 diagnosis of sepsis and therefore excluded from
9 our prior measure, tended to have pretty low
10 mortality rates because we were losing their
11 sickest patients.

12 And there was a relationship between
13 your tendency to code and how you performed on
14 the measure, which isn't clinically sensible.
15 And when we changed our approach, we no longer
16 saw this relationship.

17 Now, there's not a strong relationship
18 between what proportion of your patients are
19 septic or not and your performance.

20 Now, there's still a lot of variety in
21 the proportion, but we think we're getting a more
22 coherent and consistent population across

1 hospitals.

2 So, that's not a classic validity
3 test, but for us it was a sign of validity of the
4 change we had made to the measure.

5 DR. MURRAY: Thank you.

6 CO-CHAIR LANG: Bruno, go ahead.

7 DR. DIGIOVINE: Yeah, certainly a key
8 part of this measure is having pneumonia
9 identified as present on admission. I don't know
10 -- I know very little about coding, but how
11 reliable or how valid is coding to actually
12 identify those things that are present on
13 admission, and those things that truly do develop
14 later in the hospitalization?

15 DR. DORSEY: We have done some
16 analysis of present-on-admission coding and said
17 that there's, you know, been a good uptake since
18 it was mandated to be used for hospital-inquired
19 conditions. And those hospitals used these and
20 they applied them according to the guidelines and
21 they are applied correctly.

22 DR. LAMPONE: I just have one closing

1 comment. On the risk adjustment, I saw in the
2 documentation where you do have a number of
3 diagnoses that are used in the age range over 65,
4 which I think is good.

5 The question I have about this as it
6 relates to validity is when you have patients
7 that score high risk that come in with pneumonia
8 and they die, is there any adjustment in the
9 reporting where you would have patients that
10 would have a high expectation of nonsurvival of
11 that event within 30 days?

12 Because I think you're going to have
13 hospitals depending upon their geographic area,
14 they may have -- or just the demographic area of
15 that hospital where they may have higher numbers
16 of these folks coming in.

17 DR. DORSEY: So, the purpose of the
18 risk adjustment that we apply in the measure is
19 to account for differences in-house, patients are
20 at some hospitals versus others. Their burden of
21 disease when they walk in the door. When they
22 first get/seek treatment at the hospital. So,

1 that's the purpose of the risk model.

2 And what the measure does is it
3 basically takes into account how sick the
4 patients are at each individual hospital and it
5 assesses what we would predict the mortality rate
6 would be given how sick the patients at that
7 hospital are. And then it compares it to a
8 calculated national average of how -- an average
9 hospital would do with that patient -- with that
10 hospital's case mix.

11 DR. LAMPONE: So, you can predict the
12 mortality --

13 DR. DORSEY: Right. We predict it
14 based on -- and then compare it to the nation.

15 MS. BAL: Anyone listening on the
16 phone, please mute your computer. We're getting
17 a little bit of feedback of an echo. Thank you.

18 CO-CHAIR LANG: Additional
19 comments/questions concerning validity.

20 Bruno.

21 DR. DIGIOVINE: One more.

22 CO-CHAIR LANG: Go for it.

1 DR. DIGIOVINE: Mortality. So, in the
2 Medicare data patient population that I think is
3 easier for you to gather, how confident are you
4 that you have a valid way of assessing mortality
5 in patients under the age of 65?

6 DR. DORSEY: So, to address that I'll
7 basically explain how we developed our all-payer
8 model for the measure. And we actually did
9 retest it in the expanded cohort, but we use
10 state data from California which is one of the
11 states that has an all-payer database that
12 combines mortality information with inpatient
13 claims information.

14 So -- and outpatient claim -- just
15 inpatient claims information. So, we're able to
16 look at -- we're able to look in that setting in
17 California state, 18 and over, we're able to look
18 at -- build an all-payer measure and test it.

19 Not all 50 states obviously collect
20 mortality data or link it with claims in a way
21 that we would be able to use it and we have not
22 explored the implementation of something that

1 could work across 50 states. And recognize the
2 concerns about the current environment with
3 respect to HIPAA and moving away from unique
4 patient identifiers and restricting the kinds of
5 entities that can collect identifiers and
6 linkable data.

7 So, it's a, you know, it's a valid
8 concern about implementation, but currently the
9 measure is only reported in Medicare fee-for-
10 service over 65 for exactly that reason.

11 CO-CHAIR LANG: Additional discussion?
12 If not, Janine.

13 MS. AMIRAULT: Validity for 0468.
14 One, high; two, moderate; three, low and four,
15 insufficient.

16 (Voting.)

17 MS. BAL: Ella, please send in your
18 vote.

19 (Voting.)

20 MS. AMIRAULT: Two high, 14 moderate,
21 four low and one insufficient. Based on the
22 percentage, we can move along.

1 CO-CHAIR LANG: Feasibility.

2 DR. MURRAY: So, all data elements are
3 in fine fields in electronic claims and generated
4 or collected by and used by healthcare personnel
5 during the provision of care.

6 The data are coded by someone other
7 than the person obtaining the original
8 information. So, the feasibility should be
9 pretty good.

10 Any questions or discussion on that?

11 MS. WEST: I think that the only thing
12 that we had discussion about, and it's similar to
13 what -- when I just mentioned the concern about
14 capturing death --

15 DR. MURRAY: Right.

16 CO-CHAIR LANG: Any further
17 discussion? Do you want to say something?

18 DR. BERNHEIM: Just to respond to
19 that, I think, you know, the issue would be if an
20 entity wanted to use this measure in a broader
21 population. In its current use, again, it's used
22 just for the over 65 in Medicare. So, the death

1 capture is not an issue.

2 We purposely specified it to have
3 potentially use in other settings. So, any given
4 state that does have the ability or a health plan
5 that's got the right linked data obviously could
6 use it in a broader population we've shown that
7 the model works, but it shouldn't be used if
8 there's not a reliable source of death
9 information. And so, I think that's just a
10 limitation to the use of the all-payer measure.

11 CO-CHAIR LANG: Janine.

12 MS. AMIRAULT: Feasibility for 0468.
13 One, high; two, moderate; three, low or four,
14 insufficient.

15 (Voting.)

16 DR. NISHIMI: Crystal, can you submit
17 your vote?

18 (Voting.)

19 MS. AMIRAULT: Eight high, 13
20 moderate, zero low and zero insufficient. Based
21 on the percentage, we will move on.

22 CO-CHAIR LANG: Usability and use.

1 MS. WEST: Okay. As was already
2 mentioned, it's being used, the measure right
3 now, in the IQR program, the CMS IQR program, as
4 well as value-based purchasing.

5 CO-CHAIR LANG: Discussion.

6 (No response.)

7 CO-CHAIR LANG: All right. Seeing no
8 hands, we'll proceed to you, Janine.

9 MS. AMIRAULT: Usability and use for
10 0468. One, high; two, moderate; three, low and
11 four, insufficient.

12 (Voting.)

13 MS. AMIRAULT: Nine high, nine
14 moderate, three low and zero insufficient. Based
15 on the percentage, we will move on.

16 CO-CHAIR LANG: Now, we will consider
17 the overall suitability of the measure.
18 Discussion, additional questions for the
19 developers who are both here and I think they're
20 on the phone -- doesn't matter. They're here.

21 Any additional questions or comments?

22 (No response.)

1 CO-CHAIR LANG: Seeing none, we will
2 proceed to vote on the overall suitability for
3 endorsement of the measure.

4 MS. AMIRAULT: Overall suitability for
5 0468. One, yes; two, no.

6 (Voting.)

7 MS. BAL: Ella, please send in your
8 vote -- oh, never mind. We received it.

9 (Voting.)

10 MS. AMIRAULT: 17 yes, four no. So,
11 based on the percentage, this will be
12 recommended.

13 DR. MURRAY: David, where's the
14 related pneumonia mortality rate that comes up?
15 When do you want to talk about that? Should we
16 talk about it now?

17 DR. NISHIMI: No, we're going to
18 discuss --

19 DR. MURRAY: Do that later?

20 DR. NISHIMI: -- the last measure.
21 I'd like everyone to move crisply, and then we'll
22 be able to finish on time and we can have related

1 offline --

2 CO-CHAIR LANG: So, we're moving
3 forward to coup de grace for our two-day
4 experience, which is 1893, hospital 30-day, all-
5 cause, risk-standardized mortality rate following
6 chronic obstructive pulmonary disease
7 hospitalization.

8 MS. GORHAM: Before we move on, can I
9 ask how many of you have to leave before 2:30?

10 (Off microphone comment.)

11 MS. GORHAM: Okay. So, we'll still
12 have quorum. So, we can do this last one. Thank
13 you, gentlemen.

14 CO-CHAIR LANG: Thank you. You will
15 be conspicuous in your absence. Thank you.

16 Would the developers wish to make some
17 brief comments regarding the measure?

18 DR. DORSEY: I'll be very brief. This
19 measure assesses mortality within 30 days of
20 admission to the hospital for chronic obstructive
21 pulmonary disease for Medicare fee-for-service
22 for those 65 and older.

1 It has not changed since it was
2 previously endorsed. Although, we do present
3 some updated data.

4 CO-CHAIR LANG: Bruno, evidence.

5 DR. DIGIOVINE: We didn't think there
6 was any need to vote on the evidence.

7 CO-CHAIR LANG: Any further
8 discussion, comments? If not, we will pass and
9 then proceed to performance gap.

10 Bruno.

11 DR. DIGIOVINE: Yes. So, I think
12 performance gap is going to be the same. So,
13 I'll just highlight what I'm seeing.

14 So, at this time I don't think this
15 data is summarized. So, if it does look like
16 it's going 7.7, 8.1, 7.4, 7.8 over four
17 consecutive years and there doesn't seem to be a
18 difference across the different performance
19 groups, so I think there is still a concern that
20 we had about showing that there's a gap in care.

21 DR. DORSEY: That last column is a
22 three-year average. Sorry.

1 MS. BAL: Yeah, sorry about that.
2 That was a typo on staff's part.

3 DR. DIGIOVINE: But the -- okay. So,
4 again, I guess 7.6 -- 7.7 to 6.7 you're
5 interpreting as an improvement in care.

6 DR. DORSEY: It's small.

7 (Laughter.)

8 DR. DORSEY: But I'll also just, you
9 know, direct your attention to the range that we
10 still see, you know. It's a little narrow, even
11 narrower than the last measure we talked about,
12 but there still is a range of performance.

13 DR. BERNHEIM: Mark, our clinical
14 expert, is on the phone. Mark, do you want to
15 add any points to that sort of evidence of a
16 performance gap for mortality for patients with
17 COPD?

18 DR. METERSKY: Yeah. There have been
19 studies, although some of them are a little
20 dated, showing that some of the established
21 processes of care, that there are gaps in the
22 performance of those.

1 We certainly see problems with
2 transitions of care. Now, I'm speaking
3 anecdotally, but we see that all the time and a
4 lot of these patients will die after their
5 discharge, but granted it has been tough to show
6 improvement.

7 Probably many of you are aware of the
8 study seeking to improve post-discharge outcomes
9 looking at intensive contact with patients and it
10 actually increased mortality. So, it is a
11 difficult problem, but clinicians who work with
12 COPD do see gaps and certainly the evidence in
13 some process gaps is clear.

14 CO-CHAIR LANG: Is there additional
15 discussion?

16 (No response.)

17 CO-CHAIR LANG: Janine.

18 MS. AMIRAULT: Performance gap for
19 1893. One being high; two, moderate; three, low
20 or four, insufficient.

21 (Voting.)

22 MS. AMIRAULT: Two high, 14 moderate,

1 four low and zero insufficient. And based on the
2 percentage, we can move along.

3 CO-CHAIR LANG: Validity --
4 reliability, yes.

5 DR. DIGIOVINE: That's okay. So, in
6 terms of reliability the test was sort of an
7 interclass correlation coefficient with the main
8 testing we saw.

9 The split sample analysis was 0.51
10 which is lower than the sort of minimal
11 acceptable 0.7. There was a high, however, that
12 I didn't understand. So, I guess the developer
13 can help with the "however" piece of that, but
14 that was, I think, our concern in terms of
15 reliability.

16 DR. BERNHEIM: The "however" is mostly
17 that we use a very conservative approach. So, in
18 our measures that have lower volumes, we tend to
19 see slightly lower numbers, you know.

20 We're not allowing for any overlap
21 between the patients that are tested in the test
22 and retest. So, we're sort of doing the most

1 conservative testing.

2 And in both COPD and AMI where we have
3 lower volumes, we don't get quite to the same
4 level as we do in the higher volume measures.

5 We do have a lot of things built into
6 our measure to prevent us from misclassifying
7 small volume hospitals. I mean, that's one other
8 thing I'll say is that we exclude hospitals with
9 fewer than 25 patients from reporting.

10 And we, you know, use an interval
11 estimate for classifying hospitals that also
12 ensures that we're really confident about how we
13 classify them in the IQR program. So, that helps
14 with the reliability.

15 CO-CHAIR LANG: Are there any
16 questions/further comments regarding reliability?
17 I'm told that we can proceed to validity without
18 voting on reliability.

19 Is there an objection to proceeding to
20 validity?

21 (No response.)

22 CO-CHAIR LANG: With all due respect,

1 Janine, we're going to proceed to validity. Take
2 it away, Bruno.

3 DR. DIGIOVINE: Okay. So, validity
4 was done based on face validity. And, again, I
5 think I was somewhat -- the -- what is the
6 summary there says that 90 percent of the expert
7 panel agreed that it had face validity, but
8 conversely 60 percent were able to agree at a
9 level of -- that was either moderate or strong,
10 which meant that 40 percent did not agree that it
11 was either moderately or strongly had face
12 validity in terms of that this measure was an
13 accurate reflection of quality.

14 And so, that was certainly my concern
15 and the concern of our group.

16 DR. BERNHEIM: Yes. So, when we
17 developed this measure, we had developed a number
18 of claims-based measures where we had the
19 advantage of having the chart data to show the
20 validity of the risk model with the chart data.

21 For COPD we didn't have the same
22 advantage. We didn't have a national dataset of

1 chart-abstracted data. So, we have had to rely a
2 little on the fact that we've done a number of
3 measures where we've successfully done a chart
4 validation.

5 So, we've done that for stroke, AMI,
6 pneumonia, heart failure, many measures where
7 we've had chart data and showing the claims-based
8 models work.

9 I think when we don't have that data,
10 it's a little harder to get that strong validity.
11 So, we've depended on clinical experts.

12 This measure has now been out and
13 reporting for a number of years pretty
14 successfully. So, it's gaining face validity
15 since the time that it was developed, but the
16 numbers are what you see.

17 DR. O'BRIEN: There was -- I can't
18 remember if it was this measure of the prior one.
19 There was discussion -- previous discussion about
20 the hospice exclusion of the first day versus
21 subsequent days and looking at those.

22 For pneumonia, obviously as an acute

1 illness construct I get the notion that you can
2 enroll people and hospice changes their goals of
3 care as a result of patients getting worse
4 because of poor care.

5 With a chronic illness like COPD, that
6 actually may be a patient-centered outcome as
7 enrolling them in hospice yet they may die within
8 the next 30 days.

9 Have you had the chance to look at,
10 again, the enrollment in hospice not just on day
11 one, but subsequently during the hospitalization
12 to see how much of an impact that change in
13 exclusion might be?

14 DR. DORSEY: We've not looked at it
15 freshly. We did address this when we first
16 brought the measure before NQF and we found that
17 there's very, very little enrollment actually
18 during the index stay. And most enrollment
19 happens on discharge.

20 So, it's a very small, small group of
21 people who we identify by looking at days during
22 the index, or even before the index. Even before

1 the index it's less than two percent. So, we
2 haven't renewed that analysis.

3 DR. O'BRIEN: It just, for me, raises
4 the question of if it was actually included as a
5 longer exclusion, might that actually prompt
6 greater enrollment in hospice?

7 DR. DORSEY: Right. And the balance
8 -- the counterbalance to that is that we don't
9 want to mask signals of quality. So, we
10 purposely don't enroll after day one, because
11 decisions to move towards hospice could be
12 related to problems in care or harmed patients
13 during hospitalization. And so, that's the --
14 that's the balance.

15 DR. BERNHEIM: And, Mark, I'm going to
16 ask if you want to weigh in at all on this issue
17 of sort of whether it is different in a COPD
18 chronic condition population than in the
19 pneumonia population thinking about the exclusion
20 in the later days of stay.

21 DR. METERSKY: I think it's the same
22 concept, you know. If you don't do a good job

1 early and they end up on the ventilator, then
2 it's -- you're more likely to have that
3 conversation about hospice in a patient who if
4 care had been good, wouldn't have ended up on the
5 ventilator.

6 And I think it's a bigger issue for
7 COPD in that pneumonia is more often, as you
8 said, an acute issue and the expectation is that
9 most patients will get off the ventilator as
10 opposed to COPD where many patients may not once
11 they end up on the ventilator. So, it is a
12 balancing act. I agree with that.

13 CO-CHAIR LANG: Additional discussion?

14 (No response.)

15 CO-CHAIR LANG: So, I'm told that
16 similar to reliability with respect to validity,
17 although according to the algorithm this is
18 eligible for moderate or low, not high, we can
19 proceed to skip over pointing our blue gadgets at
20 Janine again and move forward to feasibility.

21 DR. DIGIOVINE: I'm going to take this
22 personally, David, you realize, but that's okay.

1 CO-CHAIR LANG: I understand. I
2 understand.

3 DR. DIGIOVINE: I'll keep moving.

4 CO-CHAIR LANG: I understand. Unless
5 there's an objection, we'll proceed to
6 feasibility without voting.

7 Bruno.

8 DR. DIGIOVINE: Feasibility,
9 electronic data, again, other than mortality
10 which we've already, I think, gone through, don't
11 need to go through it again, there's really
12 nothing else about it that makes it difficult to
13 collect.

14 CO-CHAIR LANG: Additional
15 discussion/questions for the developers?

16 (No response.)

17 CO-CHAIR LANG: Janine.

18 MS. AMIRAULT: Feasibility for 1893.
19 One, high; two, moderate; three, low or four,
20 insufficient.

21 (Voting.)

22 MS. AMIRAULT: Would you mind just

1 giving it one more shot? Thanks.

2 DR. NISHIMI: We have the votes on the
3 phone.

4 MS. AMIRAULT: Okay. 10 high, nine
5 moderate, zero low and zero insufficient. Based
6 on the percentage, it's grey zone.

7 (Off microphone comment.)

8 MS. AMIRAULT: Okay. Sorry about
9 that. It passed.

10 CO-CHAIR LANG: Couldn't wait for
11 everybody.

12 (Laughter.)

13 CO-CHAIR LANG: Usability and use.

14 DR. DIGIOVINE: Usability and use.
15 So, it's publicly reported in Hospital Compare.
16 I guess on use the question becomes one of
17 improvement whether it's actually showing that
18 there's been improvement. Other than that, I
19 don't think there's any issues.

20 CO-CHAIR LANG: Discussion?

21 (No response.)

22 CO-CHAIR LANG: Move forward to a

1 vote, usability and use.

2 MS. AMIRAULT: Usability and use,
3 1893. One for high; two, moderate; three, low or
4 four, insufficient.

5 (Voting.)

6 MS. AMIRAULT: Five high, 12 moderate,
7 two low and zero insufficient. Based on the
8 percentage, we can move on.

9 CO-CHAIR LANG: Overall suitability
10 for endorsement of the measure. Discussion?

11 (No response.)

12 CO-CHAIR LANG: Seeing no desire for
13 further discussion, we will proceed to Janine for
14 a vote.

15 MS. AMIRAULT: Overall suitability for
16 1893. One for yes, and two for no.

17 (Voting.)

18 MS. AMIRAULT: 18 yes, one no. And
19 based on the 95 percent, it can be recommended.

20 CO-CHAIR LANG: Thank you, Bruno.
21 That was excellent.

22 All right. So, now we have

1 harmonization or, I mean, the first two measures,
2 one of them failed. Go ahead. I'm sorry.

3 MS. BAL: Yeah. So, just out of
4 respect to everyone's time, we're going to not
5 discuss ruling competing. We'll bring that up at
6 the post-draft call.

7 We will not have a follow-up call, but
8 Janine will go over that in a second. But so,
9 we're just going to bring it up in the post-draft
10 call and give everyone a little bit extra time
11 today.

12 Would that be okay, or did you guys
13 want to discuss those?

14 CO-CHAIR LANG: I see no objection.

15 MS. AMIRALT: So, as Poonam just
16 mentioned due to the amount of grey zone measures
17 and other things to continue discussions, we're
18 going to hold two post-meeting calls. So, you
19 can expect a doodle poll -- excuse me -- two
20 post-draft comment calls.

21 And we will be sending a doodle call
22 out to everybody just to capture the availability

1 and organize.

2 MS. BAL: Okay. Just a little
3 clarity. There's two different types of calls.
4 So, we have a post-meeting call that was
5 originally scheduled for this coming Tuesday.

6 We will be canceling that call. We
7 were able to get through all the measures,
8 because you all are very amazing. So, thank you
9 for that. So, we do not need the post-meeting
10 call.

11 However, the post-draft call or the
12 post-comment call which happened after the open
13 commenting period, we will be scheduling an
14 additional call for that due to the number of
15 grey zone measures. And we want to make sure
16 that you have enough time to really discuss those
17 measures instead of the scheduled two-hour call.

18 Were there any questions about next
19 steps? Yes.

20 DR. O'BRIEN: Can you just comment
21 maybe about what the format of those calls are
22 going to be like for the post-draft comment

1 calls?

2 MS. BAL: It will be very similar in
3 concept to this. However, since most of them
4 fell in the grey -- or not fell -- they all --
5 many of them have grey zone, we would just start
6 at the end.

7 So, even if they had grey zone
8 throughout the review, we would start at the end
9 to see what your vote would be and you basically
10 review overall suitability for that vote.

11 Obviously you can bring up -- we would
12 ask the developer to provide more clarification
13 based off your notes and such.

14 DR. NISHIMI: If we have a quorum, we
15 will vote on the call.

16 MS. BAL: Any additional questions?

17 (No response.)

18 MS. BAL: All right. Thank you so
19 much, everyone. Especially the people on the
20 phone. We really appreciate your active
21 participation.

22 MS. MUNTHALI: And, I'm sorry. I just

1 wanted to -- I'm hoarse today, but wanted to
2 thank you all again adding to Poonam's gratitude
3 and especially to your co-chairs.

4 This was a great meeting. I know it's
5 very long and a lot of the issues are very
6 difficult, but we think it was very successful.
7 So, we'll be seeing you online. Thanks again.

8 DR. KAZEROONI: Thank you.

9 DR. POLLART: Thank you.

10 (Whereupon, the above-entitled matter
11 went off the record at 2:40 p.m.)
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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Pulmonary and Critical Care
Standing Committee Meeting

Before: NQF

Date: 03-16-16

Place: Washington, DC

was duly recorded and accurately transcribed under
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