

NATIONAL QUALITY FORUM

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ENDOCRINE MEASURE ENDORSEMENT PROJECT
STANDING COMMITTEE

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THURSDAY
FEBRUARY 27, 2014

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The Standing Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:00 a.m., William Golden and James Rosenzweig, Co-Chairs, presiding.

PRESENT:

WILLIAM GOLDEN, MD, Co-Chair
JAMES ROSENZWEIG, MD, Co-Chair
ROBERT BAILEY, MD, Janssen Scientific Affairs
TRACY BREEN, MD, North Shore-LIJ Health System
WILLIAM CURRY, MD, Penn State College of
Medicine, American Academy of Family
Physicians
JAMES DUDL, MD, Kaiser Permanente
INGRID DUVA, PhD, RN Veterans Health
Administration
STARLIN HAYDON-GREATTING, Pharmacy Quality
Alliance
ANN KEARNS, MD, PhD, Mayo Clinic
SUE KIRKMAN, University of North Carolina
Diabetes Care Center
ANNE LEDDY, MD, American Association of
Clinical Endocrinologists
GRACE LEE, MD, Virginia Mason Medical Center
LAURA MAKAROFF, DO, Health Resources Services
Administration (HRSA)
ANNA MCCOLLISTER-SLIPP, Galileo Analytics
PATRICIA McDERMOTT, RN, Aetna

JANICE MILLER, CRNP, Thomas Jefferson
University School of Nursing
CLAUDIA SHWIDE-SLAVIN, American Association of
Diabetes Educators
JANET SULLIVAN, MD, Hudson Health Plan
WILLIAM TAYLOR, MD, Beth Israel Deaconess
Medical Center, Harvard Medical School

NQF STAFF:

POONAM BAL, Project Analyst
HELEN BURSTIN, MD, Senior Vice President,
Performance Measurement
KAREN JOHNSON, Senior Director,
Performance Measurement
KAREN PACE, PhD, Senior Director,
Performance Measurement
LINDSEY TIGHE, Senior Project Manager,
Performance Measurement

ALSO PRESENT:

NONI BODKIN, Centers for Medicare and Medicaid
Services (CMS)
KYLE CAMPBELL, FMQAI, CMS*
KEZIAH COOK, Acumen, LLC
DEBORAH DIETZ, Acumen, LLC*
SOEREN MATTKE, RAND Corporation, CMS
ELIZABETH RICKSECKER, Centers for Medicare and
Medicaid Services (CMS)
ALMUT WINTERSTEIN, PhD, University of Florida,
CMS*

* present by teleconference

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

(8:06 a.m.)

CO-CHAIR GOLDEN: Good morning, everybody. Thank you for hanging in there yesterday. I hope you had a pleasant evening. I don't know about you but I woke up this morning and was wondering whether my dreams were valid and reliable.

The scary part was if we were a psychiatry panel, you would now be voting.

So we have another busy day. And I think we have a new agenda. Jamie, do you want to make any comments about yesterday? I know you are eating your breakfast. And we need to move along.

Does anyone want to have any comments or questions about yesterday? I talked with a couple of you and you thought things went reasonably well, all things considered. And we appreciate your attentiveness throughout the whole day. I think people were on track and having good

1 conversations. We actually got some things
2 done. So, it is good.

3 We go to 519 and there is a new
4 agenda and that is going to be the CMS measure
5 on foot care. And out discussant is Sue
6 Kirkman.

7 MS. TIGHE: And I will just jump
8 in. Operator, does Deborah Dietz have an open
9 line?

10 CO-CHAIR GOLDEN: Is she there?

11 MS. TIGHE: Cathy?

12 OPERATOR: Yes, ma'am?

13 MS. TIGHE: Does Deborah Dietz
14 have an open line?

15 OPERATOR: I'm not showing she has
16 joined at the moment.

17 MS. TIGHE: Okay. She might be
18 joining in the next couple of minutes. If you
19 could just give her an open line when she
20 calls in.

21 OPERATOR: Okay.

22 MS. TIGHE: Thank you.

1 OPERATOR: You're welcome.

2 MS. COOK: Hi, everybody. I am
3 Keziah Cook and I am with Acumen, LLC. We are
4 one of the companies working to develop
5 Measure 0159.

6 One of my colleagues, Deborah
7 Dietz should be joining us shortly. And
8 unfortunately with the reschedule, none of our
9 other colleagues are able to join but Deborah
10 and I should be able to answer your questions.

11 The measure captures whether there
12 is documentation in the home health clinical
13 record of both patient education and diabetic
14 foot care that includes monitoring of the
15 patient's lower extremities for evidence of
16 skin lesions.

17 Just to give a little background
18 about why CMS believes this measure is
19 important to continue reporting.

20 CMS began publicly reporting
21 quality data on the Home Health Compare
22 website in 2003. And initially all of the

1 reported measures were outcome measures.
2 However, we received significant input from
3 NQF and others that process measures,
4 including diabetic foot care in patient
5 education were important. So, these measures
6 were added in 2010 to capture aspects of care
7 that are directly under the provider's control
8 and to capture quality of care even for
9 patients who aren't likely to improve.

10 In addition to providing
11 information to consumers, the public reporting
12 of the measures was designed to reduce
13 variation and practice and otherwise to
14 incentivize agencies to adopt the best
15 practices of care for patients with diabetes.

16 The measure does seem to be moving
17 practices in that direction. There has been
18 steady improvement since adoption in 2010 and
19 CMS believes it is important to continue
20 reporting this measure. However, the measure
21 is based on generally accepted standards of
22 care. These standards of care applicable to

1 home health. The measure includes both foot
2 care and monitoring and also patient
3 education. So it important to note that even
4 though some of the literature regarding
5 interventions relating exclusively to patient
6 education are a bit mixed, we do also include
7 monitoring and foot care.

8 Between 2010 and 2013, the home
9 health agency average score on this measure
10 increased from 89.1 percent to 93.4 percent.
11 And this is based on all Medicare home health
12 agencies with at least 20 home health quality
13 episodes.

14 In 2013, there were about 850 such
15 agencies. That is about 71 percent of all
16 agencies. And as mentioned previously, this
17 is an existing measure that has been publicly
18 reported since 2010.

19 MEMBER KIRKMAN: Okay, so as you
20 heard, this is the measure is Diabetic Foot
21 Care and Patient Education Implemented. CMS
22 is the measure steward.

1 The description of the measure, as
2 you heard, is the percentage of home health
3 episodes of care in which diabetic foot care
4 and patient/care giver education were included
5 in the physician-ordered plan of care and
6 implemented for diabetic patients. And the
7 rationale is, as she said, that instruction on
8 foot care is expected to influence health
9 outcomes, fewer acute care visits for EDUs,
10 acute care hospitalizations, through reducing
11 diabetic foot ulcers. There has been
12 improvement in the measure over time.

13 The numerator is the number of
14 home health episodes. We are at the end of
15 the episode diabetic foot care and education
16 specified in care plan had been implemented.
17 So, my understanding is the numerator is
18 basically a checkbox on the form, although
19 there is significant sort of background
20 documentation that exists. And the
21 denominator is the number of home health
22 episodes of care, ending with a discharge or

1 transfer to inpatient facility during the
2 reporting period, other than those covered by
3 generic or measure specific exclusions.

4 And the denominator exclusions are
5 the patient is not diabetic or had bilateral
6 foot and lower leg amputations and also
7 episodes ending in patient death.

8 It is a process measure. It is
9 collected purely through electronic clinical
10 data and the facility, so the home health
11 agency is the unit of analysis.

12 In terms of the evidence, the
13 measure developers submitted 88 guidelines
14 regarding foot care and education. They also
15 submitted a systematic review, a Cochrane
16 review of patient education. The conclusion
17 is that there is insufficient evidence showing
18 that limited patient education alone is
19 effective in reducing diabetic foot ulcers.
20 I think sort of like the discussion we had
21 yesterday, I think most of the literature is
22 about a sort of comprehensive path of care

1 from risk assessment and then referring high-
2 risk people into some sort of comprehensive
3 program that includes foot care and patient
4 education but it is hard to kind of separate
5 out any one component.

6 The other comment I had about the
7 literature is that I am sure it is all
8 ambulatory care patients. So, it is here
9 being applied to home health care patients.

10 So, do I stop here and we talk
11 about evidence? Okay.

12 CO-CHAIR GOLDEN: Okay, was there
13 -- and I guess discussion of the committee
14 group, the subcommittee was reasonable,
15 unreasonable -- the question was by itself,
16 the evidence would be limited for
17 effectiveness as opposed to a component?

18 MEMBER KIRKMAN: Right. I think
19 the discussion was, and again, our workgroup
20 had the four foot care measures so I am sort
21 of forgetting when the discussion happened.
22 But I think for all of them it was the same

1 discussion that there is evidence but it is
2 typically not evidence for X component versus
3 not doing X component. It is typically sort
4 of a comprehensive program versus usual care.
5 So, it is very hard to kind of separate out
6 the evidence --

7 CO-CHAIR GOLDEN: It doesn't
8 necessarily stand alone but is a part of a
9 continuum and so forth.

10 MEMBER KIRKMAN: As part of a
11 continuum, there seems to be evidence. And
12 again, for this particular measure the patient
13 population studied, I don't think has
14 typically been a home health population. But
15 you could say in many ways they are probably
16 older and have more vascular disease and
17 probably may be higher risk for foot ulcers.
18 So, it sort of makes sense that they would be
19 a high-risk population.

20 CO-CHAIR GOLDEN: Comments and
21 questions about evidence>

22 MEMBER SULLIVAN: I have one

1 question for the developer. How is the foot
2 care education defined for them to be able to
3 check off a box? And also the exam, what is
4 their definition that they have to follow?
5 And how do you know if all of that is
6 followed? I know you do chart reviews.

7 MS. COOK: So, I can probably pull
8 up the exact guidance in a moment, if you are
9 curious. I believe that the education
10 component specifies that it is a comprehensive
11 education meeting standard practices. The
12 foot care component itself requires physical
13 examination of the feet, looking for lesions.

14 MEMBER MILLER: Are you talking
15 about diabetes education specific to foot care
16 or is it comprehensive diabetes education?

17 MS. COOK: It is diabetes
18 education specific to foot care.

19 MEMBER MILLER: And are there
20 specific components that are identified in
21 that?

22 MS. COOK: The general approach

1 with the various home health interventions
2 that are captured in the process of care
3 measures is to leave the specific
4 interventions up to the home health agency and
5 the patient's physician. What CMS collects is
6 whether or not interventions that meet best
7 practices were incorporated into the patient's
8 plan of care and implemented.

9 So the exact interventions are
10 left to the clinical discussion of the care
11 team.

12 MEMBER MILLER: Thank you. So, it
13 is kind of similar to what we talked about
14 yesterday with diabetes education being so
15 varied and so non-specific from agency to
16 agency. Thank you.

17 MEMBER CURRY: Sue, if you said
18 this while I was looking at the evidence
19 algorithm, forgive me. But has your group
20 recommended it is rated as insufficient
21 evidence with exceptions. Is that what you
22 came to?

1 CO-CHAIR GOLDEN: You may not have
2 gotten there.

3 MS. COOK: No, we did get there.

4 MEMBER KIRKMAN: Well, so it is a
5 process measure. There is a systematic review
6 with QQC ratings. And then yes, I think we
7 would get to 5c, that the systematic review
8 concludes that -- let's see.

9 Yes, so the systematic review
10 concludes that there is insufficient evidence
11 showing that limited patient education alone
12 is effective in reducing foot ulcers. But I
13 guess we felt like again, you have that
14 problem of trying to isolate out one specific
15 thing and also this measure is more than just
16 patient education. It is also inspection of
17 the feet, for whatever that adds.

18 But yes, I guess if we --

19 MEMBER SHWIDE-SLAVIN: I was
20 wondering how you got to insufficient evidence
21 with exception because we when we followed the
22 algorithm, we got to raise level from 5c.

1 MEMBER CURRY: So, one might look
2 at box 3 and then if the answer is no to
3 above, go from that point. Because is the
4 evidence really about the measure or is it
5 about other things around the measure and not
6 directly related to the measure.

7 Then you could go to box 7 and
8 then you could go to box 10, and then walk
9 over to what is insufficient with exception.

10 MEMBER KIRKMAN: Yes, although
11 there is a systematic review with grading of
12 the evidence. I'm not sure. I'm sorry.

13 DR. PACE: And I think the point
14 that you made about the measure is more than
15 just the education. So, if it were just the
16 education, you might up picking the low box.
17 But there still is an option to consider the
18 exception. But I think the question is, with
19 this having both components, is the other one,
20 as you were just describing, get you down to
21 looking at this as an exception.

22 And I guess the other question is,

1 is this any different -- you mentioned you
2 were looking at the other or yesterday looked
3 at the other foot measure. Is what is being
4 measured here much different? And would the
5 evidence requirement be different than what
6 you looked at before?

7 CO-CHAIR GOLDEN: So, just to
8 parse this out, you start to parse out what
9 evidence you are looking for. So, I guess the
10 first question is is any kind of education
11 about foot care a valid activity or just foot
12 care in general? And then you get into the
13 question of does this intervention that they
14 are measuring in the house have evidence of
15 value?

16 So, I think depending on how you
17 parse that, you can get into different
18 supports for the measure, I would think.

19 MEMBER KIRKMAN: Right. The other
20 thing is the Cochran review talks about
21 limited patient education. And so again, I
22 don't know whether your education is more than

1 limited. I mean, it is just very difficult.
2 And it is a lot like the measure yesterday.
3 I am reluctant to say that the evidence is low
4 because I think we are hampered by this,
5 trying to isolate out a specific component of
6 a bigger care process that does have evidence.
7 But if you look at one specific component of
8 it, you may not be able to prove that that
9 prevents foot ulcers.

10 CO-CHAIR GOLDEN: And I would
11 assume also that this measure would not
12 replace care in an office setting. So, it
13 would be a component of something that would
14 go along with other activities in the clinical
15 spectrum.

16 MEMBER KIRKMAN: Right. So, I
17 think if the home health patient has a primary
18 care physician, that they are still seeing the
19 primary care physician would still be
20 potentially held to the foot exam measures,
21 for example.

22 CO-CHAIR ROSENZWEIG: I was

1 curious why patients who were not amenable to
2 foot care education, such as patients with
3 dementia and various other categories were not
4 denominator exclusions.

5 MS. COOK: So, the measure
6 actually specifies that the education can be
7 provided either to the patient or to a
8 caregiver, such as a spouse or another family
9 member. So, if the patient is not able to
10 receive the education directly, then
11 presumably the home health agency would target
12 it toward a care giver.

13 CO-CHAIR ROSENZWEIG: Thank you.

14 MEMBER TAYLOR: Is it possible to
15 click on the link for the Cochran review?
16 Because it has a little short paragraph that
17 tells us what the review found about the
18 evidence. It's pretty revealing.

19 CO-CHAIR GOLDEN: I think if you
20 look in your book here, I think it should be
21 in here somewhere. Maybe not. Is that it?

22 MEMBER TAYLOR: Can people read

1 it? Would it help if I read it?

2 CO-CHAIR GOLDEN: If you have got
3 it, sure. Just summarize it.

4 MEMBER TAYLOR: Of the 12 RCTs
5 included, the effect of patient education on
6 primary --

7 CO-CHAIR GOLDEN: Page 28, by the
8 way.

9 MEMBER TAYLOR: -- endpoints was
10 reported in only five. Pooling of outcome
11 data was precluded by marked mainly clinical
12 heterogeneity. One of the RCTs showed reduced
13 incidence of foot ulceration, relative risk
14 0.31 with 95 percent confidence interval 0.14
15 to 0.66, and amputation relative risk 0.33
16 with a confidence interval of .15 to .76.
17 During one year follow-up of diabetes patients
18 at high risk of foot ulceration after a one-
19 hour group education session.

20 However, one similar study with
21 lower risk of bias did not confirm this
22 finding. Relative risk of amputation 0.98, 95

1 confidence interval of 0.41 to 2.34, relative
2 risk of ulceration 1.00, 95 percent confidence
3 interval of 0.70 to 1.44. Three other studies
4 also did not demonstrate any effect of
5 education -- likely underpowered.

6 Patients' foot care knowledge was
7 improved in the short-term in five of eight
8 RCTs in which this outcome was assessed as was
9 patients' self-reported self-care behavior in
10 the short-term in seven of nine RCTs.

11 Callous, nail problems, and fungal infections
12 improved in only one of five RCTs. Only one
13 of the included RCTs was at low risk of bias.

14 CO-CHAIR GOLDEN: Any other
15 comments or questions on this?

16 MEMBER SHWIDE-SLAVIN: Just as Sue
17 noted, one of the problems is that we are
18 talking about home health care and these
19 studies are not in home health care.

20 I just found another supporting
21 article when I was trying to find out more
22 about foot care education and there is a

1 randomized controlled trial that was published
2 in '89 of 203 patients that were randomized
3 into groups that got education and didn't get
4 education. And the group with education had
5 a p value of 0.0005 for the significance of
6 the education.

7 So, I think there is -- no,
8 amputation. I'm sorry. So, they were looking
9 at the incidence of lower extremity amputation
10 in diabetic patients, exactly what we are
11 looking at in these foot measures.

12 MEMBER KIRKMAN: The ulceration
13 rate.

14 I think another problem with all
15 these studies is it is a little bit like
16 education about kidney disease and trying to
17 show that you lower the rates of dialysis.
18 You know again, it is part of a comprehensive
19 thing. Yes, I agree that the evidence is
20 fairly mixed, if you try to pull out patient
21 education alone.

22 CO-CHAIR GOLDEN: Are we ready to

1 vote? Bill, you have one last comment?

2 MEMBER TAYLOR: Yes, the patient
3 education that is studied in the studies are
4 things like a one-hour group. And we are
5 talking about somebody at a home health agency
6 checking off a box that they did, this
7 required foot education.

8 MS. COOK: Can I just clarify?
9 The documentation on the OASIS instrument is
10 saying that there is evidence in the clinical
11 record that the intervention was performed.
12 The intervention itself in many cases is
13 significantly more extensive and it can even
14 include, over time, a nurse might be visiting
15 the patient every week for multiple times a
16 week and can include both an initial
17 information session and then also follow-up
18 with that patient.

19 Again, CMS doesn't dictate exactly
20 the education that the caregivers must provide
21 but at least some of the home health agencies
22 do provide much more significant education

1 than just a one-hour group session.

2 CO-CHAIR GOLDEN: Ready to vote?
3 You have the last question.

4 MEMBER HAYDON-GREATTING: I'm
5 sorry. If they don't dictate what type of
6 education, does CMS expect a standard, like a
7 nationally recognized program like what is in
8 LEAP or what other diabetes educators that are
9 accredited and certified are capable of doing?

10 MS. COOK: Can I actually ask if
11 Deborah Dietz managed to join the fun?

12 MS. DIETZ: Yes, I am here. Thank
13 you.

14 There is no specified national
15 standard. However, the way that this is
16 worded is that the agency must collaborate
17 with the physician to come up with orders for
18 specific interventions and then they must
19 implement. There must be evidence in the
20 record that they implemented those
21 interventions.

22 So, they are required to discuss

1 with the physician what education and
2 monitoring are appropriate for that patient
3 and then implement that.

4 MEMBER SHWIDE-SLAVIN: I just
5 wanted to point out even though when we
6 initially looked at this and the evidence
7 looked low, I really liked the way Bill
8 proceeded through the algorithm. Because I
9 think if it is rated as low, they won't
10 continue with the measure and then home health
11 agencies won't be accountable for doing the
12 foot care and education.

13 Whereas, if we rated it as
14 insufficient evidence with exception, then I
15 think the measure, we can move forward in our
16 grading of the measure.

17 CO-CHAIR GOLDEN: That would be
18 correct.

19 MEMBER KIRKMAN: Although, again,
20 I think we have to rate the evidence the way
21 we think the evidence really is. Right?

22 CO-CHAIR GOLDEN: Sure. It is

1 time to vote.

2 MS. BAL: Voting is open.

3 (Pause.)

4 MS. BAL: We have moderate one;
5 low four; intermediate one; and then
6 insufficient evidence with exception 13. So,
7 it goes forward.

8 CO-CHAIR GOLDEN: So, we will
9 continue. That means that would pass for
10 continued discussion.

11 So, we go to the next item, which
12 would be performance gaps.

13 MEMBER KIRKMAN: So, in terms of
14 performance gaps, they have a lot of data and
15 the average performance on the measure is
16 quite high. It is 93.4 -- I was reading that.
17 That's okay, I can read it from here. The
18 average performance on the measure is 93.4
19 percent. There is a basically a 17 percent
20 gap between the 90th and the 10th percentile.
21 And a 7.7 percent gap between the 25th and
22 75th percentile.

1 They do present results from 2010
2 to 2013 and there has been I think it is a
3 pretty slight improvement but some
4 improvements. And all groups in the disparity
5 stratification are above 90 percent. And for
6 2013, the 25th percentile was above 90
7 percent.

8 So, I don't think there is a large
9 gap because basically the agencies are all
10 doing quite well in this measure. I mean
11 again, I think it is sort of set up to be --
12 it is almost mandatory that the box be
13 checked. You know I am sure there is a lot of
14 documentation behind that but I think that
15 this is one where it is fairly straightforward
16 to meet the measure, technically.

17 So, it is hard to say from these
18 data that there is a large gap in care or
19 opportunity for improvement.

20 CO-CHAIR GOLDEN: Question for the
21 developer, CMS. This is embedded into OASIS.
22 Is that correct?

1 MS. COOK: That's right.

2 CO-CHAIR GOLDEN: So, regardless
3 of, I mean if -- there are elements in OASIS
4 that are not NQF measures. Correct?

5 MS. COOK: Exactly, yes.

6 CO-CHAIR GOLDEN: So, if there
7 isn't a performance gap, it would be up to you
8 whether you wanted to continue measuring it or
9 not really. So the impact of the NQF measure
10 per se would be for, I guess, maybe for
11 incentives or things?

12 MS. COOK: So, CMS prefers to
13 publicly report measures that are NQF-
14 endorsed. So for the most part, OASIS-based
15 measures that are not NQF endorsed are only
16 reported confidentially to the agencies. And
17 we have certainly seen that with these measure
18 of various types that look at interventions,
19 the improvement, since the adoption of OASIS
20 seen in 2010 has been much more substantial
21 for those that are publicly reported. So, the
22 agencies do seem to be motivated by public

1 reporting.

2 CO-CHAIR GOLDEN: Other comments
3 or questions on performance gap? Down at the
4 end, yes, Patricia.

5 MEMBER McDERMOTT: Based on what
6 was just stated, that there is an order first
7 from the doctor and really it is based on what
8 the doctor's order that the home health agency
9 is doing what the doctor ordered around
10 education and foot exam, I think that is what
11 I heard. This is really their documentation
12 that they followed a doctor's order. Did I
13 misunderstand?

14 MS. DIETZ: The only thing I would
15 add is that they, in home health, many of the
16 physician orders come at the behest of the
17 agency. So, that it means that they have
18 pursued this line of inquiry with the
19 physician, which got an ordered and then gone
20 ahead and implemented.

21 CO-CHAIR GOLDEN: I believe that
22 your issue about how -- and denominator

1 inclusion, that would be a specification
2 question about how the denominator gets
3 created. Is that your question?

4 MEMBER McDERMOTT: Well really if
5 it is an exercise in knowing that you followed
6 what a doctor asked you to do, it is not
7 something they are initiating on their own.
8 Right?

9 MEMBER KIRKMAN: But they have to
10 get the doctor's order, too. In other words,
11 they can't just assume that the doctor is
12 going to order it. So, they have to actually
13 sort of seek out the order, is my
14 understanding as part of to meet the measure.

15 MEMBER SULLIVAN: At least I know
16 for our enrollees, we ask the doctor for the
17 orders. We tell the doctor what we want in
18 the orders. Now, the doctor is completely
19 free to disagree with us but if you leave it
20 to the doctors to make the order, it is likely
21 that nothing would be ordered. I mean, it is
22 just not what they are thinking about, so that

1 is just now how it works.

2 I mean my feeling, I just want to
3 say just about the doctors' orders but also
4 about doing this, if it went -- I mean even
5 though there is no gap and that all the
6 agencies are doing it, if it wasn't in the
7 OASIS form, they wouldn't be doing it.

8 I know they could but I am just
9 saying if it wasn't in the form, it wouldn't
10 happen at all.

11 CO-CHAIR GOLDEN: It helps direct
12 activity. Yes, Bill.

13 MEMBER TAYLOR: I'd like to
14 clarify what that means about being in the
15 doctor's order. I am a primary care doctor
16 and I only take care of about 400 patients.
17 Most primary care doctors take care of between
18 2,000 and 3,000.

19 I send a patient home from the
20 hospital or somehow they get a referral to
21 home health agency. What happens as a
22 consequence of that is I get a form in the

1 mail sometime later, telling me to certify the
2 care for a certain period of time.

3 I have only said the patient needs
4 to go home and have services and I get about
5 a seven- to ten-page form with all sorts of
6 boilerplate written in it and I have to sign
7 my name and write a date at the bottom of each
8 one of those pages. I actually physically see
9 each page because I have to turn it. Do I
10 read it? Do I know if the home health agency
11 has included diabetic foot care in there,
12 which I am sure they have because we now have
13 94 percent compliance? I have no idea if that
14 is what I am signing.

15 CO-CHAIR GOLDEN: So let me just,
16 before we get too deep into this because I
17 think we are mixing up a little bit
18 specifications and performance gap. So, I
19 guess the question is, does this measure
20 include anybody with diabetes and home health
21 care or anybody with diabetes in home health
22 care with a doctor's order?

1 MS. COOK: It is anybody in home
2 health care with diabetes, with the very rare
3 exception of those who have bilateral
4 amputation.

5 CO-CHAIR GOLDEN: Okay. So, the
6 doctor's order is somewhat irrelevant because
7 if the patient --

8 MEMBER KIRKMAN: Well, they all
9 have doctor's orders typically.

10 CO-CHAIR GOLDEN: I understand.

11 MEMBER KIRKMAN: Or, if the
12 patient dies while under home health --

13 MS. COOK: Yes, that is quite
14 rare, too.

15 MEMBER KIRKMAN: Right.

16 MEMBER TAYLOR: In only mention
17 that because it was a question if this
18 communicates to the doctor and he makes a plan
19 of care and so on, I wanted a little reality
20 of how, at least in one person's practice that
21 works.

22 CO-CHAIR GOLDEN: Are we ready to

1 vote about performance gap? Okay.

2 MS. BAL: Voting is open.

3 (Pause.)

4 MS. BAL: We have moderate 11; low
5 eight.

6 CO-CHAIR GOLDEN: Okay, that puts
7 us in the 58th percentile. So that is
8 continued. Okay? Not a ringing endorsement
9 but continued.

10 So, high priority.

11 MEMBER KIRKMAN: So the group
12 agreed that the condition is high priority,
13 you know amputations, diabetes is high
14 priority. You know, I think it is a little
15 bit indirect thinking but I think presumably
16 the home health patient with diabetes is a
17 very high-risk patient. So, I think
18 potentially it could be a high priority
19 measure. But it is hard to say.

20 So, some one of the comments was
21 the condition is relatively common and
22 severely impacts quality of life, cost, and

1 life expectancy. However, I am not sure the
2 measure is evidence-based, nor that
3 performance gap remains justified.

4 And somebody else said it
5 addresses a health concern that causes
6 significant morbidity, contributes to
7 mortality and adds to cost.

8 CO-CHAIR GOLDEN: Comments or
9 questions about priority. Ready to vote?

10 MS. BAL: Voting is open.

11 (Pause.)

12 MS. BAL: Okay, we have high nine;
13 moderate eight; low one; insignificant one.

14 CO-CHAIR GOLDEN: Okay, liability.

15 MEMBER KIRKMAN: So, they did
16 present reliability data. They have a very
17 high the beta binomial method value of 0.7 or
18 above is considered acceptable. And theirs
19 was 0.92 is the mean. And they were able to
20 look at interclass correlation coefficient for
21 agencies that have at least 40 valid episodes
22 of care and felt that most of the total

1 variation is between agency variation, which
2 would be what you would want to see. But if
3 you are comparing agency to agency, that is
4 where most of the variation is.

5 So, I think we felt like it was a
6 highly reliable measure.

7 CO-CHAIR GOLDEN: Ready to vote?

8 MS. BAL: Voting is open.

9 (Pause.)

10 MS. BAL: High 17; moderate one;
11 low one.

12 CO-CHAIR GOLDEN: Now we get to
13 validity.

14 MEMBER KIRKMAN: So the developer
15 did empiric validity testing comparing
16 performance on this measure with other
17 publicly reported measures for home health
18 agencies and found some significant
19 correlations between performance on this
20 measure and other measures like a pressure
21 ulcer plan and a slight negative correlation
22 with emergency department visits. And then

1 they also have some face validity reports that
2 they felt were high.

3 So, is this where we talk about
4 exclusions? So, I got a little confused on
5 the phone call about whether CMS is removing
6 an exclusion that was previously there. But
7 I guess before there was an exclusion,
8 previously there was an exclusion for long-
9 term care episodes. And I think it was
10 thought by NQF that it would be more difficult
11 to collect if someone was in home health for
12 two years. But I think the developer says
13 that it is collected once at the end of the
14 episode, so it doesn't really matter the
15 length of the episode. So, they didn't really
16 think the exclusion was necessary. Correct
17 me, if I am wrong.

18 MS. COOK: Right. And we are
19 proposing to remove that restriction. So, the
20 measure as submitted to the committee would
21 include all home health episodes, regardless
22 of length.

1 CO-CHAIR GOLDEN: To be clear, the
2 measure as submitted includes that now but at
3 some point you would be changing that?

4 MEMBER KIRKMAN: No, it is not in
5 there.

6 MS. COOK: No, the measure as
7 submitted does not include that. Once we
8 finish this process, we will instruct the
9 measure implementer to remove that exclusion
10 and their calculations.

11 MEMBER KIRKMAN: So, the currently
12 endorsed measure has the exclusion but you are
13 proposing -- this measure that we are voting
14 on now does not have the exclusion. Too many
15 negatives here, but yes.

16 MS. COOK: I don't have the time
17 line in front of me but I believe the publicly
18 reported measure on Home Health Compare right
19 at this instant has the exclusion but as early
20 as the end of April, which is the next Home
21 Health Compare release, that exclusion can be
22 removed.

1 MEMBER KIRKMAN: So anyway, I
2 think the committee felt the validity was
3 high, reasonably high.

4 CO-CHAIR GOLDEN: Vote.

5 MS. BAL: Voting is open. Sorry,
6 hold on. Too many -- now open.

7 (Pause.)

8 MS. BAL: Okay, we have high 15;
9 moderate four.

10 MEMBER KIRKMAN: Feasibility is
11 next. So, this seems to be a highly feasible
12 measure. Again, it is a very easy measure
13 because the ultimate collection is a checkbox
14 on the OASIS form, which they are required to
15 submit anyway. So, essentially, they have no
16 missing data and it has been collected with
17 the greatest of ease.

18 CO-CHAIR GOLDEN: I see people
19 voting already but we are not open yet.

20 (Laughter.)

21 CO-CHAIR GOLDEN: Another false
22 start and you will lose your medal. I think

1 we are ready to vote.

2 MS. BAL: Voting is open.

3 (Pause.)

4 MS. BAL: All right, high 19.

5 MEMBER KIRKMAN: In terms of
6 usability and use, it has already been in use
7 for three or so years. It is publicly
8 reported. So, it is felt to be highly usable.
9 It is also used for internal quality
10 improvement. There was some comment in the
11 workgroup that a potential unintended
12 consequence would be the time and attention
13 spent on patient education and foot care might
14 be better spent on something else. That was
15 someone's comment.

16 CO-CHAIR GOLDEN: Comments,
17 questions? Vote time.

18 MS. BAL: Okay, voting is open.

19 (Pause.)

20 MS. BAL: We have a couple of
21 people missing. Could we all just click one
22 more time? Thank you.

1 (Pause.)

2 MS. BAL: All right, we have high
3 12; moderate seven.

4 CO-CHAIR GOLDEN: Global
5 endorsements.

6 MS. BAL: Voting is open.

7 (Pause.)

8 MS. BAL: The final result is yes,
9 17; no, two.

10 CO-CHAIR GOLDEN: Thank you,
11 Susan.

12 I was going to turn this podium to
13 you, Jim, but you are doing the next
14 discussion.

15 MEMBER DUDL: Is that the
16 hyperglycemia?

17 CO-CHAIR GOLDEN: It is the
18 hyperglycemia, 2362.

19 MS. TIGHE: Operator, do we have
20 the developers for Measure 2362 and 2363 on
21 the line?

22 OPERATOR: The lines are open.

1 MR. CAMPBELL: Yes, this is Kyle
2 Campbell.

3 MS. TIGHE: Okay, great. Thank
4 you.

5 MR. CAMPBELL: Can we go ahead
6 with the opening?

7 CO-CHAIR GOLDEN: Yes, please.

8 MR. CAMPBELL: Okay. Well, good
9 morning. My name is Kyle Campbell and I am a
10 pharmacist and Executive Director for the CMS
11 Medication Measures Special Innovation Project
12 at FMQAI.

13 Our project is tasked with both
14 maintaining and developing medication-related
15 measures for CMS and specifically for the
16 hospital study, we are tasked with developing
17 new electronic health record-based measures
18 that address adverse drug events and adverse
19 events in medical care.

20 The measures have been in
21 development for the past two years and have
22 undergone a very rigorous development and

1 testing process, guided by a technical expert
2 panel as specified in the CMS measure
3 management system blueprint.

4 The measures were developed in
5 partnership with a large academic medical
6 center and tested in eight hospitals across
7 the country that were selected for key
8 criteria, such as the size, teaching status
9 and the EHR vendor which they use. We found
10 the measures to be feasible across all the
11 hospitals in which they were tested.

12 These paired glycemic control
13 measures that are submitted for your
14 consideration today are the first eMeasures to
15 be completed under a project. And in terms of
16 importance, inpatient glycemic control has
17 been identified as a major gap in the NQF
18 portfolio for both inpatient and outpatient
19 hyper and hypoglycemia have been associated
20 with poor outcomes in the hospital setting,
21 including increased morbidity and mortality.

22 Regarding the evidence per

1 direction from the workgroup, we have
2 submitted a briefing document with additional
3 studies cited to supplement our submission to
4 demonstrate a strong relationship with
5 glycemic control and in-hospital mortality.

6 Furthermore, to underscore the
7 importance, the measures have been recommended
8 in the National Action Plan for ADE Prevention
9 recently published by the Department of Health
10 and Human Services. The specifications are
11 precise and the measures are paired to avoid
12 unintended consequences associated with
13 reporting either measure alone.

14 For hyperglycemia, to capture the
15 at-risk population, we identified patients
16 with diabetes through diagnosis or drug proxy
17 and were inclusive of patients with a blood
18 glucose greater than 200 milligrams per
19 deciliter. The measure focuses on sustained
20 hyperglycemia of greater than 200 milligrams
21 per deciliter defined as two measures at least
22 six hours apart, rather than a single incident

1 to reflect a validated mechanism of
2 hyperglycemia on morbidity and mortality.

3 The threshold of 200 milligrams
4 per deciliter was discussed extensively by the
5 TEP and was selected since 200 milligrams per
6 deciliter was generally the highest threshold
7 considered by clinical practice guidelines and
8 primarily the upper limit that has been used
9 for safety in clinical trials.

10 Issues related to differences of
11 testing frequency have been addressed in the
12 measure algorithm to assure hospitals with
13 limited blood glucose monitoring would not be
14 incentivized by the measure.

15 And finally for reporting
16 purposes, our TEP suggested stratifying the
17 measure by ACU, ICU, med versus surge, and
18 patients receiving high-dose steroids.

19 For the hypoglycemia measure, the
20 measure identifies for public reporting severe
21 hypoglycemic events, those less than or equal
22 to 40 milligrams per deciliter. And this

1 threshold is consistent with the definition of
2 safety outcomes in the majority of clinical
3 trials that have evaluated the effects of
4 glucose controls on morbidity and mortality.
5 Severe hypoglycemic events are potentially
6 life-threatening adverse drug events that can
7 largely be prevented by appropriate monitoring
8 and glycemic control.

9 I want to thank you for your
10 consideration of these measures and we look
11 forward to your review.

12 CO-CHAIR ROSENZWEIG: Okay, thank
13 you. This particular measure is an inpatient
14 intermediate outcome measure. And it
15 basically identifies patients in the hospital.
16 And if within a given 24 or a given daily care
17 you have two or more blood glucoses that are
18 measured within a four hour period was it --
19 I'm sorry -- six hour period, then that
20 particular day is considered to have
21 hyperglycemia or was counted as being one of
22 the percentage of days, one of the particular

1 parts of the days that is considered to have
2 a hyperglycemic episode.

3 Now, there is no question that --
4 I mean they present a lot of evidence here and
5 there is quite a bit of evidence showing that
6 hyperglycemia within the hospital setting is
7 associated with a number of adverse outcomes,
8 including morbidity and mortality. But a lot
9 of the -- most of the studies that look at
10 this define hyperglycemia in different ways.
11 So, none of them specifically define them
12 exactly in this particular manner, the blood
13 glucose over 200 twice over a six-hour period.

14 So, the question is does the
15 evidence for hyperglycemia being a negative
16 outcome or negative intermediate outcome is
17 quite clear, I think from a lot of the data
18 from the analyses. The issue you would have
19 to decide is whether this particular method of
20 measuring hyperglycemia during the course of
21 a hospital stay is an appropriate one and an
22 adequate one, basically as an intermediate

1 measure for identifying greater versus less
2 than greater hyperglycemia.

3 They specifically exclude patients
4 who were admitted with diabetic ketoacidosis
5 and hyperglycemic nonketotic state, which are
6 obviously situations in which the patient
7 comes in with fairly significant hyperglycemia
8 and is supposed to be treated for this.
9 However, I think that it may be that it is
10 reasonable to exclude these because it is
11 apples versus oranges. These are people who,
12 by the very nature of the situation are being
13 admitted for uncontrolled hyperglycemia,
14 whereas, in the other situation you are
15 looking for patients who come into the
16 hospital for other reason and develop
17 hyperglycemia.

18 But still, patients with
19 hyperglycemia I think, to a certain extent,
20 patients with hyperglycemia nonketotic state
21 or a DKA would benefit from improved control.
22 But there is limit to a certain extent as to

1 how fast you can bring the blood glucoses down
2 and under control. And that may be more
3 related to severity of illness than it is
4 related to the degree to which the patient,
5 the optimal degree to which the patient is
6 cared for.

7 So it seems like those are, to me,
8 reasonable denominator exclusions.

9 So with respect to evidence, I
10 think the evidence for control of
11 hyperglycemia in a number of different
12 settings is very, very high. The question is
13 whether there is evidence for the use of this
14 particular way of identifying hyperglycemia,
15 that is the percentage of days in which you
16 have two blood glucoses greater than 200 in a
17 particular six-hour period, whether or not
18 that is the best way of being able to identify
19 patients with hyperglycemia. And I would say
20 that would be at a lower level of evidence.

21 Yes?

22 MEMBER CURRY: I'm having

1 difficulty understanding the measure, as it is
2 calculated. So, in the numerator we are
3 talking about a sum of percentage of hospital
4 days. In the denominator, we are talking
5 about the total number of admissions. And
6 those aren't the same. In my mind, they
7 aren't the same values. So, I have difficulty
8 understanding how the measure is calculated.

9 MR. CAMPBELL: This is Kyle
10 Campbell with FMQAI. I am going to defer that
11 question to Almut Winterstein from the
12 University of Florida.

13 DR. WINTERSTEIN: I didn't hear
14 the last part, Kyle. I just had to unmute
15 myself but I think you deferred to me. Right?

16 MR. CAMPBELL: Yes, that is
17 correct. And did you hear the question from
18 the Steering Committee?

19 DR. WINTERSTEIN: Yes. Yes, I did
20 hear the question.

21 MR. CAMPBELL: Okay.

22 DR. WINTERSTEIN: Yes, this is one

1 of those measures and there are several
2 measures in the NQF portfolio that are
3 constructed in a similar fashion. And it is
4 a little bit difficult to think through this
5 at the very beginning.

6 Essentially when you look at the
7 numerator and denominator, that gives you the
8 average of the percent of days for each
9 patient that was hyperglycemic. So,
10 essentially the measure is constructed in two
11 stages. The first stage, we look at every
12 single patient's admissions, take the total
13 number of days for this patient, identify the
14 days that are hyperglycemic, according to our
15 definition, and that gives the percentage for
16 an individual patient.

17 And then all those percentages are
18 summed up and divided by the total number of
19 admissions, which basically gives us the
20 average number of hyperglycemic days across
21 all admitted patients. Does that make sense?

22 CO-CHAIR ROSENZWEIG: Well, I

1 think Dr. Curry is raising an interesting
2 point. Because couldn't you just basically
3 identify the total number of admission days
4 the person has had within a given year and
5 divide that by the total number of days that
6 have hyperglycemic episodes? I mean, you
7 don't have to necessarily divide it up by
8 individual admissions, unless I am seeing
9 something that --

10 DR. WINTERSTEIN: That's right,
11 yes. I mean basically, we could either report
12 the percent days across all hospital days that
13 were hyperglycemic or we express it on the
14 level of individual patients, essentially.

15 We decided on the latter, from the
16 reporting standpoint because typically when
17 you look at information that evaluates how
18 consumers interpret measures, it is easier to
19 get your arms around something that is
20 expressed on the level of patients than on the
21 level of days.

22 So right now, the measure would

1 basically tell me as a patient if I am
2 admitted and I am at risk for hyperglycemia
3 because I have diabetes or because I am
4 starting on steroids or I have post-surgical
5 catabolic stress, then my individual risk for
6 becoming hyperglycemic is roughly 20 percent
7 of all my hospital days might be hyperglycemic
8 or 30 percent.

9 In contrast, if we went with the
10 database measure, we essentially, a consumer
11 would say okay, across all patients who are
12 hospitalized, roughly 20, 25 percent are
13 hyperglycemic. So it is just a matter of
14 trying to make the information more palatable.

15 CO-CHAIR GOLDEN: So I am going to
16 step in here for a second just to shape the
17 conversation, if we could. And kick me in the
18 shins if I got this wrong. On the table here
19 is a question of evidence related to the
20 measurement of hyperglycemia and whether
21 hyperglycemia is something that has impact,
22 you know whether glucose over 200 while

1 hospitalized is something to measure.

2 The last little bit of
3 conversation is really into how it was
4 reported and how it is used. Because the data
5 is collected and then it gets constructed into
6 a measure.

7 So, I was going to say that we
8 could talk about the construction later but on
9 the table right now is the evidence about
10 hyperglycemia itself and the measurement of it
11 and the definition of what is hyperglycemia,
12 as opposed to the reporting of the measure.

13 Yes, Tracy.

14 MEMBER BREEN: Thank you. So full
15 disclosure. I oversee inpatient diabetes
16 operations in my health system. And so we
17 have spent a lot of time on this concept of
18 data collection. And what we are really
19 talking about is glucometrics. That is the
20 wonky term, glucometrics, how you identify
21 hyperglycemia in the hospital and how you
22 define it.

1 From my understanding, there has
2 been no really good studies looking at the
3 best way to define glucometrics. This is one
4 proposed method but the methodology of
5 identifying glucometrics in the hospital is
6 still really being worked out. And there are
7 lots of different ways to do things.

8 So that is my concern. Number
9 one, I think the data that has been presented
10 is about the risk of hyperglycemia. But this
11 measure is also specifically saying this is
12 how they are going to define hyperglycemia in
13 the hospital with their glucometric
14 methodology. So that is my concern, number
15 one.

16 My concern, number two, is there
17 is no benchmark for where this should be. So
18 if a measure reports something and a hospital
19 says well we are a 30 percent hyperglycemic,
20 according to this and another hospital says we
21 are a 50 percent hyperglycemic, I am not sure
22 that we have a gold standard or benchmark to

1 say where that should even be.

2 And so to put up a measure without
3 a benchmark is my concern, number two.

4 I had a third concern but I am
5 losing it. So, I think we should really spend
6 some time on the evidence about this.

7 CO-CHAIR GOLDEN: Your comment is
8 there is a question about a new word for me,
9 glucometrics.

10 MEMBER BREEN: Glucometrics.

11 CO-CHAIR GOLDEN: And so is there
12 data about glucometrics as something to be
13 measured? But then you also say that there is
14 no evidence that there is a standard of a
15 number 200 versus 250 and also the frequency.

16 MEMBER BREEN: And also how you
17 define. So, in this concept of glucometrics,
18 just to give the group some idea of how many
19 different ways you can do this. So, some
20 systems say well, you dump the first 24 hours,
21 because that is the most active part of
22 admissions. So, you don't even start the

1 clock until 24 hours after admission and then
2 you start the clock. So there are patient-
3 specific glucometrics, which this is. It
4 relates to the patient. But again, if a
5 patient has a two-day stay versus a 12-day
6 stay and on that patient's two-day stay they
7 have one hit on one day, they come up with a
8 50 percent hyperglycemic rate; whereas,
9 someone with a 12-day stay who is
10 hyperglycemic maybe on three days had more
11 hyperglycemia, their percentage comes out
12 lower. So then you get into the what is a
13 weighted glucometric scale? How do you make
14 it patient-specific?

15 It has been so hard because there
16 are so many data points. We know so in
17 hospitals point of care testing ranges between
18 5,000 to 30,000 tests per year. It varies in
19 some patients, they get so many tests, so
20 there is so much data and noise we have all
21 had a lot of struggle to define how to make
22 that very patient specific.

1 CO-CHAIR ROSENZWEIG: Yes, I think
2 that gets directly to the point of what Dr.
3 Curry was mentioning as well. If a person is
4 in the hospital for 20 days and has
5 hyperglycemia for a certain percentage of
6 days, let's say 40 percent out of those days
7 have two blood glucoses greater than 200, that
8 is counted as one admission. And another
9 admission of two days would be counted as a
10 separate admission. And as far as I could
11 tell from the way this is calculated, each
12 would be weighted the same. And it might be
13 --

14 Now this doesn't directly pertain
15 to evidence except if it does because we know
16 that there is good evidence for a relationship
17 of hyperglycemia -- extent of hyperglycemia to
18 poor outcomes. The question is whether or not
19 we are measuring that within the context of
20 this measure.

21 MEMBER BREEN: And we also don't
22 have -- we have data about hyperglycemia in

1 very specific sub-populations of patients,
2 critical care, cardiothoracic surgery
3 patients. We don't have good data on the
4 general med surge population in inpatients for
5 a potential single day of hyperglycemia as
6 this would potentially define. So there is no
7 data to say someone coming with an elective
8 knee repair who is in the hospital for three
9 days and has a hyperglycemia hit on one of
10 those days so they come up with a 30 percent
11 rate, we don't have data to say that that has
12 some associated risk for them for a consumer
13 to look at a hospital report and say oh, I
14 have got a 30 percent risk of having
15 hyperglycemia if I got me knee done.

16 I'm just uncomfortable.

17 DR. PACE: Would they be in the
18 denominator, unless they -- I mean --

19 MEMBER BREEN: Yes.

20 DR. PACE: If they don't have
21 diabetes?

22 MEMBER BREEN: But I don't know.

1 But if the measure is also saying this is how
2 they are defining hyperglycemia, I think that
3 has got to be a -- I mean we can get to it
4 there but the data is not just about
5 hyperglycemia. It is about how they are
6 measuring and defining hyperglycemia in this
7 measure.

8 CO-CHAIR ROSENZWEIG: Exactly.
9 And a lot of the other studies don't define
10 hyperglycemia by two blood glucoses greater
11 than 200. A blood glucose greater than 200
12 occurs quite frequently in the setting of all
13 sorts of different situations. A person
14 getting an IV stick in the wrong place, a
15 variety of other things.

16 The way the data would be
17 collected in this measure couldn't distinguish
18 between all of those things.

19 A blood glucose, let's say, then
20 in addition, how would you weight a blood
21 glucose of 350 versus 202. So, if you had two
22 blood glucoses of 350, they are counted in the

1 same way as if you had two blood glucoses of
2 201. And perhaps there is a big difference
3 between the two.

4 Yes? Oh, I'm sorry.

5 CO-CHAIR GOLDEN: Oh, that's okay.

6 Let me go to the far end.

7 MEMBER DUDL: Well, just to ask
8 Tracy, do you think then this fits the issue?
9 I mean we know it is important to measure. We
10 don't know exactly how to do it. There is not
11 proof. Is this insufficient data but with
12 exception?

13 MEMBER BREEN: I'm so conflicted
14 about this because hospitals need to show how
15 they are doing. Right? So, I can say from my
16 experience in many, many hospitals, hospitals
17 have no idea how they are doing. And there is
18 this vast treasure trove of data that they are
19 sitting on that nobody looks at. Right? It
20 is where all those 50,000 data points of point
21 of care the patients suffer through, get their
22 finger tested. Nobody looks at them or uses

1 them to manage care.

2 So, we are struggling with that.

3 And when you begin to look at it, then you
4 unearth that you have huge chunks of patients
5 who are hyperglycemic and potentially at risk
6 but we are almost, we are so far behind that
7 without having hospitals begin to look at the
8 data, we don't even know where we are.

9 That is my concern here. We don't
10 even have a good baseline assessment of where
11 hospitals are right now to say that okay, we
12 are all here, so we should then get here. And
13 this measure begins to get at that at least in
14 some way but again, there is no benchmark
15 associated with it. And we are going to jump
16 to unintended consequences but of course the
17 unintended consequences of that are --

18 CO-CHAIR GOLDEN: Sue?

19 DR. WINTERSTEIN: This is Almut
20 Winterstein. It is very unfortunate that we
21 were not allowed to attend the meeting in
22 person.

1 CO-CHAIR GOLDEN: Can I hold you
2 off until -- I have a couple of committee
3 members and then we will have you chime in.

4 DR. WINTERSTEIN: Okay. I was
5 asking there were a few clarifications, I
6 think we would provide. So yes, as long as
7 you have us in mind, it might help the
8 discussion.

9 CO-CHAIR GOLDEN: Okay.

10 MEMBER KIRKMAN: So, maybe I'm
11 just being too concrete here but I still think
12 the evidence is really the evidence about that
13 hyperglycemia is bad and that there is some
14 evidence that managing it is better.

15 I think a lot of this really is
16 about the specifications. And I agree that
17 that sort of relates to evidence but we know
18 that there is not a consistent way that things
19 are measured in all these different studies.

20 So I mean I just sort of feel like
21 we need to just vote on the evidence and then
22 move on to talk about specifications because

1 otherwise I think we are getting too much into
2 other things.

3 CO-CHAIR GOLDEN: There is a fine
4 line here. I mean I could see Tracy's point.
5 But I can see otherwise we will end up --

6 MEMBER KIRKMAN: And then in terms
7 of a benchmark, I mean I sort of agree with
8 you but on the other hand, we all kind of
9 agree that a lowered number is better. And so
10 you are going to have all these publicly
11 reported hospitals and everybody is going to
12 try to move down. I am not sure that it is
13 really necessary to say that it should be less
14 than ten percent but maybe I am wrong.

15 CO-CHAIR GOLDEN: So I am going to
16 go to Bill and then I am going to go to the
17 phone.

18 MEMBER TAYLOR: Thank you. Until
19 Sue just mentioned we know that higher glucose
20 is bad and Jamie gave us the powerful evidence
21 that high glucose is associated with mortality
22 and so many other adverse outcomes but Sue

1 said and we know that controlling it is good.

2 You endocrinologists --

3 MEMBER KIRKMAN: I didn't say
4 that.

5 MEMBER TAYLOR: You didn't. Okay.

6 So I would love to hear a little about the
7 evidence that we are actually helping people
8 when the high glucoses are controlled.

9 Because my understanding, and I am far from an
10 expert in this area, is that there have been
11 a lot of disappointing studies that have shown
12 that when you control more tightly that you
13 don't improve outcomes. And the concern is
14 that high glucose may be a marker for being
15 sick and having a bad outcome, rather than
16 that the control of it is necessarily going to
17 improve things.

18 And if we are using this as a
19 marker of quality and say you are a bad
20 hospital if you have a lot of people with
21 hyperglycemia, are we in danger of saying you
22 are a bad hospital because you take care of a

1 lot of sick people?

2 CO-CHAIR GOLDEN: I'm going to
3 give this to Jamie to discuss.

4 CO-CHAIR ROSENZWEIG: Yes, I mean
5 this speaks to a lot of the major studies have
6 been in the ICU setting and it has been going
7 on -- there has been a controversy that went
8 on for quite a number of years, starting with
9 the van den Bert study in Belgium in which
10 they were able to show -- and there were some
11 differences between surgical ICUs and ICU
12 settings but it was clear that some studies
13 seem to show that evidence of very tight
14 control would be beneficial with respect to
15 outcomes, both in the hospital and then post-
16 hospital. But subsequent studies didn't bear
17 those out.

18 And I think the question was
19 mostly settled by the nice sugar study, which
20 came out a couple of years which was a large
21 multi-center study, international study that
22 looked at patients with very tight control,

1 compared with patients with less tight
2 control. But both of those population groups
3 were still lower than blood glucoses over 200.

4 So the difference was between
5 keeping blood glucoses being between 90 and
6 110 and the keeping them between 110 and 180.
7 And between those two groups it looked like
8 perhaps the patients in the 110 to 180 group
9 actually had fewer adverse outcomes or at
10 least mortality-related outcomes.

11 So, that was a question of very
12 tight control but I think most of the data
13 would say that patients with hyperglycemia,
14 per se, both in the hospital -- certainly
15 within the ICU setting, if it is defined as
16 greater than 200, that that would constitute
17 potentially association with adverse events.

18 CO-CHAIR GOLDEN: I am going to go
19 to the phone and then I will go to the other
20 folks. So, there was a comment from one of
21 the developers on the phone.

22 MR. CAMPBELL: Yes, I would start.

1 This is Kyle Campbell with FMQAI.

2 Just in regard to the benchmarking
3 question, I think you know hospitals, we
4 aren't setting a specific benchmark. More
5 than likely, this would be reporting on how
6 hospitals are compared to the mean of all the
7 hospitals within the country. And those that
8 are statistically significantly above the mean
9 and those that are statistically significantly
10 below the mean and we think that this would
11 start, as mentioned by the Steering Committee,
12 there is this treasure trove of data and we do
13 know there is a clear quality gap here. And
14 this would start the conversation about moving
15 toward better glucose control.

16 In terms of the specifications, we
17 did wrestle a lot with how the day should be
18 measured, what day should start, what day
19 should end. And I would just defer again to
20 my colleague at the University of Florida,
21 Almut Winterstein, for a little bit of an
22 explanation of that.

1 DR. WINTERSTEIN: Okay, thank you,
2 Kyle.

3 Yes, I very much appreciate the
4 concern about glucometrics and I hadn't heard
5 that term before either but I think it is a
6 pretty good term.

7 If you look at the clinical trials
8 that have provided evidence on this, they
9 usually average their glucose results, which
10 makes sense because they follow a clinical
11 trial protocol, so there was a number of tests
12 available for a given day and, therefore, an
13 average will probably will fairly well capture
14 what is going on in a particular day.

15 And if you look at van den Berg,
16 this was one of the studies that was quoted
17 earlier. The average glucose, I believe, for
18 the control group, was somewhere in the 180s,
19 I think 178 or something like this. And then
20 for the intervention group it was at 105 or
21 108.

22 And as was already pointed out, I

1 am not aware of any trial where the upper
2 limits in the control group was below 200 --
3 sorry -- above 200. So, usually, the
4 titration regimens for patients in the control
5 group was set as such that insulin had to be
6 introduced or had to be increased when glucose
7 values exceeded 200.

8 So, this is kind of where we were
9 coming from when we were trying to construct
10 the measure here.

11 Now, the thing is, of course, in a
12 hospital environment in real life we don't
13 have clinical trial conditions and we don't
14 have the protocols that prescribes how often
15 glucose would be measured. And if they are
16 indeed if there is just one or two or three
17 values and we average those values, we will
18 definitely remove the extremes from the
19 overall glucose management. An average is
20 always, obviously, in the middle of two
21 values. So, we wouldn't really properly
22 capture whether they really were hyperglycemic

1 events.

2 At the same notion, it is fairly
3 clear from the pharmacological perspective
4 that sustained hyperglycemia is really what
5 the issue is and that single peak is probably
6 not the important part.

7 So, this is why we decided to
8 propose to go over the measure that would
9 capture sustained hyperglycemia, defined as
10 having at least two hyperglycemic events that
11 are at least six hours apart, suggesting that
12 there were a longer time period where glucose
13 values at a given day exceeded even what the
14 control group in a clinical trial setting.

15 I think the other part that is
16 important to mention here is that we were
17 trying to deal with an area that hospitals
18 essentially didn't measure. So we have in the
19 measure a numerator, another parameter that
20 deals with situations where just one glucose
21 value is available that is above 200. In
22 those instances, we consider that also

1 hyperglycemic with the idea that if nobody
2 measured again, very unlikely was there
3 anything done about trying to get
4 hyperglycemia down because typically when I am
5 introducing insulin or increasing insulin
6 dose, I would go measure again. So, the idea
7 was not to incentivize hospitalize hospitals
8 that essentially ignore an elevated glucose
9 value.

10 CO-CHAIR GOLDEN: Thank you very
11 much. We should soon get to vote about
12 evidence. Evidence is going to be about --
13 and we are going to get back to specifications
14 and a variety of other issues. So, we will be
15 reprising a lot of this conversation.

16 I am going to go Jessie because
17 she hasn't said anything. And then I will go
18 to Tracy.

19 MEMBER SULLIVAN: I'm sorry. I'm
20 going to ask the developers to answer Bill's
21 question, which was because I just don't know.
22 Is there evidence that a better control of

1 hyperglycemia in the hospital leads to better
2 outcomes? Because I think what we just heard,
3 if I understood what you said, James with
4 that, in the nice sugar control, slightly
5 looser control is better than very tight
6 control, if I understood that right. But what
7 I didn't hear is keeping the blood sugar below
8 200 better than -- or is high blood sugar just
9 a marker of sick people?

10 CO-CHAIR ROSENZWEIG: No, I think
11 there is a lot of evidence suggesting that
12 keeping blood glucoses under 200 is
13 beneficial. The issue is more related to --
14 the issues that came up were more related to
15 under 200 if blood glucose is very, very
16 tightly controlled versus somewhat more
17 loosely controlled, which is better. So, that
18 is the situation.

19 So, I think the evidence for blood
20 glucoses in general of being over 200 not
21 being good is there. But I did, as I
22 indicated before, suppose blood glucoses are

1 over 300 or over 400, should that be weighted
2 differently than two blood glucoses? That is
3 a separate issue. I don't know it pertains to
4 the evidence but it is a separate issue.

5 CO-CHAIR GOLDEN: That will get
6 into specs and so forth. Tracy?

7 MEMBER BREEN: To make the
8 discussion about evidence strictly related to
9 hyperglycemia in the hospital, I think there
10 are two issues we are talking about. One is
11 maintaining control, which is doing something
12 to prevent high glucose. The only
13 interventions that have shown any benefit have
14 been in the ICU setting. There has been no
15 good evidence in the non-ICU setting that an
16 intervention is going to really have good
17 impact.

18 Now, there has been association
19 data in the non-ICU setting. So, there have
20 been associations to say the higher glucoses
21 in the general med-surg populations are
22 associated with increased length of stay,

1 catheter-associated infections, potentially
2 poor wound healing, but there haven't been the
3 same level of detailed studies on
4 interventions in this non-ICU population.

5 So all the intervention studies
6 that the developer is presenting, especially
7 in terms of the data collected have all been
8 ICU-based populations. So again, I just had
9 a concern about using this ICU-based data and
10 applying it more broadly, especially with the
11 data collected in terms of risk. So, even
12 those ICU studies, each one of those patients
13 are having their blood sugar monitored very
14 one to three hours. That is a lot of data
15 points in one day, as opposed to a non-ICU
16 population where patients might have two
17 values, anywhere from two to four or five.
18 And so I don't know how to compare those two.

19 So again, forgetting the way it is
20 measured, if we are just talking about
21 hyperglycemia in an inpatient setting, the
22 association is there for morbidity in the non-

1 ICU population. But the data, as far as I
2 know, there has been no good intervention
3 study in the non-ICU hospital population. But
4 if anyone has any data about that, I would
5 love to hear about it.

6 CO-CHAIR GOLDEN: Sue.

7 MEMBER KIRKMAN: Well, I think the
8 -- I just can't remember if it is RABBIT 1 or
9 RABBIT 2 in the surgical patients that was a
10 non-ICU population and did show better
11 outcomes with sort of basal-bolus therapy and
12 better glycemc control versus sliding scale
13 and worse glycemc control. And they were
14 pretty hard outcomes including, I think,
15 mortality was actually reduced, although that
16 may have been a fluke.

17 The other thing I wanted to say
18 about the evidence is I mean I agree that ICU
19 data is where most of the data lies. And I
20 think we get into trouble when we say because
21 really, really tight control was no better or
22 was worse than moderate, therefore, there is

1 no evidence for treating hyperglycemia. I
2 mean I don't think that is what Bill was
3 saying. But it is sort of like saying because
4 the ACCORD blood pressure trial didn't show
5 increased benefit for less than 120, other
6 than on a stroke, we shouldn't treat blood
7 pressure anymore.

8 And the other thing I wanted to
9 say about the non-ICU setting is there
10 considerable consensus from multiple
11 organizations, you know Society of Hospital
12 Medicine, the ADA, ACE, et cetera, et cetera,
13 et cetera, for this sort of 140 to 180 range.

14 So, that is --

15 MEMBER BREEN: But that is based
16 on the ICU data. I agree but that is based on
17 those numbers from the ICU and sort of
18 outpatient --

19 MEMBER KIRKMAN: It is based on
20 the ICU data and a look at the totality of
21 evidence. So, there is a lot of -- and I
22 agree, it is lower level evidence.

1 And this performance measure is
2 really looking above that. I mean, I agree if
3 it sort of said the percent that are between
4 140 and 180, that would be taking it a little
5 bit too far. But I think that some of the
6 evidence is reasonable.

7 CO-CHAIR GOLDEN: I think after
8 Jamie, I would like to try to vote. Helen, do
9 you want to comment?

10 DR. BURSTIN: Just one quick
11 comment about the lack of benchmarks. Because
12 this has come up in other measures and it is
13 pretty common to have measures that are viewed
14 as adverse events, for which there is no
15 number as to what the right number is. Lower
16 is better, higher is better, depending on what
17 you are talking about. Adverse events it is
18 certainly lower.

19 But very similar discussions we
20 have had over the year about C-section rates,
21 for example. So, I don't want that to feel
22 like that is an issue that would really focus

1 on the evidence. I think the benchmark issue
2 is a little bit outside the scope.

3 CO-CHAIR ROSENZWEIG: Just with
4 respect to the evidence, Tracy, in Umpierrez's
5 article 2012 in the non-critical setting, it
6 did make recommendations for generally better
7 control. You could say the evidence may not
8 be strong but it was there.

9 MEMBER BREEN: Yes, I and I
10 respect and have sat on many of the committees
11 saying this is good because we know in our
12 heart of hearts that it is good. But if we
13 are saying is there evidence, right, so we
14 have our expert opinion, our recommendation
15 evidence and that is a lower, you can say
16 whatever grade that is.

17 But in terms of intervention done
18 in a non-ICU setting, a lot of these
19 interventions have also just compared two ways
20 of controlling hyperglycemia. It is not like
21 they have said okay in one unit you are just
22 going to do whatever you are going to do and

1 allowed to be hyperglycemic and in another
2 unit you are going to control. They have
3 really been looking at two different ways of
4 controlling glucose and finding out which is
5 the best way to control the glucose. And we
6 are getting way into the weeds on this. I
7 know this but I just -- yes.

8 CO-CHAIR GOLDEN: I am trying to
9 get us to a vote. Bill, do you have something
10 else?

11 MEMBER TAYLOR: Is there a way we
12 are supposed to proceed if we feel like the
13 information we have been given about the
14 evidence is inadequate? I mean you
15 endocrinologists know a great deal about this
16 and I think we can all trust you.

17 CO-CHAIR GOLDEN: Well, I mean you
18 have got the vote coming up would be you think
19 the evidence is high, moderate, low,
20 insufficient, or insufficient with exception.

21 MEMBER TAYLOR: Well, In think the
22 evidence we have been shown is inadequate.

1 CO-CHAIR GOLDEN: Okay, then you
2 vote that way.

3 MEMBER TAYLOR: No, but there is
4 evidence that we haven't been shown. I know
5 we have to vote today and so on but it is a
6 problem of our process that the developers
7 provided us information that showed high
8 glucose is bad without going into this other
9 important discussion about and what is the
10 evidence that bringing it down is helpful.

11 CO-CHAIR GOLDEN: Over here.

12 MEMBER DUVA: I just have a quick
13 comment. I mean I think that this is a great
14 discussion. I know we have time limitations
15 but I also just want to point out that the
16 evidence we have been considering for each of
17 the measures has had similar issues. And so,
18 I feel like we just need to be aware of kind
19 of raising the bar of our expectations of
20 evidence or what our consistency is, as we go
21 through the meeting.

22 CO-CHAIR GOLDEN: Yes, Helen? Not

1 Helen -- Karen. I'm sorry.

2 DR. PACE: Just one other comment
3 about the intervention. I mean as Helen said,
4 with outcomes in general, we are measuring
5 outcomes that are important. We are looking
6 at outcomes that are associated, in this case,
7 this is an intermediate outcome associated
8 with other kinds of bad things.

9 But we don't need to know that
10 there is a benchmark because the whole point
11 of this is to look at in comparison and learn
12 from that. And also, we may not know all of
13 the right interventions. But again, that is
14 the value of measuring outcomes, so that
15 things that maybe people think can't be done
16 or there may be multiple ways to address it,
17 that that is not what we are trying to get at.

18 So, obviously if you think that
19 here is really, if this is something that
20 can't be treated or there is unintended
21 consequences, then we need to think about
22 that. But I don't know that those two

1 questions directly relate to evidence.

2 CO-CHAIR GOLDEN: We are going to
3 repeat some of this about the thresholding and
4 the normative aspects during the other pieces.

5 Do you really want to say
6 something?

7 MEMBER BREEN: It's very brief.

8 CO-CHAIR GOLDEN: Okay.

9 MEMBER BREEN: So, it is so brief
10 because I know we are going to talk about this
11 later. But at the final state if we are
12 talking about glucoses of 200, greater than
13 200 is bad. So I mean that is what all the
14 data shows. We know that there is an
15 association of risk with glucoses greater than
16 200. And if we want hospitals to report that,
17 which I think we do and we don't need a
18 benchmark, which is great, that is very
19 reassuring. So again, if we are looking at
20 the evidence around hyperglycemia and not
21 about the way that they are measuring it and
22 we are going to talk about that, then I just

1 wanted to clarify my position that yes, there
2 is risk and harm associated with glucoses
3 greater than 200. So, that is reasonable to
4 think about.

5 CO-CHAIR GOLDEN: So when the fog
6 is rolled in, the fog is rolled out, and the
7 fog has rolled back in.

8 (Laughter.)

9 CO-CHAIR GOLDEN: So I think
10 people are ready to vote. Let's try to vote.

11 MS. BAL: Voting is open.

12 (Pause.)

13 MS. BAL: Okay, we have high five;
14 moderate eight; low one; and insufficient
15 evidence with exception is five. So, it will
16 go through.

17 CO-CHAIR GOLDEN: So we will move
18 on and probably re-circle. Performance gap.

19 CO-CHAIR ROSENZWEIG: Yes, so I
20 think it was generally recognized that there
21 is a fairly substantial performance gap, both
22 in the ICU setting and in the non-ICU setting

1 with respect to this particular -- with
2 respect to measurement of hyperglycemia.
3 Actually, the existence of hyperglycemia in
4 those circumstances.

5 CO-CHAIR GOLDEN: I'm going to
6 suggest we focus our discussion on this aspect
7 to is there a performance gap or practice
8 variation in management of blood sugars in the
9 hospital? We can talk about thresholds and
10 levels elsewhere, but is there practice
11 variation in managing glucose levels in
12 hospitalized patients?

13 CO-CHAIR ROSENZWEIG: Yes, I would
14 say yes, absolutely.

15 CO-CHAIR GOLDEN: I just wanted to
16 get that started. All right, ready to vote?
17 Let's vote.

18 MS. BAL: Voting is open.

19 (Pause.)

20 MS. BAL: Okay, we have high 16;
21 moderate three.

22 CO-CHAIR GOLDEN: All right,

1 impact.

2 CO-CHAIR ROSENZWEIG: Here again,
3 I think we felt that the impact of -- that
4 this actually does actually address or maybe
5 not this measure but the issue of identifying
6 hyperglycemia and treating it in the hospital
7 setting. It does address a specific national
8 health goal and priority. It is a major
9 health goal and priority.

10 And the issues of the caveats of
11 how the measure is defined and so forth in
12 dealing with other sections but I would say
13 yes.

14 CO-CHAIR GOLDEN: Comments or
15 questions? Ready to vote? Please vote. Wait
16 a minute. It's not ready yet.

17 MS. TIGHE: It is open now.

18 (Pause.)

19 MS. BAL: Sixteen high; two
20 moderate; and one insufficient.

21 CO-CHAIR GOLDEN: Okay. So, now
22 we get into -- coming up now to reliability

1 and validity. And I believe that -- let's
2 make sure before we get too deep into this --
3 reliability would be the accuracy of what gets
4 recorded; whereas, validity gets into some of
5 the thresholding and so forth.

6 CO-CHAIR ROSENZWEIG: Yes, with
7 respect to the reliability of collecting data
8 of this sort, I think there are obviously
9 problems. Some hospital systems have ability
10 to collect all of the finger stick data and
11 integrate them into the electronic medical
12 record. Others are less able to do so.

13 And this can become a major issue.
14 So, if you are actually not able to sample, to
15 actually collect all of the samples, then your
16 ability to actually identify the number of
17 hyperglycemic episodes will be diminished.
18 And there is also --

19 CO-CHAIR GOLDEN: So just to
20 clarify, this is only an eMeasure. Correct?
21 This is not an abstracted measure

22 CO-CHAIR ROSENZWEIG: Yes, it is

1 an eMeasure but many hospital electronic
2 medical records don't necessarily easily --
3 they probably will in the future but don't
4 necessarily easily incorporate finger stick
5 blood glucoses completely. You would have to
6 collect the finger stick blood glucoses from
7 a separate database and so forth. And then
8 how to integrate them with the lab glucoses
9 which are also collected on different samples,
10 blood samples.

11 I would just say that there may be
12 some reliability issues. And then the other
13 issue is the sample variation. So, if a
14 patient is not -- obviously, if blood glucoses
15 are not measured within a six-hour period,
16 then you are going to be underestimating the
17 degree of hyperglycemia.

18 CO-CHAIR GOLDEN: Let's go down to
19 the far end there.

20 MEMBER McCOLLISTER-SLIPP: Well, I
21 guess my question was why would that be
22 difficult? I can't imagine. I mean my

1 company deals with aggregated EHR data and
2 every data set we have looked at has static
3 glucose measures. Now I don't know, it
4 doesn't say whether that was taken at bedside
5 or whether that was some sort of lab value
6 that was just a static measure.

7 But I just can't imagine. I mean
8 maybe I am just naive and I have never had to
9 work with an EHR directly but I just can't
10 imagine that that would be difficult.

11 I guess one of my questions,
12 though, as somebody who deals with this on a
13 consumer level and is involved in these issues
14 as a patient with FDA and stuff is the
15 reliability of the point of care meters. I
16 mean, is that something we need to take into
17 consideration. I know you guys are in the
18 process of narrowing the margin of error but
19 if it is 202 versus 199 from a clinical
20 perspective, that is not going to make any
21 difference. But from a measure perspective,
22 it would.

1 So, I mean it is part question
2 part philosophical point.

3 MEMBER BREEN: It is about the way
4 hospitals collect this data. So all hospitals
5 have access to this. If you check a point of
6 care glucose, you have access. It sits in
7 your point of care database and there is a
8 very hardworking, dedicated point of care
9 supervisor who usually sits in the basement
10 with no windows sitting on all this data.

11 From how that data gets to the
12 hospitals, the lab systems are basically two
13 ways. One, it is either hand transcribed by
14 staff, so staff check on their ACCU-CHEK.
15 That ACCU-CHEK data is delivered
16 electronically to the ACCU-CHEK database,
17 which is the RALS system. And then a medical
18 assistant or someone else hand transcribes
19 into the medical record. That has some errors
20 built into it and we already know that there
21 are transcription errors.

22 The second way is that there is

1 various patches available for hospitals to
2 purchase at a certain cost which allows that
3 data that is sitting in a point of care
4 database to be transmitted electronically.

5 So all hospitals have access to
6 this data. Whether or not they are using it
7 or using it fully is another issue. But I
8 think the data is fairly reliable, once you
9 get to that point of care database.

10 The concern, potentially, that you
11 are bring up about the reliability of the
12 ACCU-CHEK or just the meters in general, they
13 are typically ACCU-CHEK, but any glucose meter
14 that is being looked at by the FDA, there is
15 a built-in variability that is allowed for,
16 whether it should be or not on the hospital.
17 And that is just standard of care. So, I
18 don't know that we necessarily need to address
19 the meter reliability right now on this.
20 Because that is just what we are using for
21 clinical practice at this moment.

22 The question comes up, though, in

1 terms of the measure, in practice many
2 clinicians at the bedside, when they get an
3 abnormal value will repeat it within five
4 minutes, just to make sure that it is really
5 abnormal. And then they will repeat it again
6 five minutes later to really make sure it is
7 really abnormal.

8 And so again, when you get into
9 reliability, if you are saying you are getting
10 two values within six hours but two of those
11 values were within five minutes, it is really
12 the same value. Right? And so what does that
13 mean in terms of how reliable it is?

14 CO-CHAIR GOLDEN: The bench was
15 two values six-hours apart.

16 MEMBER BREEN: No, within six
17 hours. It is within a six-hour window.

18 CO-CHAIR GOLDEN: Oh.

19 MEMBER BREEN: Maybe the developer
20 can comment on that but it is my understanding
21 it is within a six-hour window.

22 DR. WINTERSTEIN: It is six hours

1 apart. It is not within.

2 MEMBER BREEN: Six hours apart.

3 DR. WINTERSTEIN: Yes.

4 MEMBER BREEN: So, but then can
5 you describe the window? So, on a particular
6 day, so if we are talking about a 24-hour
7 cycle, you are saying that two values six-
8 hours apart in that cycle would count.

9 DR. WINTERSTEIN: Correct.

10 MEMBER BREEN: At least six hours
11 apart.

12 DR. WINTERSTEIN: Yes.

13 MEMBER BREEN: Okay, thank you.
14 Never mind.

15 CO-CHAIR GOLDEN: Sue.

16 MEMBER KIRKMAN: Yes, I just
17 wanted to address Anna's comment about the
18 meter reliability, which I think is a good
19 point but the variation is on both sides of
20 the numbers. So, you are going to have
21 equally as many that are below 200, when they
22 really were above 200. And it also is not

1 going to vary between hospitals.

2 So, if you are comparing hospital
3 X to hospital Y, it is not like hospital X was
4 more effective by meter variability than the
5 other hospital. So, I think it will all wash
6 out but it is a good point.

7 CO-CHAIR GOLDEN: Jessie?

8 MEMBER SULLIVAN: Yes, I just have
9 clarification for the developer from the last
10 thing that you said. If it is six hours
11 apart, if one blood glucose is drawn on
12 Tuesday and it is 250 and it is not drawn
13 again until Thursday, is that two days of
14 hyperglycemia?

15 DR. WINTERSTEIN: No, it is always
16 calculated for a particular day. So, the
17 measure requires that there are two measures
18 at a given day there were at least six hours
19 apart and that were 200.

20 The only exception to this if
21 there were just one measure available at a
22 given day, just one, and that single one was

1 above 200, that would be counted as a
2 hyperglycemic day as well, with the idea that
3 people essentially ignored it and didn't
4 remeasure. And we didn't want to incentivize
5 hospitals that don't remeasure.

6 MEMBER SULLIVAN: Okay, so just
7 to make sure I understand. So, if we get 250
8 on Tuesday and 300 on Thursday, that is two
9 hyperglycemic days, Tuesday and Thursday. And
10 there was on measure on Wednesday, so that is
11 not a hyperglycemic day. Is that --

12 DR. WINTERSTEIN: No, that is not
13 correct. So if Tuesday we had a 250 and all
14 the other values that were done on Tuesday
15 were below 200, Tuesday would not be a
16 hyperglycemic day because we don't have two
17 independent measures more than six hours apart
18 on Tuesday.

19 Wednesday, if there were no
20 measures done whatsoever that would count as
21 a hyperglycemic day, unless the patient was
22 normal glycemc for two days, at that point,

1 we allow that no measurement is done
2 whatsoever.

3 And then on Thursday, the same
4 thing. If there is just one single value
5 above 300 and all the other values are below
6 200, Thursday would not be counted as a
7 hyperglycemic day.

8 MEMBER SULLIVAN: So I guess I had
9 said in my example a patient is in the
10 hospital Tuesday, Wednesday, and Thursday.
11 During that time, they have two blood glucoses
12 drawn, period. No other blood glucoses. One
13 is on Tuesday and is 250, one is on Thursday
14 and is 300. How is that counted?

15 DR. WINTERSTEIN: They all would
16 be hyperglycemic. Sorry, I misunderstood you.
17 Yes, if there was only one value that was
18 elevated on Tuesday, that would be counted as
19 hyperglycemic. If Wednesday there was no
20 measurement done altogether and the previous
21 day was hyperglycemic, then the idea is nobody
22 looks but very likely, things have not

1 improved. So Wednesday would be counted as
2 hyperglycemic and Thursday as well.

3 MEMBER SULLIVAN: Thanks.

4 CO-CHAIR GOLDEN: So again, for
5 the developer, a quick question. If someone
6 gets admitted at night, what happens there at
7 night? If someone gets admitted at 8:00 or
8 9:00 at night and has a blood sugar of 250,
9 are those in the calculations or out of the
10 calculations?

11 MEMBER BREEN: Are they calendar
12 days or are they 24 hours from the time of
13 admission?

14 DR. WINTERSTEIN: Yes, they are
15 calendar days. So, if somebody gets admitted
16 after noon of a particular day, the following
17 day is not looked at all. So, it actually is
18 more than a 24 hour period that we would not
19 look. We use calendar days just for
20 simplicity to put the measurement algorithm in
21 place.

22 So, if a patient is admitted

1 before noon at a given day, then we would
2 start to look the following day for
3 hyperglycemia, unless the patient came in with
4 a blood glucose value of lower than 400, at
5 which we would give another day to allow
6 slower titration.

7 CO-CHAIR GOLDEN: So the first day
8 is not counted. Okay.

9 DR. WINTERSTEIN: The following
10 day is the block for measurement.

11 And then the overall follow-up
12 that might be important to know as well, we
13 truncate follow-up at day ten of hospital
14 admission. So, there is no patient who would
15 contribute 20, or 30, or 90 days to the
16 measure.

17 CO-CHAIR GOLDEN: We are starting,
18 again, to bleed into reliability and validity.
19 But we are trying to understand what we are
20 looking at.

21 Go ahead, Tracy.

22 MEMBER BREEN: I have a question

1 for the developer. So, when you define
2 admission, are you saying admission to the
3 hospital or presentation to the ED? Because
4 many patients stay in the ED upwards of 22
5 hours. So, does the clock start ticking when
6 they present to the ED if they are
7 subsequently admitted or is it their official
8 admission date?

9 DR. WINTERSTEIN: The admission
10 time is set at when the admission order is
11 written and that is consistent with the CMS
12 definition of admission and all the other
13 measures that look at admission time that are
14 currently endorsed use that time.

15 CO-CHAIR GOLDEN: Okay, ready to
16 vote?

17 MS. BAL: Voting is open.

18 (Pause.)

19 MS. BAL: Okay, we have high one;
20 moderate 17; low one. So, we move on.

21 CO-CHAIR GOLDEN: So, now we go to
22 validity. Have fun.

1 (Laughter.)

2 CO-CHAIR ROSENZWEIG: My statement
3 here would be that in ideal situations in
4 hospitals that have the appropriate situation
5 validity can be achieved but that probably in
6 a large number of hospitals currently will
7 have difficulty implementing this and will
8 have to put into place more extensive ways of
9 being able to identify this.

10 CO-CHAIR GOLDEN: Yes, I think
11 that is in usability and feasibility.

12 CO-CHAIR ROSENZWEIG: Oh.

13 CO-CHAIR GOLDEN: So, this is
14 where we get into the specs.

15 CO-CHAIR ROSENZWEIG: Oh, I'm
16 sorry. Okay, yes. So, I think there was a
17 certain amount of I think -- I guess face
18 validity is probably moderate to high.

19 CO-CHAIR GOLDEN: So let's make
20 sure we understand when we have the validity.
21 So, what we have understood now is that it is
22 six hours apart; that the first day is not

1 included; that the ER values are not included.

2 And again the developer, maybe you
3 can help us here, I think I heard you say that
4 if somebody is admitted with a high blood
5 sugar there is also a compensation for that.
6 So, if somebody gets admitted with a blood
7 sugar of 300 or 400 because they have been at
8 home with that for a month or two, what
9 happens to those patients?

10 DR. WINTERSTEIN: Yes, if somebody
11 is admitted with a sugar over 400, we give
12 another day to bring the sugars down. So
13 typically, if somebody is admitted before
14 noon, we would start to look the following
15 day. If somebody is admitted afternoon, we
16 give already another day. So, we are
17 basically starting to look at hospital day
18 three.

19 If somebody is coming in with an
20 elevated sugar, so the first admission sugar
21 is over 400, in that instance, we add another
22 day in which we are not looking.

1 CO-CHAIR GOLDEN: And my last
2 question is and this measure is reported --
3 when it gets reported, I wasn't clear just how
4 exactly is it reported. So it is percentage
5 of days hyperglycemic or number of days
6 hyperglycemic?

7 DR. WINTERSTEIN: It is the
8 average percent of hyperglycemic day per
9 patient. That is how it is reported.

10 CO-CHAIR GOLDEN: An average
11 percent of hyperglycemic days per -- so, if
12 somebody had one day and they were in the
13 hospital for -- well, --

14 So, if the patient is in the
15 hospital for say three days and the first day
16 doesn't count, you then have two days. So,
17 you would end up with, if you were
18 hyperglycemic on a second day, it would be one
19 out of two. So, it would be 50 percent?

20 DR. WINTERSTEIN: That's right.
21 Yes, it would be 50 percent.

22 CO-CHAIR GOLDEN: Fifty percent,

1 okay.

2 DR. WINTERSTEIN: But keep in
3 mind, that is average to cross roughly 2,000
4 patients. So, it actually comes out very
5 similar to averaging across all days because
6 there are so many of those.

7 CO-CHAIR GOLDEN: And in your
8 testing of the activities, what kind of
9 average number were you seeing in terms of --
10 you say this is a normative measure. What is
11 your -- what has been the experience in terms
12 of the typical number that you get or range?

13 DR. WINTERSTEIN: Yes, it is
14 roughly between 20 and 30 percent of all days.
15 There are a few outliers that are below 20 and
16 above 30. But if I had to characterize the
17 interquartile range, that is roughly where it
18 is.

19 CO-CHAIR GOLDEN: Comments and
20 questions otherwise? Ann.

21 MEMBER KEARNS: Yes, I had a
22 question about why it says in the denominator

1 that after you exclude the first day or the
2 first two days, depending, then it is
3 truncated at ten days.

4 So anybody who is in the hospital
5 for 11 days, the 11th day doesn't count or the
6 12th day?

7 DR. WINTERSTEIN: Yes.

8 MEMBER KEARNS: And why is that?

9 DR. WINTERSTEIN: Just to avoid
10 that an individual patient contributes a lot
11 of time and starts to skew the measure. That
12 concern was mentioned earlier. I mean you
13 know we could theoretically include patients
14 who were in the hospital for 90 days. And if
15 for some reason one had decided that the
16 current regimen is fine and every single day
17 is hyperglycemic, that patient would dominate
18 the measure to a certain extent. But just in
19 an effort to normalize the data.

20 CO-CHAIR GOLDEN: Tracy?

21 MEMBER BREEN: I have a question
22 for the developer about your definition of

1 diabetes. How are you defining or indicating
2 patients have diabetes in the hospital? It
3 says with a diagnosis. But primary diagnosis,
4 secondary diagnosis, any other way you are
5 tagging people as having diabetes in this?

6 DR. WINTERSTEIN: Yes, the
7 denominator uses three ways of identifying
8 diabetes and there is different reasons for
9 this.

10 The first one is just a diagnosis
11 of 250 at any diagnosis field. So that could
12 be the principle or any secondary diagnoses.
13 The second is the presence of any
14 antihyperglycemic medication. And the third
15 is a single blood glucose value of 200.

16 And I tell you why that third we
17 included is because that might not be
18 intuitive. That is related to those patients
19 who develop hyperglycemia, even though they
20 don't have diabetes in the hospital. So, that
21 is the classic patient who is on hydrosteroids
22 or post-surgical. Those patients, if they

1 were not started on anti-diabetic regimen
2 would not be captured in the denominator in
3 any other way.

4 So, a single value will flag them
5 as being at risk for sustained hyperglycemia.
6 And that would make it in the denominator as
7 well.

8 And quite interestingly, if you
9 take the three definitions, they are really
10 complementary. So, there is different patient
11 populations. Of course, there is some overlap
12 but there is actually really different patient
13 populations that are captured.

14 CO-CHAIR GOLDEN: Tracy.

15 MEMBER BREEN: Hi, this is Tracy.
16 For the developer. So, in terms of you
17 including in the definition of people with
18 diabetes a single patient with a glucose of
19 200, let me imagine this case scenario.

20 A patient with COPD being treated
21 for steroids has a single episode of glucose
22 of 210. So they are now flagged as part of

1 your cohort. The steroid step, they get no
2 more further glucose testing for the remainder
3 of their three days but they are in your pool.
4 So you are going to have three days where no
5 glucose testing was done. The way you
6 described it, each one of those days will
7 count against the hospital because they have
8 not checked a glucose and they will be assumed
9 to be hyperglycemic.

10 DR. WINTERSTEIN: Yes, it would
11 count against in hospital if there were not
12 two days -- with the previous day was not
13 normal glycemc. So the idea is if I had a
14 patient who had a 210 yesterday and I don't
15 check today, we will count that as a
16 hyperglycemic day. That is correct.

17 But then again, if I had a patient
18 who had a 201 yesterday, I will check today to
19 see whether the glucose came down.

20 CO-CHAIR ROSENZWEIG: And these
21 would be people who don't necessarily have
22 diabetes.

1 DR. WINTERSTEIN: Yes. In fact,
2 in our formative testing hospital, where we
3 developed all of this, this is a very large
4 tertiary care hospital with a large transplant
5 population, large surgery population, we had
6 a good third of patients who were not diabetic
7 but have sustained hyperglycemia.

8 CO-CHAIR ROSENZWEIG: Now, in our
9 discussion over the phone, I think you were on
10 that call, there was the issue that was raised
11 about mixing apples and oranges such as if a
12 person is in the MICU for a certain number of
13 days and then is on the floor for a certain
14 number of days and yet all of the data is
15 aggregated into one pool for one admission.

16 You mentioned something about
17 actually collecting separate data for MICU --
18 for ICU versus non-ICU but I didn't see it in
19 the measure worksheet. Could you just
20 describe what the plans are for that?

21 DR. WINTERSTEIN: Kyle, would you
22 like to respond to this or should I continue?

1 MR. CAMPBELL: Sure. Sure. So,
2 our plans were to, in terms of the reporting
3 of the measure, to stratify the reporting so
4 that there would be a separate score for ICU
5 versus non-ICU and med versus surg patient
6 populations, to provide a little bit of
7 additional information for the hospitals about
8 the differences in those subgroups.

9 CO-CHAIR GOLDEN: Sue.

10 MEMBER KIRKMAN: So, just to go
11 back to the single blood glucose over 200. I
12 mean you know this better than I do but the
13 people that have hospital hyperglycemia
14 without a diagnosis of diabetes are actually
15 the highest risk patients and have been
16 included in all those studies that have
17 generated the high or low evidence. So that
18 is one thing.

19 And the other thing is that I do
20 think -- I don't think you should have a blood
21 sugar over 200 and then just ignore it and
22 never check it again. So, I think this

1 incentivizes people to keep checking, which
2 means if it really did go away, they would
3 look good on the measure or to treat the
4 patient appropriately if it doesn't go away.

5 So, I think that is reasonable. I
6 mean I think, if anything, it is going to
7 incentivize follow-up and potentially
8 treatment for those patients.

9 And I think if you excluded that,
10 then you could have the patient who has a
11 blood glucose of 280 and everybody says oh,
12 well it is just the steroids. We are never
13 going to check it again and they wouldn't show
14 up in the data.

15 MEMBER BREEN: I have a question
16 for the developer in terms of your
17 stratification based on ICU or floor. How are
18 you attributing patients to each of those
19 populations? Because as we just brought up,
20 there are patients who obviously move around.
21 Right? So, if a patient starts in the ICU,
22 starts in the ED, goes to the ICU, is

1 discharged from the floor, how do you weight
2 which part of their time? Which group are
3 they going to fall into, in terms of their
4 hyperglycemic scores, the ICU group or the
5 floor group? How do you determine that?

6 MR. CAMPBELL: It is where they
7 spend the majority of their time during that
8 calendar day. So, if they spent the majority
9 of the time of the ICU, then their day would
10 contribute in the ICU score or that day would
11 contribute for the ICU. And then once they
12 transfer, the majority of the second day was
13 in the acute care unit and it would contribute
14 in that way.

15 MEMBER BREEN: Thank you.

16 MEMBER BAILEY: So my question
17 comes along the lines of the end use. If the
18 goal is for public reporting for
19 hospitalcompare.gov or something similar, how
20 do you deal with that stratification when you
21 are reporting that to the public to consume?

22 Because we understand or if you

1 report it back to the institution and you
2 stratify if by site of care or where the
3 patients spent the preponderance of their
4 time, the institution can understand that but
5 how can the general consumer understand that
6 when it is publicly reported?

7 MR. CAMPBELL: So, what we
8 envision at this point is providing a score,
9 for example, in easy to understand from the
10 patient's perspective the measure score with
11 critical care. So if I average percent of
12 time for patients that were in critical care,
13 you know, here is a score, and the average
14 percentage of time in hyperglycemia for acute
15 care. And then medical versus surgical
16 patients.

17 So, that is, at this point, what
18 we are considering. But a decision hasn't
19 been made in terms of exactly how the measure
20 would be reported yet on Hospital Compare or
21 if it would be reported on Hospital Compare,
22 I should say.

1 MEMBER BAILEY: So, a follow-up
2 question on that would be a tertiary care
3 hospital that gets very complex patients could
4 appear to have very poor performance but a
5 primary care center that doesn't have a high
6 acuity may appear to do very well then. And
7 wrong decisionmaking may occur from the
8 patient perspective. Correct?

9 MR. CAMPBELL: Right. So, Almut,
10 do you want to address that?

11 DR. WINTERSTEIN: Sure. Well,
12 interestingly, since we have quite some
13 diversity in our fuel testing hospitals, the
14 tertiary care institution did actually very,
15 very well. And that is probably really
16 related to the fact that there was more of a
17 knowledge base and how to deal with
18 hyperglycemia on their standardized insulin
19 infusion protocols available. And that was
20 actually the same thing we saw when we were
21 comparing our ICUs to the ACUs. The ICUs did
22 actually better than the ACUs. And I think

1 that is the exact same reason we have
2 standards protocols that start insulin drips
3 in the OR for post-surgical patients and that
4 insulin drip is continued in the ICU. Once
5 patients are transferred to the ACU, things
6 usually go a little bit more awry because then
7 patients have to be switched to subcutaneous
8 insulin. So, we actually saw the opposite
9 than what would have been expected. And I
10 think that is important to consider.

11 This is the nice part about having
12 a surrogate outcome. It is actually quite
13 manageable with insulin as long as someone has
14 the knowhow to do so. And there are very good
15 standardized insulin infusion protocols
16 available these days to control glucose quite
17 tightly in the ICU environment. The ACU is
18 probably the bigger challenge.

19 CO-CHAIR GOLDEN: So I am going to
20 just suggest that that was more of a usability
21 question but we will get there.

22 Any other comments or questions on

1 validity? Bill?

2 MEMBER TAYLOR: I wonder if Tracy
3 or one of our other experts who knows a lot
4 about this could give us a little reflection
5 on this. We are about to vote on
6 specifications consistent with evidence. We
7 heard from Jamie that the way the evidence was
8 collected about the high glucose being
9 associated with risk was collected in all
10 sorts of ways that were different from this.
11 And I would like to hear a little bit about
12 how you put this together as we get to this
13 vote.

14 DR. PACE: Can I also mention you
15 are not just voting on the specifications
16 consistent with the evidence. It is all that
17 goes into validity. So, they also provided
18 empirical validity testing, et cetera.

19 MEMBER BREEN: Yes, I think we are
20 still going to have some more discussions when
21 it comes to usability. But my take on this is
22 we are talking about reliability and validity

1 testing of the process that they put forth to
2 assess hyperglycemia, as they have defined
3 greater than 200. It seems reasonable to me
4 it has got good validity. It has got good
5 reliability as a measure, to measure
6 something. I think we already addressed the
7 evidence of both those things. I think we
8 still have some things to discuss about
9 usability and how it might impact.

10 So, that is my take on how we --
11 it is a reasonable process.

12 CO-CHAIR GOLDEN: I think the
13 issue is how it was collected. So waiting a
14 day, not the ER, all those things go into
15 those issues. But when somebody gets dinged,
16 if you will, there is a reason and there is a
17 reasonable reason for what I got dinged.

18 Ready to vote?

19 MS. BAL: Can people turn off
20 their microphones? There we go. Okay, voting
21 is open.

22 (Pause.)

1 MS. BAL: Okay, we have high four;
2 moderate 14; low one. So, it will proceed.

3 CO-CHAIR GOLDEN: Feasibility.

4 CO-CHAIR ROSENZWEIG: I think
5 here, I think that implementation of this
6 measure would require a lot of effort and a
7 lot of data collection but it is feasible,
8 especially in large medical centers where they
9 have the appropriate data management systems
10 to be able to do this.

11 The issue was that in there are a
12 lot of centers in which it would be very
13 difficult to implement from the beginning but
14 maybe the implementation, the initiation of a
15 measure of this sort might lead to better data
16 collection in the long-run.

17 CO-CHAIR GOLDEN: So, I have a
18 question for the developer. In terms of case
19 finding, I can understand if you are admitted
20 with diabetes but now you are saying anybody
21 with a blood sugar over 250. What kind of a
22 mechanism or how difficult is it to run that

1 kind of data analysis, to identify those
2 patients? And is that -- how burdensome is
3 that?

4 MR. CAMPBELL: So this is Kyle
5 Campbell from FMQAI. We did extensive
6 feasibility testing with all of our field
7 testing hospitals. And we found that the
8 measure was feasible to extract and calculate
9 without exception across all the hospitals.
10 And we did submit as part of our submission
11 NQF had recommended to provide a feasibility
12 score card with regard to the measure. And I
13 will note that the average score on that was
14 a 2.85 across all 10:02:03.

15 So, in our findings, I think the
16 folks on the Steering Committee are correct in
17 saying that the hospital will have to have
18 some effort in terms of setting the measure up
19 but it will be much less burdensome for the
20 hospital, once the measure is programmed
21 compared to manual chart of distraction.

22 And so for that reason and with

1 the reason that we found that all of these
2 data were retrievable, including the point of
3 care data that was discussed earlier, we
4 consider this measure from an electronic
5 perspective highly feasible.

6 CO-CHAIR GOLDEN: And a follow-up
7 question. When you were doing your testing,
8 how much software programming needed to be
9 done? And were the test hospitals reimbursed
10 for the software programming?

11 MR. CAMPBELL: Actually in this
12 case, the test hospitals were not reimbursed
13 for the software programming. They
14 volunteered to participate in this project
15 with us.

16 I would say on average -- I don't
17 know. Maybe I will defer this question Almut
18 because she was closely involved at the
19 academic institution where we did our
20 formative testing. Do you have a sense,
21 Almut, of how many hours in terms of
22 programming?

1 DR. WINTERSTEIN: I think it is
2 really important to differentiate between the
3 initial setup and any subsequent data
4 retrieval.

5 And I hope that I don't go too
6 long now but obviously one of the most
7 important data elements in here is lab values.
8 And just to give you an idea about this, our
9 hospital has about 800 different lab values in
10 the system and different ways those can be
11 ordered. And if you look at glucose, glucose
12 can be ordered as part of several test
13 batteries.

14 So to find the individual orders
15 that could have been a metabolic panel or just
16 a normal daily morning draw and so forth, as
17 well as the chem sticks of course, there is
18 actually a variety of different lab values
19 that can be used.

20 Now, as part of meaningful use,
21 lab values will have to be standardized and
22 coded with coding systems, which eventually

1 will look like an ICD-9 code. So, in a year
2 from now very likely most hospitals can just
3 be told we want code 1, 2, 3, 4, 5 and that
4 will automatically pull all of those glucose
5 values.

6 In our case, this hadn't been
7 implemented as it hadn't for many hospitals,
8 which basically means there needs to be a hand
9 search of the lab values that really need to
10 be included into the measure. Once this is
11 done, the extraction out of the system is very
12 simple and straight forward. So, it is more
13 really using the dictionary correctly to find
14 the information that is really needed that
15 concerns the medications as well as the
16 laboratory values that were used in this
17 particular measure. All other pieces before
18 you are standardized already because they
19 actually belong to the charge or the
20 administrative systems that are use and
21 hospitals and that have been used for many
22 years. So, admission tests and things like

1 that are in fact standardized data values
2 already.

3 So altogether, I think once the
4 measure is set up, the retrieval itself is
5 essentially really a push of a button. And
6 the code that we wrote to run the measure of
7 values that looks at the admission time and
8 defines when patients enter the denominator
9 and numerator and so forth, all of this
10 readily available.

11 CO-CHAIR GOLDEN: Comments or
12 questions?

13 DR. BURSTIN: I just wanted to
14 point out this is actually one of the first de
15 novo eMeasures that NQF has received. We did
16 this work for CMS and ONC about a year ago, I
17 guess, to come up with a score about data
18 feasibility because there was a lot of
19 concerns about new eMeasures being brought
20 forward where the data was actually not
21 feasible to collect. So, these were actually
22 done with an expert panel, came up with those

1 particular data availability, data accuracy
2 and data standards, to allow committees like
3 you to have some confidence that what you are
4 putting out there is actually findable and in
5 a standardized and reliable way in an EHR.

6 So, this is actually quite a good
7 score overall but actually we are just really
8 pleased to sort of see the light of day. And
9 I think we have heard a lot, particularly from
10 hospitals about how difficult it is,
11 sometimes, to implement some of the eMeasures.

12 So, I think since this is a
13 relatively not very complex set of data to put
14 together, but just wanted to put that -- give
15 you that perspective.

16 CO-CHAIR GOLDEN: Any other
17 comments and questions? Ready to vote?

18 MS. BAL: Voting is open.

19 (Pause.)

20 MS. BAL: Okay, we have high nine;
21 moderate eight; low one.

22 CO-CHAIR GOLDEN: Usability.

1 CO-CHAIR ROSENZWEIG: We didn't
2 discuss this at length. I don't think we had
3 time to discuss this at length at our
4 conference call. But my sense is that this is
5 a usable measure.

6 CO-CHAIR GOLDEN: I guess a
7 question for the developers in terms of CMS,
8 not every hospital can do this. What is your
9 perception over time about requiring reporting
10 versus -- I mean obviously if you have an EMR
11 you can do it but if you don't have an EMR,
12 you can't.

13 So, are there plans down the road
14 about requiring hospitals to do this over a
15 period of time?

16 MR. CAMPBELL: This is the
17 developer. And I would not be able to answer
18 that question for CMS. I don't know if anyone
19 from CMS is available to respond.

20 MS. BODKIN: Hi, I'm Noni Bodkin.
21 I am from CMS. I am from the Quality Measure
22 Health Assessment Group in the Centers for

1 Clinical Standards and Quality. So, that is
2 the birthplace of many, if not most of the
3 quality measures you are familiar with.

4 And I cannot speak about our
5 policy but it is my understanding that the
6 first step for this measure is to be
7 considered for our meaningful use Stage III.

8 So, that is a really important
9 initial step. We don't know what will happen.
10 We are very excited to have probably the first
11 de novo ECQM before a Steering Committee.

12 So, we will keep you posted on
13 that and we will follow all the normal
14 processes with public comment, our notice of
15 public rulemaking, and very careful
16 evaluation. Thank you.

17 MEMBER McCOLLISTER-SLIPP: So, I
18 have a question about that because I mean is
19 this something -- so, this is going to require
20 some degree of algorithm using EHR data of
21 some form or another. And one of the
22 questions I had and I didn't know if it was

1 around harmonization that we would get to this
2 is how does this fit into meaningful use. And
3 I mean I understand with where we are with
4 meaningful use but I haven't gone through and
5 looked at the specific elements of it.

6 So, is this data not the composite
7 measure, which is calculated by data that is
8 entered. Is all this stuff part of meaningful
9 use as it currently stands? Do you know?

10 CO-CHAIR GOLDEN: I think
11 meaningful use here would be that this measure
12 would be a requirement to achieve meaningful
13 use Stage III certification. You have to be
14 able to calculate this measure.

15 MEMBER McCOLLISTER-SLIPP: Well,
16 that is Stage III but is the data, are the
17 data fields that as currently dictated part of
18 the existing like meaningful use Stage I and
19 II in terms of having those fields already
20 available?

21 CO-CHAIR GOLDEN: I can tell you
22 from experience of looking at my own

1 institutional EMR, lots of data fields exist.
2 Whether you can collect them all is another
3 matter altogether. So, just because the data
4 fields exist doesn't mean they can be
5 integrated. It gets, unfortunately, it is
6 often a disappointing level of why isn't this
7 working better.

8 Bob?

9 MEMBER BAILEY: So, one could
10 argue, since we are at use and usability now,
11 that incorporating it into meaningful use,
12 there are financial incentives for
13 institutions to implement these programs.
14 And, as Tracy mentioned and as Sue mentioned
15 earlier, there are opportunities for these
16 organizations to look at their data, determine
17 where they are, then also determine where they
18 are with respect to their peers.

19 So, I see this as benefits. And
20 then if institutions don't comply with
21 meaningful use Stage III, subsequently they
22 will be financially penalized. So, it is a

1 positive outcome, I would suggest.

2 CO-CHAIR GOLDEN: Tracy.

3 MEMBER BREEN: I think it is
4 interesting because there is nothing there
5 right now. I mean this is truly a new way for
6 hospitals to look at data that they have been
7 sitting on for many, many years.

8 I think that it is very usable.
9 It will be interesting to see and it is a
10 place to start, in my mind. My reservations
11 are so small in terms of the unintended
12 negative consequences, to give one anecdote,
13 though about unintended consequences, one of
14 the SCIP scores used in the post-operative
15 CTICU realm has been no patient to have a
16 glucose greater than 200 without a lower
17 level. So, zero is less than 200, as I like
18 to say. And so one of the unintended
19 consequences has been that many CTICUs or
20 post-operative units have done very well on
21 their SCIP scores, they don't have any
22 glucoses higher than 200. But then when you

1 begin to look at their hypoglycemia, we are
2 going to get to hypoglycemia, they have had
3 surprisingly high hypoglycemia that they
4 didn't know because they weren't looking at
5 it.

6 So, I think the power of looking
7 at something is very powerful. So, I think
8 this tool will be a very powerful tool for
9 hospitals and I think some people are going to
10 get a very rude awakening of what their
11 numbers are.

12 I think it is reassuring to me
13 that they are going to be at least shown to
14 other similar hospitals. I think the
15 stratification of place seems reasonable, ICU
16 versus the floor. And again, it is a good
17 first start. My only tiny reservation is that
18 again, how we are defining persistent
19 hyperglycemia by basically putting this in
20 play, does it then prevent other potentially
21 more robust ways of measuring hyperglycemia
22 from being investigated? Whatever. Smart

1 people out there will figure out what to do.

2 But that is a very, very small revision.

3 CO-CHAIR ROSENZWEIG: You know I
4 also think, though, that the process of
5 implementing this would allow for collection
6 of a lot of data, much more data than we
7 currently have. And that whatever the
8 specific thresholds for defining good versus
9 bad control in the hospital are identified
10 here, it could lead to more accurate data in
11 the future.

12 CO-CHAIR GOLDEN: Are we ready to
13 vote?

14 MS. BAL: Voting is open.

15 (Pause.)

16 MS. BAL: So, we have high 11;
17 moderate seven; low one.

18 CO-CHAIR GOLDEN: All right, now
19 we are into the big picture. So any final
20 comments on this, otherwise we can vote on
21 endorsement, yes or no.

22 Not yet. Not yet. We have a

1 comment from Sue.

2 MEMBER KIRKMAN: Just to clarify.
3 This is going to be paired with the
4 hypoglycemia, right? So what she mentioned
5 about people could look really good on this
6 measure because their patients are all in the
7 30s, potentially wouldn't happen. Right?

8 CO-CHAIR GOLDEN: Yes, you know
9 pairing is interesting in that they are not
10 necessarily -- well, yes, they won't be in
11 isolation.

12 MEMBER BAILEY: So just to be
13 clear, so if this one passes and the
14 hypoglycemia one does not, then what happens?

15 CO-CHAIR GOLDEN: We will think
16 about that.

17 (Laughter.)

18 MEMBER McCOLLISTER-SLIPP: Just
19 for color commentary, my father has Type 2
20 diabetes. He was diagnosed, I don't know,
21 maybe about 20 years ago. At the
22 complications. He is in his 80s. And he has

1 had lots of hospital visits over the last few
2 years. Because I am nerdy enough to know
3 about the data about in-hospital glucose
4 control, I have had my mother stay on top of
5 it.

6 In terms of like the hospitals
7 variability in different institutions in the
8 region where he is, it is considerable in
9 terms of their willingness, and their ability,
10 and their intent to focus on this particular
11 measure. I mean some of them are completely
12 on top of it, some they would never check if
13 my mother wasn't bothering them or if he
14 didn't have his own meter.

15 So, I think this is a very helpful
16 important step for us to do to incentivize.

17 CO-CHAIR GOLDEN: Let's open the
18 polls.

19 MS. BAL: Voting is open.

20 (Pause.)

21 MS. BAL: Okay, we have yes, 18
22 and no, one.

1 CO-CHAIR GOLDEN: All right.
2 Thank you all. I think that the next one will
3 probably go a little faster.

4 So, it is 10:20. So I would
5 suggest we reset our biologic parameters and
6 re-gather at 10:30. So take a break.

7 (Whereupon, the foregoing matter
8 went off the record at 10:16 a.m.
9 and went back on the record at
10 10:29 a.m.)

11 CO-CHAIR GOLDEN: So, as we being
12 to re-gather, before we do the next measure,
13 it is time for I think if we are going to be
14 doing a variation on the Powerball. And
15 yesterday people were talking about the fact
16 that you would be open for a two- or a three-
17 year term. And so there is some -- do we have
18 the -- where is the magic hat? Oh, there it
19 is. Okay.

20 So we have the sippy cup and
21 people will choose their fate. It is like a
22 Magic 8 ball here.

1 So we are going to be going around
2 and let people know what your number is.

3 MS. TIGHE: And I will just jump
4 in with a little bit of the rationale for this.
5 We are moving to standing committees, as we
6 discussed yesterday. And so we do need to
7 kind of split your term, so we are not
8 refilling the committee in its entirety all at
9 one point in time. That said, if you get a
10 two-year term and you are just really wanting
11 to stay on the committee for another three-
12 year term, you are welcome to reapply at that
13 point in time. Our policy is written so that
14 committee members can stay on for two terms in
15 a row. After that, we will ask you to stay
16 off for a full term before applying again.

17 So, two years could be extended to
18 five if you wanted it to. Three years could
19 be extended to six, if you wanted it to.
20 Either way we have appreciated having you on
21 at least for this meeting and two years going
22 forward.

1 CO-CHAIR ROSENZWEIG: How about
2 allowing people to trade terms?

3 (Laughter.)

4 MS. TIGHE: Certainly, if there
5 are any conflict with what you draw or need to
6 reevaluate the terms, just let our staff know.

7 CO-CHAIR GOLDEN: So, you have
8 these numbers and do you have to have folks
9 report to you about the numbers or how do you
10 want to handle these?

11 MS. TIGHE: Poonam will go around
12 and record.

13 CO-CHAIR GOLDEN: Okay, good.

14 CO-CHAIR ROSENZWEIG: I'll go
15 ahead to the next measure, which is glycemc
16 control hypoglycemia. Let me just get my
17 materials here.

18 This is number 2363. And are the
19 measure developers on the line? So, if you
20 would like to describe the measures to us, we
21 would appreciate it.

22 DR. WINTERSTEIN: Yes, we are

1 here. I have to unmute myself again.

2 MR. CAMPBELL: Yes, I am here as
3 well.

4 MS. TIGHE: Kyle, do you have any
5 comments to add about this measure before the
6 committee begins to review?

7 MR. CAMPBELL: You know in the
8 beginning when we introduced this, we
9 introduced both of them at the same time. I
10 would just say that for public reporting, we
11 are looking at severe hypoglycemic events, so
12 then less than or equal to 40 milligrams per
13 deciliter. And this threshold has been
14 consistent with a definition of safety in the
15 majority of clinical trials. And we found,
16 through our work in testing these measures
17 that most of these events, at least according
18 to our clinical reviews, largely prevent it.

19 So, thank you and we appreciate
20 your consideration and look forward to any
21 questions you have about this measure.

22 CO-CHAIR GOLDEN: Okay.

1 MEMBER LEDDY: We can start.

2 CO-CHAIR GOLDEN: Thank you.

3 MEMBER LEDDY: This measure looks
4 at the rate of hypoglycemic events following
5 the administration of an anti-diabetic agent.
6 The rationale relates to glycemic control and
7 hypoglycemia management in the hospital
8 inpatient setting and is proposed as a
9 companion measure to the measure we just
10 discussed and voted on, glycemic control.

11 It is an intermediate outcome
12 occurring in the inpatient setting. It has
13 serious consequences, longer stays in the
14 hospital, increased mortality.

15 So, the developers see important
16 benefits arising from the implementation of
17 this measure. One is that providers will be
18 incentivized to recognize hypoglycemia,
19 prevent it, treat it, and as a result, there
20 will be shorter hospital stays and fewer or
21 lower mortality.

22 It does really point toward

1 advancing quality of care in this area of
2 patient safety. It has been identified as a
3 very important issue by the National Quality
4 Strategy.

5 The numerator statement looks at
6 the total number of hypoglycemic events that
7 were preceded by the administration of rapid
8 or short-acting insulin within 12 hours or an
9 anti-diabetic agent, other than short-acting
10 insulin administered within 24 hours, not
11 followed by another measure of glucose greater
12 than 50 within five minutes. And the events
13 would need to be at least 20 hours apart.

14 There was an optional numerator
15 statement given but the developer just
16 mentioned that the key number here is less
17 than 40. That is a very critical glucose
18 value.

19 And let's see. The denominator's
20 total number of hospital days on which an
21 anti-diabetic agent was administered. There
22 is a single denominator exclusion, which is

1 admissions less than -- admissions greater
2 than 120 days. It is my understanding that
3 this 120 day definition is really standard for
4 looking at a lot of measures.

5 This is an outcome measure. The
6 data is from electronic records. Electronic
7 clinical data in the pharmacy and the
8 laboratory. It is a facility-level analysis.

9 So moving on to evidence, I think
10 the evidence is very good. Five studies were
11 reported. Guideline recommendations were
12 included. However, these were not -- the
13 guidelines that were included were not the
14 focus of the measure. They had to do with
15 treating hyperglycemia. Of course, this
16 measure is about treating hypoglycemia or
17 preventing it. The evidence, however, is
18 sufficient.

19 The main points are that patients
20 with hypoglycemia, less than 40, are at
21 greater risk of in-hospital mortality and that
22 patients with hypoglycemia had longer lengths

1 of stay.

2 We did not use a grading system
3 but the studies were described carefully and
4 the results were consistent.

5 There are two ways of looking at
6 the evidence. One, if one believes that it
7 represents a formal systematic review, one
8 goes to the algorithm boxes 3, 4, and 5b. If
9 not, you move down to 7, 8, and 9. But either
10 way, we get to a moderate rating.

11 So perhaps this would be a good
12 time to talk about the evidence. Any
13 comments?

14 We all know that hypoglycemia is
15 very dangerous and the hospital is a very
16 dangerous place for Type 1 diabetics and to a
17 little bit lesser extent, Type 2s. You have
18 to have a family member there to take care of
19 them.

20 CO-CHAIR ROSENZWEIG: Is it clear
21 really that hypoglycemia should be considered
22 in an intermediate outcome? I mean in and of

1 itself, isn't it a --

2 MEMBER LEDDY: That is a really
3 good point because it could be curtains --

4 CO-CHAIR ROSENZWEIG: Exactly.

5 MEMBER LEDDY: -- could be the
6 outcome, the ultimate outcome.

7 CO-CHAIR ROSENZWEIG: So I mean it
8 is intermediate towards death or brain damage.
9 But seriously, I think it could be considered
10 an actual negative outcome in and of itself.

11 MEMBER McCOLLISTER-SLIPP: Sorry.
12 I need to hold my card up or whatever. But
13 would that make a difference in terms of the
14 implications of this measure? I mean so
15 whether it is intermediate or just an outcome?

16 DR. BURSTIN: The only difference
17 and Karen can weigh in on this is that if it
18 is an outcome, you just have to provide a
19 rationale for the evidence, as opposed to firm
20 evidence because there is just sort of on the
21 very basis, a bad outcome is a bad outcome.
22 How much evidence do you need for it?

1 Anything to add?

2 DR. PACE: Though this would
3 probably be considered an intermediate.

4 DR. BURSTIN: But they are just
5 saying now they think it is an outcome, not an
6 intermediate.

7 MEMBER LEDDY: Intermediate
8 outcome.

9 DR. PACE: Right. And I think
10 this is a problem with our submission form.
11 I don't know that we have that option for an
12 intermediate outcome.

13 So for intermediate outcome, we
14 like to see the link to other outcomes. We
15 have talked about that, mortality and
16 morbidity. If it is an end result outcome,
17 then as Helen said, we ask for a rationale
18 that there are healthcare services and
19 interventions that can affect it but it is
20 really more of a rationale discussion than the
21 actual evidence.

22 CO-CHAIR ROSENZWEIG: Because the

1 staff review had mentioned that it is an
2 intermediate outcome and requires evidence of
3 linkage to health outcomes.

4 DR. PACE: Right. So, you think
5 it is more of an outcome. Okay, that's fine.

6 CO-CHAIR ROSENZWEIG: Yes, Sue?

7 MEMBER KIRKMAN: So, I mean it is
8 potentially an outcome of treatment but it
9 also is a marker for a sicker patient. So, I
10 think in some ways it is a little bit of an
11 intermediate outcome. It is a little bit
12 semantics. But even people not on insulin can
13 have severe hypoglycemia in the hospital and
14 they have a very poor prognosis.

15 So, there is linkage to the final
16 outcome but it is not necessarily --

17 DR. PACE: So you know this where
18 things stop and outcome begins, there is not
19 hard and fast lines. I think maybe we can
20 hear from the developer. I think they
21 submitted evidence of linkage to other
22 outcomes. So, they probably conceptualized it

1 that way. Developer?

2 MR. CAMPBELL: Yes, this is Kyle
3 Campbell at FMQAI. We did envision it as an
4 intermediate outcome with a hard outcome of
5 mortality and morbidity. And as mentioned, we
6 identified, I think, nine in all now with the
7 supplement that we provided to the Steering
8 Committee, you know evaluated mortality. And
9 there was consistency in magnitude of
10 direction and effect for those studies.

11 I mean my take on this is we would
12 still consider it an intermediate outcome, in
13 keeping with the nomenclature for the
14 hyperglycemia measure.

15 DR. PACE: Is there any question
16 of the linkage between this intermediate
17 outcome and mortality and other morbidity?

18 CO-CHAIR ROSENZWEIG: I think
19 there is. Well, our review work addressed
20 that, yes.

21 MEMBER LEDDY: I think there is
22 really strong linkage between the evidence and

1 the outcomes.

2 CO-CHAIR ROSENZWEIG: I think one
3 issue that should be mentioned is that the
4 evidence between linkage of hypoglycemic
5 events and falls is reasonably robust. And
6 falls are a never event for payment for
7 hospitals. So, they are very, very
8 incentivizes to reduce hypoglycemia. I think
9 there was some discussion as to whether or not
10 severe hypoglycemia itself was to be
11 considered a never event. I don't know if
12 that has happened or not. Does anyone?

13 But clearly, the incidence of a
14 fall, of major falls have to be reported by
15 hospitals and the causes of them have to be
16 determined. And in patients with
17 hypoglycemia, this could be --

18 MS. TIGHE: I worked on the NQF
19 Serious Reportable Events Report and I will
20 just speak to the fact that it is classified
21 under a medication error because typically you
22 have that severe hypoglycemia as a result of

1 mismanagement of medication. So, it is
2 something captured as an NQF serious
3 reportable event, which is the foundation for
4 the never events.

5 CO-CHAIR ROSENZWEIG: So you have
6 to actually determine that there is a
7 mismanagement of medication?

8 MS. TIGHE: The trigger for the
9 event is patient injury or serious harm. But
10 yes, it is related to the medication
11 mismanagement.

12 CO-CHAIR ROSENZWEIG: Well, in any
13 case, clearly the hospitals that implement
14 this would be very highly incentivized to
15 measure this.

16 So any other comments?

17 MEMBER LEDDY: I have no other
18 comments.

19 CO-CHAIR ROSENZWEIG: Any
20 questions?

21 MEMBER LEDDY: Can we vote?

22 CO-CHAIR ROSENZWEIG: I think we

1 can, yes.

2 MS. BAL: Voting is open.

3 (Pause.)

4 MS. BAL: Okay, high 13; moderate
5 six.

6 MEMBER LEDDY: Okay, moving on to
7 1b, gap in care. This was a new measure. So,
8 it was presented to eight testing hospitals.
9 The performance data is available. The range
10 of occurrence of or reported performance was
11 between 0.36 percent and 0.89 percent.

12 This is really when you look at
13 things in a low incidence of outcome but
14 considering that it is such a severe and
15 dangerous event, even those low numbers look
16 like a gap to me.

17 Looking at the cited studies,
18 there was no address made to the variability
19 and performance but the rates for patient days
20 were higher in patients in the ICU than in the
21 non-ICU setting. And then some rates per
22 admissions were between 2.3 and 3.5 percent.

1 So I think that even though it is
2 quite small, really any gap is very serious.
3 And I would like to call for a vote, except
4 Bob has a comment.

5 MEMBER BAILEY: Although there is
6 not much of a gap now, we need to consider
7 that there may be a widening gap going forward
8 with a focus on controlling hyperglycemia.
9 So, that should come into consideration as
10 well.

11 MEMBER LEDDY: Absolutely. It is
12 so important to have this as a companion
13 measure. A very, very good point.

14 CO-CHAIR ROSENZWEIG: Okay, let's
15 vote.

16 MS. BAL: Okay, voting is open.

17 (Pause.)

18 MS. BAL: Okay, we have high 12,
19 moderate six; low one.

20 CO-CHAIR ROSENZWEIG: Okay, going
21 on to --

22 MEMBER LEDDY: To 1b, disparities.

1 The developer actually stratified the measure
2 by age, race, ethnicity and payer source and
3 concluded there were no significant
4 differences by race or age groups.

5 There was no information on how it
6 was determined that there were no significant
7 differences.

8 The rates varied by race for the
9 Hispanics, 0.4 percent; African Americans,
10 0.67 percent.

11 There were a couple of studies
12 cited. I think one of them was in an acute MI
13 setting, where when they looked at incidence
14 of hypoglycemia, it was more common in elderly
15 people, women and one ethnic group, which I
16 don't remember. And then there was another
17 study cited where there was also older
18 patients and also women.

19 But to my review, it just did not
20 seem to me that disparities was really an
21 issue.

22 MS. TIGHE: Just a process point.

1 That actually falls under 1b, which we just
2 voted on. Not to cut conversation short.

3 MEMBER LEDDY: Okay, thank you for
4 your help.

5 MS. TIGHE: That shouldn't be
6 factored into your vote on priority of high
7 impact.

8 MEMBER LEDDY: Okay, so here we
9 are at priority. The occurrence of
10 hypoglycemia in the hospital is a very
11 significant adverse drug reaction. It is the
12 most common drug reaction and accounts for
13 about a third of all adverse drug reactions in
14 the hospital. It is a very high priority for
15 I guess the National Quality Survey.

16 So, does the measure address a
17 significant health problem? And may we vote?

18 MS. BAL: Voting is open.

19 (Pause.)

20 MS. BAL: Okay, the results are
21 high 17; moderate two.

22 CO-CHAIR ROSENZWEIG: Okay,

1 reliability. Any comments?

2 MEMBER LEDDY: We have discussed
3 in the previous measure the eMeasure. And the
4 eMeasure technical review that has been. I
5 believe the developers have given us a good
6 reason not to consider the optional numerator.
7 It would, if we had a higher optional
8 numerator of less than 70, maybe more folks
9 would have their daily glucose records
10 reviewed in the hospital by their provider and
11 maybe some more hypoglycemic events of
12 severity would be avoided. But I, personally,
13 would like to see it remain at 40 or less.

14 I would remove the optional
15 numerator. Any comments about that?

16 MR. CAMPBELL: This is the measure
17 developer. And just to comment in terms of
18 the optional numerator, when this measure went
19 out for national public comment, we received
20 comments from hospitals that asked us to
21 consider for internal quality improvement an
22 optional numerator. And so that is the origin

1 of why the optional numerator was included.

2 We are not recommending that for
3 public reporting but internal quality
4 improvement only.

5 MEMBER LEDDY: Is it possible to
6 have two numerators in the same measure?

7 MR. CAMPBELL: It is from our
8 perspective because the publicly reported
9 measure would just be one numerator.

10 DR. PACE: I think that would need
11 to be clearly specified. The way it is now,
12 it makes it look like you have the option of
13 using whichever one you want. So, we need to
14 be clear what NQF endorsement would be.

15 CO-CHAIR GOLDEN: So it gets back
16 to our discussion yesterday with NCQA.

17 Would CMS be adverse to
18 eliminating 70?

19 MR. CAMPBELL: We would not.

20 CO-CHAIR ROSENZWEIG: One question
21 I would have related also is usually
22 hypoglycemia is often defined, severe

1 hypoglycemia is often defined as requiring
2 help by a healthcare provider or by another
3 person in order to reverse it. Or there may
4 be issues related to whether or not there is
5 loss of consciousness involved with this or
6 Whipple's Triad. And none of those are
7 mentioned. This is purely just looking at the
8 number of actual times in which blood glucose
9 less than 40 is listed.

10 Did the measure developers
11 consider issues related to that?

12 MR. CAMPBELL: This is Kyle
13 Campbell again from FMQAI. We did consider
14 that but our focus was on what was readily
15 extractable from electronic health record.
16 And that type of information would necessitate
17 chart review in order to include.

18 CO-CHAIR GOLDEN: Yes, Sue?

19 MEMBER KIRKMAN: So, two things.
20 Just a comment on yours. I mean I think for
21 the inpatient setting, it is difficult because
22 if someone is comatose and their blood glucose

1 is 69, a health care professional would treat
2 it anyway. So it becomes a little difficult.

3 But my question goes back to the
4 optional numerator. So I mean I do think for
5 internal quality improvement, you wouldn't
6 want to just look at less than 40 because that
7 is going to be vanishingly rare in your
8 hospital, hopefully. But if you have a lot of
9 people in the 50s and 60s, then that is a
10 problem that you would probably want to
11 address internally. So, I guess it is more of
12 a process question for NQF. I mean, is there
13 a possibility to endorse the publicly reported
14 measure with an optional for internal QA or is
15 that just not -- it has to be all or none and
16 anything we endorse could be publicly
17 reported. Is that the situation?

18 DR. PACE: I think you have some
19 options here but I just think it has to be
20 very clear in the specifications that
21 component, it is not really optional. It is
22 another way to -- it is not optional in terms

1 of how you implement the measure for an
2 accountability purpose, if that is what you
3 all are saying.

4 I mean you have some options here
5 in terms of endorsing it with kind of
6 reporting both, endorse the less than 40 as
7 the one that is used in accountability
8 applications and it being very clear that the
9 less than 70 is the QI component or ask them
10 to remove it.

11 So, I think you have to have some
12 discussion about that.

13 DR. BURSTIN: It is also worth
14 noting, I believe these measures and notings
15 here have already been proposed as part of
16 some of the ongoing upcoming programs for CMS.
17 So, it may also be that you may want,
18 depending on one denominator there may just be
19 notes to implementers that you could something
20 along the lines of the optional.

21 But I don't know if anyone has any
22 comment about that. Too early. So again, it

1 could be something we could ask them to
2 consider and come back to us, just to keep it
3 simple. But for now, I would assume you
4 should look at what is the actual
5 specification, not the optional one. And we
6 can allow them to come back to us with some
7 thoughts about how we handle the optional
8 piece of it.

9 But since this measure may likely
10 be on some public reporting or payment program
11 in the future, I think we need to focus on the
12 accountability application, at this point.

13 MEMBER KIRKMAN: So does
14 everything that is endorsed by NQF could
15 potentially be publicly reported? Is that --
16 okay.

17 CO-CHAIR GOLDEN: Yes, I am a
18 little concerned by that if we make it
19 optional, it means that CMS has the option of
20 making it 70, which I don't think --

21 DR. BURSTIN: No. So the endorsed
22 measure would be whatever you think it should

1 be. I think then the question is how does CMS
2 want to handle potentially asking hospitals to
3 submit the other data more for learning than
4 anything else, as opposed to that.

5 But again, I think we need to get
6 some other input from CMS.

7 DR. PACE: Right. And perhaps one
8 way to handle it is Helen was talking about,
9 maybe rather than in the specifications, it is
10 handled under potential uses, where that may
11 be more comfortable than having it right in
12 the specifications.

13 So, I think you should first
14 consider the accountability application and
15 then make recommendations about how to handle
16 the --

17 MEMBER KIRKMAN: Yes, I just
18 wouldn't want the message that hospitals get
19 that anything above 40 is okay. I mean I just
20 don't know how to handle that.

21 MEMBER BREEN: It sounds like if
22 they have language in their comment to the

1 hospitals about how to use it, then it could
2 be there.

3 I agree with Anne, though, for the
4 purposes of this, it seems like it would be
5 clearer to just vote on this without the
6 optional piece, even though we all know that
7 the hospitals should be doing that. But
8 again, it seems like it would blur lines to
9 make it murky if it looks like that was
10 reportable.

11 CO-CHAIR ROSENZWEIG: With respect
12 to the specifications, does this measure allow
13 for distinguishing between whether or not the
14 anti-hyperglycemic medication was administered
15 intentionally or according to the orders or by
16 mistake? Since some of these episodes occur
17 because -- I think probably a significant
18 number occur because of problems with the
19 mistakes made.

20 MR. CAMPBELL: So this is the
21 measure developer. We don't distinguish the
22 administration of the medications by mistake.

1 But information comes from the electronic, the
2 eMAR, the electronic medication administration
3 record. So, we do have data that the drug was
4 actually administered.

5 CO-CHAIR ROSENZWEIG: Okay, I'm
6 not suggesting that it has to be but it would
7 be of interest.

8 MEMBER McCOLLISTER-SLIPP: So, a
9 couple points to your point earlier about
10 unconscious hypos or adverse events, I mean
11 that is highly variable from patient to
12 patient. So, I think relying on adverse
13 events or being unconscious or something
14 really bad happening is really, it is just
15 better to have a number.

16 I would think that 40 is a little
17 low. That makes me a little nervous. I think
18 70 may be a little high. So, I don't know
19 what the sweet spot is but the 40 is really
20 low.

21 And then when it comes to again,
22 meter variability, and again, I am more

1 familiar with consumer outpatient meters than
2 I am with point of care meters but once you
3 get that low, you get into reliability issues.
4 So, I think we need to think about that. I
5 mean, is 40 really 40 or is it 20 or is it 50?

6 And that is our job is not to
7 determine whether or not these meters are
8 accurate but I mean a 40 would make me very
9 nervous and I think we need to have an
10 incentive for hospitals to not --

11 I mean this is something I am
12 pretty sensitive to because I am pretty
13 insulin-sensitive when I have been
14 hospitalized, which fortunately hasn't been
15 for a while. They always want to overdose me
16 and I refuse the medication because inevitably
17 they will look at my blood sugar, which is
18 high and they will try to give me 10 units of
19 insulin and I am just like no, I don't want to
20 die.

21 So, I mean there needs to be an
22 incentive for hospitals to be very careful

1 about that, not that I think that people are
2 being careless or being egregious in their
3 carelessness. But anyway, I think I am sort
4 of rambling at this point. But this is a
5 significant issue and I think we need to give
6 real thought to does it make sense to have
7 that flexible numerator and is that area, is
8 that wide variability of that number an
9 appropriate range.

10 CO-CHAIR ROSENZWEIG: Tracy.

11 MEMBER BREEN: You know where to
12 draw your line in the sand on the hypo front
13 is very similar to the conversation we just
14 had on where to draw the line on the hyper
15 front. At some point, it is just high. All
16 right, so I think just like they had consensus
17 around anything greater than 200, most people
18 are going to agree that that is really high,
19 drawing the line at 40, everyone agrees that
20 that is low.

21 As you begin to creeping up
22 higher, this comes out to discussions with

1 laboratory people. How do you define a
2 critical value and where you draw that line.

3 But 40 is interesting because when
4 you look at meter variability and what is an
5 accepted range of what is accurate, when you
6 match it up to labs, unfortunately, you are
7 allowed kind of a 10 to 15 point variability
8 in your meters.

9 So, if you start doing the math on
10 that, if most of these glucose checks are done
11 by point of care meters and you come up with
12 a glucose check of 50 on the meter, it might
13 actually be 65 or 70. It could also be low.
14 And then you get into a glucose of 60 is very
15 normal for many people. In pregnancy, we
16 actually want that. Right? So, there is a
17 whole host of glucoses of 55 to 60 that are
18 very normal and healthy for many people in the
19 hospital.

20 At 40 though, even when you do
21 that math, maybe their glucose is really 55,
22 that is still really low. So for me, a

1 glucose of 40 is a nice anchor for just a
2 really severe hypoglycemic event. I think
3 there will be very few false negatives in that
4 pool and at least it gives the hospital some
5 kind of anchor as to what is really bad.

6 The other question is well, how do
7 you get not just the really bad but the not so
8 great. I think that is the other discussion
9 we had about the optional numerator. But
10 again, considering there is nothing right
11 there now, to me it seems like a place to
12 start, just like the hyperglycemic reporting
13 was a place to start.

14 MEMBER McCOLLISTER-SLIPP: But the
15 consequences of being slightly off for
16 hyperglycemia is very different than the
17 consequences for being slightly off for
18 hypoglycemia. I mean, especially if it
19 somebody is Type 2 and has lots of risk
20 factors for -- or Type 1 and has lots or risk
21 factors for cardiovascular disease.

22 MEMBER BREEN: Yes, but I think we

1 are saying that this is a reportable measure.
2 You know, it gives a hospital a way to anchor
3 themselves vis-a-vis other hospitals of how
4 they are doing with this severe hyperglycemia.
5 So someone doing very badly with severe
6 hyperglycemia is also probably not doing so
7 great with a not so severe hypoglycemia. To
8 me, it is just a marker for where you are,
9 vis-a-vis other hospitals. There is no -- I
10 don't think we are ever going to find a number
11 that everyone agrees on. When you look at the
12 literature on severe hypoglycemia, they even
13 define it differently, how you define severe
14 hypoglycemia. It is kind of a made up term.

15 But I think most groups would
16 agree that 40 is bad. So once you get above
17 that --

18 MEMBER McCOLLISTER-SLIPP: For
19 verification, is this hypo or is this severe
20 hypo?

21 MEMBER BREEN: They are calling it
22 -- so now we get into -- they are calling it

1 hypoglycemia but this is really severe
2 hypoglycemia. Hypoglycemia we know is defined
3 as less than 70. Right? If you look at all
4 the ADA criteria, hypoglycemia is defined as
5 less than 70 but that becomes problematic in
6 non-diabetic patient population or in a
7 pregnant patient population with diabetes.

8 So, there may be some nomenclature
9 issues about what we suggest to the developer
10 in terms of are we calling this hypoglycemia
11 or severe hypoglycemia. That is a really good
12 point.

13 MEMBER McCOLLISTER-SLIPP: Don't
14 we already have existing issues around severe
15 hypo though? I mean that is one of the few
16 things that is actually reportable to FDA
17 through AERS. I mean I know that this is
18 inpatient and it is completely different. But
19 I would think that we would -- there is a
20 distinction between severe hypo, which
21 hopefully is a never event, and hypo.

22 CO-CHAIR GOLDEN: A little while

1 ago, I looked up never events and it is severe
2 hypoglycemia with injury or morbidity. So, it
3 actually requires some adverse consequence,
4 which this would not.

5 MEMBER BREEN: This is potentially
6 a bigger pool than that. Right? It seems
7 like we are expanding the pool and the concept
8 of medication error is a huge one but not for
9 this setting, how we report errors.

10 And I would also just comment in
11 terms of how hospitals currently look at
12 hypoglycemia, this measure to me is very
13 clinically interesting because it makes it
14 patient-specific or at least it relates it to
15 patients on high-risk medications. Many
16 hospitals right now, when they try to look at
17 their hypoglycemia data just go on the ACCU-
18 CHEK data or they go so they take their
19 gazillion point of care measurements and they
20 say what percent of those gazillion point of
21 care measurements are hypoglycemia. And they
22 feel really good about themselves because it

1 is like 0.5 percent or one percent. It is not
2 clinically valid. But this seems to be a much
3 more clinically relevant way for hospital to
4 look out of all the patients treated, out of
5 all the episodes that someone received a
6 treatment with a high-risk medication, how
7 many of those were associated with severe
8 hypoglycemia, whether or not it related to
9 harm? That gives you a bigger piece of the
10 pie to kind of think about.

11 CO-CHAIR GOLDEN: Sue.

12 MEMBER KIRKMAN: So again, I think
13 this gets back to the issue of just making
14 sure that hospitals don't think that less than
15 40 is all they have to worry about. Because
16 I agree with you. I don't think less than 70
17 should be publicly reported, necessarily. But
18 I just really hope that however the
19 specifications are set up and however people
20 are doing their internal QA, they don't
21 realize that there is a lot of other
22 hypoglycemia. I mean, if you are not going to

1 call this severe hypoglycemia -- I mean that
2 would be one thing would be to call this
3 severe hypoglycemia and say that is what is
4 publicly reported. Because again, by saying
5 this is a hypoglycemia measurement and
6 hypoglycemia is less than 40, then that sort
7 of implies that anything between 40 and 70 is
8 high.

9 MEMBER BREEN: Because it is not
10 actually.

11 MEMBER KIRKMAN: I mean it is
12 fine.

13 MEMBER BREEN: It is not the right
14 definition. If we are saying hypoglycemia,
15 this is not the definition of hypoglycemia.

16 MEMBER KIRKMAN: Yes, either call
17 it severe hypoglycemia or the specifications
18 just have to be really clear or the
19 implementation has to be really clear that
20 hospitals can't ignore anything from 41 to 70.

21 DR. PACE: So I guess maybe we can
22 hear from the developer again if they would be

1 amenable to labeling it severe hypoglycemia.
2 And I think you have already said that you
3 would be willing to take the optional out of
4 the specification. So maybe you can talk
5 about it under improvement.

6 MEMBER McCOLLISTER-SLIPP: But I
7 think it is appropriate to incentivize
8 hospitals to not keep their patients hypo. I
9 mean we don't want to go hyper but that is an
10 incredibly uncomfortable place to hang out.

11 And again, I don't think there are
12 people out there who would sort of
13 intentionally keep their patients at a lower
14 level but I think it is appropriate to
15 distinguish hypo from severe hypo.

16 So I mean the question is, is what
17 is that measure? And there is significant
18 variability from patient to patient in terms
19 of the consequences of that measure. I mean,
20 if you are coming from a high and you are at
21 70, you may have heart palpitations and sweat.
22 I mean there could be -- you could even go

1 unconscious. I know people who don't have
2 great control who become unconscious at 70.

3 So, I mean in think it is
4 important to have a distinction between the
5 two, generally speaking. So, I think it is
6 appropriate to have a hypo measure but 40
7 makes me nervous just because that is really
8 low, no matter how you define it.

9 DR. PACE: So, you are suggesting
10 to have a measure with basically both
11 measures; less than 70 and less than 40? Is
12 that what you are advocating?

13 MEMBER McCOLLISTER-SLIPP: Well, I
14 think we need to hear from the developer. It
15 would be nice to hear from the developer about
16 what their goal of this is. If it is really
17 severe hypoglycemia, then maybe we just need
18 to name it.

19 MR. CAMPBELL: This is Kyle
20 Campbell again from FMQAI and that is our
21 goal, is severe hypoglycemia. From an
22 accountability perspective, we did review this

1 with our expert panel and we found that those
2 events that are less than 40 are definitely
3 preventable. And our concern with a publicly
4 reported measure, where the measure would be
5 let's say less than 70, that we begin to see
6 that many of those values aren't preventable
7 from the hospital side.

8 So while we do acknowledge that we
9 think hospitals from an internal QI
10 perspective should be looking at less than 70
11 as a mild or hypoglycemia metric for internal
12 QI, for the reporting function, we would be
13 amenable to relabeling this as severe
14 hypoglycemia.

15 CO-CHAIR GOLDEN: Just to try to
16 shape this, the thresholding is almost a
17 validity question, not a reliability question.
18 The question is can we -- is it defined so we
19 have a number. And can you measure that in a
20 reliable way?

21 DR. PACE: And they did present
22 some reliability testing data.

1 CO-CHAIR GOLDEN: Yes. So,
2 whether it is 50 or 60 or 40, the question is,
3 can you collect that data? And then we just
4 repeat the same thing for validity. But I
5 think we are discussing validity here and not
6 reliability.

7 MS. BAL: Are we voting?

8 CO-CHAIR GOLDEN: I think so.
9 Yes, we are voting on this.

10 MS. BAL: Okay, go ahead and vote.

11 (Pause.)

12 MS. BAL: Okay, we have high 11;
13 moderate seven; low one.

14 CO-CHAIR ROSENZWEIG: Okay,
15 comments about validity?

16 Yes, Patricia.

17 MEMBER McDERMOTT: I've been
18 trying to figure out when to fit this in.

19 In the denominator exclusion says
20 admissions with length of stay greater than
21 120 days. This is supposed to be a paired
22 measure with hyperglycemia, which had anything

1 greater than ten days or after days excluded.

2 How does this correlate?

3 MR. CAMPBELL: This is the measure
4 developer. The exclusion for greater than 120
5 days, I believe, one of the Steering Committee
6 members brought this up earlier is that has
7 been an exclusion of part of the inpatient
8 quality reporting measures by CMS and we
9 adopted it.

10 There are very few, and in fact in
11 this measure I need to look, but there are
12 very few, if any, patients that are excluded
13 due to that exclusion.

14 With regard to the hyperglycemia,
15 we are only looking at the first ten days of
16 measurement as Almut suggested because we are
17 trying to avoid long-term stay patients
18 skewing the measure results. So, if the
19 patient was actually in the hospital for 90
20 days and contributed a large number of
21 hyperglycemic days, we didn't want to skew the
22 measure results with that measurement. So

1 that is the rationale here.

2 CO-CHAIR GOLDEN: But I think also
3 keep in mind the first measure was a percent.
4 So, if you had a long stay, you can dilute the
5 percentage. This is a total number, correct
6 number of events.

7 Though, to follow up though, if
8 you have one very brittle patient, will that
9 skew your numbers as well? Have you given any
10 thought to the fact that if you have one
11 patient that jumps around, could that one
12 person be -- I mean and whether that is
13 relevant or not to be discussed by the group.

14 MR. CAMPBELL: I am going to defer
15 that question to Almut, who worked with our
16 technical expert panel workgroup on that
17 issue.

18 DR. WINTERSTEIN: Yes, just to
19 follow-up what Kyle just said. So patients in
20 the hypoglycemia measure, patients is the
21 length of stay more than ten days are not
22 excluded from the measure. We just truncate

1 the follow-up at this point. So, the patient
2 populations that are included in terms of
3 their length of stay are actually identical in
4 both measures.

5 In terms of having patients
6 contribute more or less in the hypoglycemia
7 measures, based on the number of events they
8 have, this is an incident-based measure. So
9 we are counting the total number of events
10 over the total number of days that patients
11 contributed in the hospital.

12 And the reason we did this is
13 because we noticed that there actually are
14 some patients who have repeated incidents of
15 hypoglycemia. And we didn't want to take this
16 out because it seemed to be important enough
17 to capture every single event.

18 So, what we are essentially
19 counting right now is the total number of
20 events that occurred during admission. Those
21 events have to be at least 20 hours apart to
22 assure that we are not looking at the same

1 incidence because there were remeasurements
2 done. And then we normalized this, we
3 standardized this to the total amount of time
4 that was available.

5 CO-CHAIR ROSENZWEIG: Sue?

6 MEMBER KIRKMAN: Yes, to me it
7 seems reasonable because this is almost a
8 safety issue. If someone is in the hospital
9 80 days and they get hypoglycemic 60 times, I
10 mean I think that is not really skewing the
11 data. That is really bad care.

12 Whereas, the hyperglycemia
13 measure, the way it is calculated, I can see
14 that your hospital's quality of care on that
15 measure, it might be skewed by these really
16 long admission patients.

17 So, I think it is reasonable to do
18 it differently for the kind of safety
19 incidence-based measure versus how your
20 hospital is doing with hyperglycemia
21 management measure.

22 DR. WINTERSTEIN: That was exactly

1 our thinking, just to respond to this. And we
2 did have one patient who had three
3 hypoglycemic events in one testing hospital.

4 CO-CHAIR ROSENZWEIG: Just one
5 comment. I think there had been a suggestion
6 about identifying a blood glucose of less than
7 40 as being considered to be severe
8 hypoglycemia. And I would caution against
9 that because I think Sue and I were on a
10 committee of the ADA that looked into these
11 definitions.

12 And the definition for a severe
13 hypoglycemia is generally hypoglycemia,
14 whatever the blood glucose that causes
15 impairment that requires assistance by someone
16 else. And that committee couldn't really come
17 up with a specific number like 40. They came
18 up with a number of 70 as an alert value for
19 hypoglycemia, as I recall.

20 So, I mean defining it as hypo, I
21 am not against the idea of using 40. I think
22 that is a very good number but to call it

1 specifically severe hypoglycemia might confuse
2 the issue.

3 Yes?

4 MEMBER KIRKMAN: Well, I am
5 concerned, though, about just calling it
6 hypoglycemia because, again, that implies that
7 anything from 41 to 70 is not hypoglycemia.

8 So, I think it does need to be
9 labeled with some term like severe or really
10 bad or dangerous hypoglycemia.

11 DR. PACE: How about just having
12 the level in the title, hypoglycemia less than
13 40?

14 MEMBER KIRKMAN: Well, I mean I
15 still think -- I don't know. I mean I
16 personally don't mind the term severe because
17 I think it is different for inpatients. And
18 I think the workgroup sort of consider the
19 ambulatory patient, for the most part.

20 I think severe kind of conveys
21 what we are talking about but I don't know.

22 MEMBER McCOLLISTER-SLIPP: I would

1 just be concerned about 70 because I mean what
2 we don't want to do is create some sort of
3 weird adverse incident. Because some people
4 like to hover around 70. I mean they do and
5 God bless them, it is a little uncomfortable
6 but I can understand. I mean there are times
7 when I want to keep it lower than others as
8 well. And I think you need to give some
9 degree of leeway to people who are more
10 comfortable at a lower level than at a higher
11 level. I mean some people prefer to hover
12 around 120 and some people are like just
13 anything that isn't insane.

14 So, I mean it is pretty easy to go
15 from 80 to 65. I mean, at 65 you are going to
16 do something about it but in terms of dinging
17 a hospital because you go from 80 to 65 or 75
18 to 65, that would make me a little nervous
19 about what would the adverse effect be in
20 terms of the way you are treated in the
21 hospital.

22 Because when you are there,

1 inevitably, the people who are giving you or
2 overseeing your insulin are nurses and they
3 can -- I mean my sisters is a nurse. Nurses
4 are brilliant. I love nurses but some of them
5 can take on a patronizing tone where they try
6 to take your pump away or they -- I mean if
7 the guidelines are too strict, then it creates
8 this sort of negative environment for patients
9 in the hospital, especially those of us who
10 are used to controlling our own glucose.

11 So, again, 70 makes me a little
12 nervous, 40 makes me a little nervous. I
13 don't know. I mean it sounds like the three
14 bears, just in terms of finding the one that
15 is just right.

16 But I mean I think we need to
17 think about what does it mean for inpatient
18 experience, especially for those of us who are
19 very neurotic about controlling our blood
20 sugar when we can be, what that is going to
21 mean in terms of patient control.

22 CO-CHAIR ROSENZWEIG: I think that

1 is precisely the issue. I mean I think less
2 than 40 is a good number for monitoring for
3 the purposes of this measure. I am not
4 disagreeing with that at all. But people have
5 defined severe hypoglycemia in a variety of
6 different ways and what was clear from that
7 particular committee was that there was no
8 consensus as to what specific blood glucose
9 defined severe hypoglycemia.

10 Yes?

11 MEMBER BREEN: I would like to
12 comment on that. Because of that, because
13 there is no consistency, I joke it is like a
14 little bit pregnant. You have just got to
15 call something something at some point.

16 The concept of the Whipple's Triad
17 was really used in the outpatient community.
18 Meaning, if you are home and you have a
19 patient who goes down and needs assistance,
20 that definition is really developed for
21 ambulatory patients. So I think on the
22 inpatient side, I am very comfortable calling

1 this severe hypoglycemia because also by
2 definition, they are going to require
3 treatment. Someone with a glucose of 40 is
4 going to get treated by somebody else. So,
5 they fed into that definition of requiring
6 treatment.

7 So, I think we should just call it
8 severe hypoglycemia.

9 CO-CHAIR GOLDEN: You want to make
10 a comment?

11 MEMBER McCOLLISTER-SLIPP: Just
12 again, I mean you get into a question of
13 confusing nomenclature then. Because when it
14 comes to adverse --

15 MEMBER BREEN: But there is no --
16 we are saying the nomenclature is already
17 fuzzy. It is fuzzy nomenclature and I think
18 no one -- I doubt that anyone is going to have
19 an issue on the inpatient side calling a
20 glucose of 40 severe hypoglycemia.

21 CO-CHAIR GOLDEN: I would like to
22 comment that right now we don't have this as

1 a measurement. This is, again, you get into
2 the issue of perfect versus the good. It is
3 a starting point. It generates data. It
4 generates discussion. It generates a whole
5 raft of, if you will, naval gazing at
6 institutions about the issues we are talking
7 about where people start talking about what
8 you are concerned with.

9 I don't think we are going to
10 solve this today but it is a place to start.
11 And so, I am comfortable with this as a valid
12 place to start, so, as opposed to sending
13 back.

14 Yes, Ingrid?

15 MEMBER DUVA: I was just going to
16 ask Lindsey to explain again the adverse, what
17 you talked about the adverse event. And so
18 can you explain that again? Because then Bill
19 defined adverse event as associated with
20 injury but I thought you were using a looser
21 term.

22 MS. TIGHE: This is related to the

1 NQF serious reportable events, which are not
2 measures but actually reportable events by the
3 states.

4 What I was saying was that the
5 trigger for reporting the hypoglycemia event
6 is patient injury or death, essentially. So,
7 it is that harm factor.

8 MEMBER McCOLLISTER-SLIPP: And
9 that is what it is for the FDA AERS data, too,
10 which is why it is kind of a joke. Because
11 you can have the same event happen if like it
12 is a pump failure or something like that while
13 you are awake and you catch it at 30 and you
14 are not unconscious but if it happens at
15 night, you become unconscious.

16 I don't want to confuse the
17 nomenclature by calling something -- I mean I
18 have had lots of 20s before where I was
19 completely conscious and nobody had any idea.
20 I mean I felt horrible and my brain hurt but
21 other than that, that would not, by FDA -- I
22 mean we are not talking about FDA here -- by

1 FDA standards of that term, it would not be
2 considered a severe hypo, even though on
3 somebody else, they might have been
4 unconscious and could have had a car accident.

5 CO-CHAIR ROSENZWEIG: Sue.

6 MEMBER KIRKMAN: So I think I
7 heard the developer say that they are
8 comfortable changing it to severe hypo and
9 that sounds like that is that kind of minor
10 change that we could go with.

11 So, can we sort of move on? Is
12 anybody that uncomfortable?

13 CO-CHAIR ROSENZWEIG: I'm not
14 pressing this point. I don't think it is --

15 MEMBER KIRKMAN: Okay. So I mean
16 is the group consensus changing this and
17 calling it severe hypo is okay for this
18 measure?

19 DR. PACE: Is there anyone who has
20 an objection to that?

21 CO-CHAIR ROSENZWEIG: Okay.

22 DR. PACE: We are talking about

1 less than 40.

2 CO-CHAIR ROSENZWEIG: Less than
3 40.

4 DR. PACE: We are only talking
5 about less than 40.

6 CO-CHAIR ROSENZWEIG: Okay. So
7 perhaps we can vote at this point.

8 MS. BAL: Voting is open.

9 (Pause.)

10 MS. BAL: Okay, we have high ten;
11 moderate eight.

12 CO-CHAIR ROSENZWEIG: Feasibility.

13 DR. PACE: So, maybe one way to
14 think about this, and we have already talked
15 about feasibility of the other measure is are
16 there any unique issues with this one from the
17 other one, since they are both eMeasures that
18 would be something that needs to be
19 considered?

20 CO-CHAIR ROSENZWEIG: You know the
21 only unique issue that might be is that you
22 have to collect data on what the patient was

1 taking, what medications the patient was
2 taking for the previous 12 and 24 hours in
3 relationship to the hypoglycemia.

4 I don't see any major problems
5 with doing that but that is a different data
6 collection than for the hyperglycemia.

7 DR. PACE: And the measure
8 developer also did a feasibility assessment
9 for this measure. So, those would be
10 additional data items. And I assume, Kyle, no
11 problem with getting the medication and timing
12 medication in your feasibility assessment?

13 MR. CAMPBELL: Right, that is
14 correct. This measure scored very similar to
15 the hyperglycemia with an overall average
16 score on our feasibility score card of 2.89.

17 CO-CHAIR ROSENZWEIG: Okay, any
18 other comments?

19 MR. CAMPBELL: And I will point
20 out that there are actually fewer data
21 elements here because we are not looking at
22 potential stratification across units. And so

1 in this case, we don't have to calculate that
2 data element.

3 CO-CHAIR ROSENZWEIG: Any other
4 comments? Okay, let's vote on feasibility.

5 MS. BAL: Voting is open.

6 (Pause.)

7 MS. BAL: Okay, we have high 15;
8 moderate four.

9 CO-CHAIR ROSENZWEIG: Usability
10 and use. Any comments by the reviewer?

11 MEMBER LEDDY: Well, the measure
12 is under consideration for CMS hospital
13 quality reporting program and meaningful use
14 Stage III. No time lines were provided. I
15 would just encourage them to get on with it.
16 We really need it.

17 (Laughter.)

18 CO-CHAIR ROSENZWEIG: Any other
19 comments? Okay.

20

21 MS. BAL: Voting is open.

22 (Pause.)

1 MS. BAL: Okay, high 16; moderate
2 two; insufficient one.

3 CO-CHAIR ROSENZWEIG: All right,
4 so now we are going to vote on the overall
5 measure. Any other comments before we vote?

6 DR. PACE: And I would say just to
7 clarify your recommendation of calling this
8 severe and removing the optional, which the
9 developer agreed to, would be what you are
10 voting on.

11 MS. BAL: Voting is open.

12 (Pause.)

13 MS. BAL: Okay, yes, 19.

14 CO-CHAIR ROSENZWEIG: Okay, very
15 good. Thank you.

16 CO-CHAIR GOLDEN: I have a
17 question. At some point we do public
18 comments. Do we do that now, do it later?

19 MS. BAL: Right before lunch.

20 CO-CHAIR GOLDEN: Right before
21 lunch. So, we would move on to -- I got the
22 wrong day -- so, if it is 11:30, it must be

1 statins. So, Bob, I think it is yours. Is
2 that right? Okay.

3 Do we have some folks from CMS who
4 want to talk to us about the adherence
5 measures?

6 MR. CAMPBELL: Sure, this is Kyle
7 Campbell again from FMQAI.

8 So, the next three measures
9 submitted for your consideration focus on
10 adherence for patients with diabetes. They
11 were originally endorsed in 2011 as a single
12 measure, with some measures for the three drug
13 classes included, which are statins, ACEI/ARBs
14 and oral diabetes agents.

15 Recently, NQF recommended to us
16 that the measures are separated but proposed
17 that they remain a pair to keep the reporting
18 and the measures linked. The measures here
19 are different. They are based on
20 administrative claims data, not electronic
21 health record data, the previous measures we
22 have discussed. And as directed by NQF during

1 the original endorsement period, we worked
2 very closely with the pharmacy quality
3 alliance to establish a standard methodology
4 for NQF-endorsed medication adherence
5 measures.

6 And the methodology selected,
7 based on extensive testing to establish
8 validity was the proportion of data covered.
9 Therefore, these measures use the proportion
10 of data to cover methodology and are
11 harmonized with the majority of NQF-endorsed
12 adherence measures, including all those that
13 are developed for CMS.

14 In terms of evidence, it is
15 important to note that the underlying RCTs
16 used to establish the efficacy of these drugs
17 and linking them to improved patient outcomes
18 are relevant and all those studies have
19 protocols to ensure medication adherence.

20 Regarding the specific selection
21 of the threshold of 80 percent, the majority
22 of studies that link outcomes to adherence do

1 use this cut point of 80 percent. And once
2 again, this was a decision that was harmonized
3 across chronic medications adherence measures,
4 in the NQF portfolio.

5 At the direction of the workgroup,
6 we did provide -- we provided supplement to
7 the original evidence form with additional
8 studies. And in each case, there is a clear
9 link between adherence and improved patient
10 outcome.

11 I think it is also important to
12 note that the denominator for these measures
13 requires at least two prescriptions, which
14 signifies the physician's intent to prescribe
15 and continue the medication and that the
16 adherence is measured across the drug class.

17 Finally, as clinical practice
18 shifts towards individualized patient goals,
19 rather than standard thresholds across all
20 patients, I think adherence measures are an
21 important tool to assist clinicians in
22 engaging those patients in the management of

1 their care. Without measures like this, it is
2 very difficult for physicians to determine
3 which patients have filled prescriptions for
4 medications for which they have been
5 prescribed.

6 And with that, I thank you again
7 for your consideration of this measure. We
8 look forward to any questions you have.

9 MEMBER BAILEY: It sounds like we
10 have a couple -- how shall we proceed? Answer
11 the questions?

12 CO-CHAIR GOLDEN: Well we have a
13 number of -- there is lots of questions we
14 could be asking. I think that we will do them
15 sequentially. So, why don't we start with the
16 evidence and just do it sequentially? And the
17 developers will be there.

18 Because otherwise, I think we
19 could end up talking about all sorts of things
20 that would get into validity and accuracy and
21 all sorts of things. So, let's just do it
22 sequentially and move forward. So, Bob?

1 MEMBER BAILEY: So, just to
2 confirm, this measure is adherence to statins
3 for individuals for diabetes and this is a
4 process measure using administrative claims.
5 And the goal here is to measure adherence to
6 statins.

7 CO-CHAIR GOLDEN: Can you move
8 your mike a little closer?

9 MEMBER BAILEY: So the goal here
10 is to measure adherence to statins using
11 proportionate days covered, which Kyle had
12 already mentioned is now the preferred and
13 harmonized measure of adherence for multiple
14 drug classes.

15 And so the numerator here is
16 individuals in the denominator with at least
17 two prescriptions of statins with a proportion
18 of days covered of greater than 0.8. And the
19 denominator is patients with diabetes with at
20 least two prescriptions of statins during the
21 measurement period for 12 consecutive months.
22 And so the idea here is to get to patients

1 that are prescribed statins with the intent of
2 continued therapy.

3 The exclusions are looking at ways
4 to get a relatively clean population of
5 patients with diabetes, eliminating patients
6 with polycystic ovary disease and steroid-
7 induced diabetes.

8 So when we look at the evidence,
9 first of all three clinical guidelines are
10 cited. Specifically, the American Diabetes
11 Association, ACE, and the American College of
12 Cardiology. And they specifically mention the
13 role of statins in terms of reducing
14 cardiovascular risk in this patient
15 population. They don't necessarily directly
16 link adherence but there is a tangible link in
17 terms of adherence to statins and the
18 reduction of cardiovascular risk in this
19 patient population.

20 They also cite several meta-
21 analyses again that point to the efficacy of
22 the reduction of cardiovascular risk in

1 patients with diabetes that are taking
2 statins. And then they cite several studies
3 that talk about the link of adherence and the
4 reduction in outcomes.

5 There were some additional studies
6 that were identified by some of the workgroup
7 members that suggested that there was
8 additional evidence creating that link between
9 adherence to statins, not necessarily
10 completely in the diabetic population but with
11 a significant proportion of the population
12 being diabetic. So again, there is a tangible
13 link in terms of adherence to statins and a
14 reduction.

15 So based on the algorithm in the
16 discussion, we came out with a recommendation
17 that this was moderate evidence to support
18 this measure.

19 CO-CHAIR GOLDEN: I have a
20 question, again, for the developer. And
21 again, I don't know whether this is evidence
22 or what have you.

1 You have the evidence about the
2 value of continuation of therapy. If this
3 measure is for accountability, who is
4 accountable and is there evidence about is it
5 a patient function, is it a provider function,
6 is it population specific? I mean, you can
7 put that in a number of categories. And I was
8 just curious if the developer used this as an
9 accountability measure. And if so, is there
10 evidence to support who was accountable?

11 MR. CAMPBELL: So we have looked
12 at that and we feel that this measure is a
13 shared accountability. So, it would be shared
14 between the patient, the clinician, and then
15 larger organizations, such as the Accountable
16 Care Organizations and plan level.

17 We do consider this might be, in
18 terms of setting, be considered for the
19 accountable care organization model. They
20 would have responsibility for the overall care
21 of the patient. But we do have the measure
22 specified across plans, Accountable Care

1 Organizations, and large physician groups.

2 CO-CHAIR GOLDEN: So that would be
3 helpful. That would put something into
4 usability or something later, or something
5 along those lines.

6 Okay, Jamie?

7 CO-CHAIR ROSENZWEIG: Yes, I have
8 a question. It is my understanding that the
9 ADA guidelines for statins include patients
10 from 40 years or older and with an option for
11 patients lower than that, if their LDL
12 cholesterol is less than 100.

13 So why did you pick 18 years and
14 older as an absolute for all of the patients?

15 MR. CAMPBELL: Again, in mind with
16 the denominator population already signifying
17 the physician's intent to prescribe the
18 medication. And one of the reasons we select
19 two prescriptions is in case patients had
20 tried a medication and failed it or had some
21 sort of adverse reaction, we take that second
22 refill when we look at the data, the intent to

1 prescribe over a longer period of time.

2 And so for that reason, we felt
3 that it was reasonable to consider including
4 all adult patients for which the physician had
5 made a decision that that patient should be on
6 statins.

7 CO-CHAIR ROSENZWEIG: Well,
8 suppose you have a patient who is 24 years of
9 age and has a very high HDL cholesterol. Why
10 should that patient necessarily be put on a
11 statin?

12 CO-CHAIR GOLDEN: I think that the
13 measure though is not prescribing it. It is
14 if you are on it, you continue it.

15 MEMBER BAILEY: Right. So, it is
16 a requirement of two prescriptions within a
17 12-month period. So, the clinician has
18 already identified that patient warrants
19 therapy and is looking at whether there is
20 adherence to therapy as prescribed.

21 CO-CHAIR ROSENZWEIG: Oh, okay.
22 Thank you very much.

1 CO-CHAIR GOLDEN: Are you okay?

2 You are okay down there. Sue.

3 MEMBER KIRKMAN: So, I sort of
4 thought of it from the other perspective
5 because I think it is clearly looking at
6 adherence when the physician has decided that
7 the patient needed to be on a statin. But it
8 doesn't really address the problem of the
9 guidelines are really that high-risk people
10 should be on statins, regardless of their LDL.
11 But there is still this perception out there
12 that if a diabetic patient who smokes and has
13 hypertension and is 55 has an LDL of 98, they
14 don't need a statin.

15 So, this isn't really going to get
16 at appropriate prescribing of the statin. It
17 is really just an adherence measure. Is that
18 correct? Because I think that is a little
19 unfortunate.

20 MR. CAMPBELL: That's correct.

21 MEMBER BAILEY: I guess this came
22 up in discussion yesterday as well in terms of

1 looking at the actually laboratory value and
2 I think we determined from NCQA that the
3 sample size is about 411 patients per plan.
4 So, you are looking at small portion of the
5 population in terms of having the laboratory
6 value. Here, you are depending on
7 administrative claims, rather than laboratory
8 values. So, you have a much larger
9 population, which you can draw assumption
10 terms of performance and intervene.

11 MEMBER KIRKMAN: But it really is
12 just measuring one specific thing, which is
13 adherence, not that the patient should be on
14 a statin.

15 CO-CHAIR GOLDEN: And I think that
16 would get into importance or impact.

17 CO-CHAIR ROSENZWEIG: But suppose
18 a person had been prescribed a statin by one
19 physician and then the second physician
20 thought it was not necessary, would that be
21 counted? Would that situation be excluded in
22 this measurement?

1 CO-CHAIR GOLDEN: That gets into
2 validity. We will get there, too. Okay, good
3 point.

4 We will ask the developer now.
5 What happens if you stop therapy? How do you
6 count that if somebody has an adverse reaction
7 or another doctor decides this is not an
8 appropriate therapy?

9 MR. CAMPBELL: And so again, that
10 would be captured by the requirement for two
11 prescriptions. But if the therapy were
12 discontinued, let's say like six or eight
13 months into therapy, that would be a scenario
14 that we would not be able to ascertain from
15 the administrative claims data. And for that
16 reason, they would be picked up in the
17 following measurement year. They would no
18 longer be in the measure in the following
19 measurement year.

20 CO-CHAIR GOLDEN: Go ahead.

21 MEMBER McCOLLISTER-SLIPP: Okay,
22 so I will go. So, does that mean that if

1 somebody starts on a statin and they take it
2 for a couple of months and they start having
3 myalgia as a result of that and they decide
4 they don't want to take it, does that mean --
5 and you know they may or may not talk about
6 that with their physician. So, the claims
7 data is based on the physician writing a
8 prescription or is it based on the filling of
9 the actual --

10 CO-CHAIR GOLDEN: It is on the
11 filling. So that patient would actually fall
12 out as a numerator failure.

13 MEMBER McCOLLISTER-SLIPP: Okay,
14 so that would be a failure, even though the
15 patient had an adverse reaction in their
16 perception that they felt like was enough to
17 make them go off.

18 CO-CHAIR GOLDEN: As this measure
19 is specified. But we will get to that, yes.

20 MEMBER DUDL: The comment by Sue
21 is very pertinent. And to set all of these
22 three things in perspective, it does require

1 two things. It requires adherence is very
2 important. If you are taking a medication
3 because the physician, by criteria and by
4 knowledge, knows it is going to save your
5 life, decrease heart attacks and strokes, then
6 being 20 percent more adherent is like adding
7 a drug that is 20 percent more effective --
8 another 20 percent. So, it is very important
9 but it is not sufficient.

10 And of course with the new ACC
11 guidelines, everybody has to rewrite what the
12 criteria will be. And at that point, of
13 course, they have said at 7.5 percent CVD risk
14 type of thing but that will come within a
15 year.

16 But this needs to go ahead because
17 it can be measured right now and it will be
18 the one important thing that we could continue
19 while we are moving from an LDL of some number
20 to a risk of some number.

21 CO-CHAIR GOLDEN: So I believe the
22 issue before is if you are on a statin, is

1 adherence important and is there evidence to
2 support that. I think we will limit it to
3 that.

4 Are we ready to vote?

5 MS. BAL: Voting is open.

6 (Pause.)

7 MS. BAL: Okay, we have high ten;
8 moderate eight; low one.

9 CO-CHAIR GOLDEN: So now you get
10 to gaps, an opportunity for improvement.

11 So, are there variations by race,
12 age, socioeconomics, et cetera in adherence?

13 MEMBER BAILEY: So, the evidence
14 that was presented by the developer suggests
15 that there is, indeed, a gap and it is based
16 on Medicare data from ten states, using 72
17 prescription drug plans and slightly more than
18 7,000 physician groups for 2012. And first of
19 all, the baseline performance at the state
20 level is about 72 percent, the drug plan about
21 72 percent, and physician groups about 70
22 percent.

1 Then when you look at the
2 distribution or the difference between the
3 10th percentile and the 90th percentile, there
4 is about a 15 percent difference, suggesting
5 that there is indeed a performance gap there.

6 CO-CHAIR GOLDEN: Okay, anybody
7 want to challenge, question, or go into
8 details on this one? I think we may be ready
9 to vote, unless you had something. No. You
10 have an old card. Okay.

11 I think we can vote on this one.

12 MS. BAL: Voting is open.

13 (Pause.)

14 MS. BAL: Okay, we have high 15;
15 moderate four.

16 CO-CHAIR GOLDEN: So, priority.
17 And I guess the question before us, it is an
18 interesting question, how you define what we
19 are going to vote on here is adherence a
20 priority item for impact in the management of
21 this issue. Is that how to frame it?

22 MEMBER BAILEY: I guess I would

1 frame it in a slightly different perspective
2 and it is based on the evidence.

3 So, given the high burden of
4 diabetes in the U.S. population and the high
5 burden of cardiovascular disease and the very
6 tangible link between adherence to statins and
7 the reduction in cardiovascular events in this
8 patient population, I would advocate that this
9 is a high priority condition.

10 CO-CHAIR GOLDEN: Okay.

11 MEMBER TAYLOR: I don't think
12 there is any question that you are not going
13 to get the benefit of statins if you don't
14 take them. There is also no question that if
15 you have had coronary disease, you benefit
16 from being on a statin.

17 People with diabetes with
18 complications have been shown in cards to
19 benefit from being on a statin. People with
20 diabetes and that all had LLT, failed to show
21 any benefit in primary prevention.

22 And the American Diabetes

1 Association -- I just went online to look up,
2 you guys probably wrote this stuff so you can
3 correct me, but the American Diabetes
4 Association says in response to the new
5 American Heart Association, American College
6 of Cardiology recommendations, which are mired
7 in the difficulty of the inaccurate risk
8 calculator that they put out, that American
9 Diabetes Association is reconsidering their
10 position and especially is not taking a
11 position on whether statins are indicated for
12 all people in primary prevention between the
13 ages of 40 and 75.

14 So for us to come out and say it
15 is important to take your statin, embedded in
16 that might be taking statins for people where
17 at least some of the experts are telling us
18 they are not sure that statins are needed.

19 CO-CHAIR GOLDEN: Sue.

20 MEMBER KIRKMAN: So, right before
21 the standards of care went to press, that is
22 when the AHA/ACC formerly NIH guidelines came

1 out. And so I think that statement was just
2 put in there to say just because people would
3 say well, why didn't you reference that or
4 whatever. I don't think it is true that the
5 ADA is reconsidering its position because
6 actually the ADA position for quite a number
7 of years has been very similar, which is most
8 high-risk people with diabetes should be on a
9 statin, regardless of what their LDL is.

10 So when the AHA guidelines came
11 out, to me it wasn't really any different for
12 people with diabetes. So, the recommendation
13 of the ADA is if you are over 40 and have one
14 other cardiovascular risk factor, which the
15 vast majority of people with diabetes,
16 particularly Type 2 diabetes have, you should
17 be on a statin, regardless of your LDL.

18 So I don't think -- and the
19 primary prevention data is fairly strong, if
20 you look at the meta-analyses of all of the
21 statin trials that were either in people with
22 diabetes or looked at diabetes as a subset,

1 there is pretty strong data for cardiovascular
2 risk reduction. I think it is not as strong
3 for mortality reduction as the secondary
4 prevention, if you have already had a heart
5 attack, but it is pretty strong for primary
6 prevention in high risk diabetics. So, I
7 don't think it is the case that there is
8 really not good evidence or that this is a
9 change from what ADA has recommended.

10 MEMBER TAYLOR: Could I read what
11 is on the ADA website? It is just one
12 sentence. It says -- this is about the new
13 guidelines from the American College of
14 Cardiology, American Heart Association, that
15 had been the NHLBI. The Association will
16 consider whether moderate dose statins should
17 be used for the primary prevention in all
18 patients 40 to 75 years of age with diabetes,
19 regardless of baseline lipid levels or the
20 presence of other cardio risk factors, notably
21 the revised guidelines and so on. And they go
22 on to talk about --

1 CO-CHAIR GOLDEN: And maybe the
2 key word there is moderate because they might
3 change it to high dose.

4 MEMBER KIRKMAN: Right but the
5 current recommendations are very consistent.
6 It is just I don't think it uses the term
7 moderate. And I think the person, it was a
8 staff person, that wrote that little
9 paragraph, I don't think she meant that AHA
10 guidelines are really different and we are
11 going to reconsider the position.

12 So, I think it is pretty
13 consistent, except that the ADA guidelines did
14 not say moderate dose statin.

15 MEMBER McCOLLISTER-SLIPP: Yes,
16 and I think it is really helpful to have Sue
17 giving us the context of how that got in
18 there. It one thing to read it without a
19 context but I think within this context, it
20 makes perfect sense.

21 CO-CHAIR GOLDEN: Are we ready to
22 vote?

1 MEMBER KIRKMAN: I personally,
2 wouldn't have put it in there, even.

3 CO-CHAIR GOLDEN: Are we ready to
4 vote? Yes.

5
6 MS. BAL: Voting is open.

7 (Pause.)

8 MS. BAL: Okay, we have high 14;
9 moderate four; low one.

10 CO-CHAIR GOLDEN: Okay, now we get
11 into the fun stuff. So now we get into
12 reliability of the specifications and
13 reliability testing.

14 So, let's make sure we are clear.
15 This is going to be if the data are collected,
16 do you actually collect it accurately as
17 opposed to the validity, which we will get
18 into some of the other issues as to what the
19 data means. Correct?

20 So, Bob, did you want to -- is
21 that a good context?

22 MEMBER BAILEY: Sure. And so

1 empiric reliability testing was performed by
2 the developer. And the reliability testing
3 was done at three different levels, the state
4 level, the prescription -- actually four
5 levels. The prescription drug plan level, the
6 physician group level, and the accountable
7 care organization level. And the minimum
8 threshold for reliability was met for all of
9 these different groups of analysis.

10 CO-CHAIR GOLDEN: So when
11 collected, it was collected accurately.

12 Comments or questions? Shall we
13 vote?

14 MS. BAL: Voting is open.

15 CO-CHAIR GOLDEN: We have one
16 listing.

17 MS. BAL: Okay, thank you.

18 (Pause.)

19 MS. BAL: Okay, the vote is high
20 14; moderate four.

21 CO-CHAIR GOLDEN: So now we get to
22 validity.

1 MEMBER BAILEY: So the validity
2 testing was done by a systematic assessment of
3 face validity, where they convene a technical
4 expert panel. And 77 or 78 percent of the
5 panel either agreed or strongly agreed with
6 the validity of the measures.

7 CO-CHAIR GOLDEN: Okay. So, let
8 me just take a look here. All right, Bill, we
9 will start with you and we can talk from
10 there.

11 MEMBER CURRY: The one area that I
12 have a question about is missing data. And
13 there are patients who I could write a
14 prescription to start a statin and they could
15 get a fill of that or a couple fills of that
16 at their local pharmacy and then they go off
17 to the VA to get their care. They could buy
18 it as a low-cost option at a large box store.
19 They could go to the grocery store that is
20 offering atorvastatin for free to get people
21 in the door. And now we are not going to
22 capture that they are going to continue to

1 have these prescriptions being filled. And so
2 they might have initial two prescriptions but
3 the coverage time might be less --

4 CO-CHAIR GOLDEN: Let me stop you
5 there for a second because that is a problem
6 with reliability. We may have to reconsider
7 reliability. In fact, I am going to consider
8 that we do so because what you have just
9 brought up is that if people pay cash, there
10 is no claim.

11 MEMBER BAILEY: Good point. And
12 if I could just raise here that the developer
13 did present the information addressing two
14 major aspects that were threats to validity
15 and the reliability, specifically the cash
16 prescriptions and that it was minimal impact
17 on the data in the analysis. And they also
18 looked at missing availability of the day's
19 supply. So, two of the major threats.

20 They did not address the one,
21 specifically the patient going to the VA and
22 getting a prescription for a portion of the

1 time as well.

2 CO-CHAIR GOLDEN: And the other
3 question I had, so I think I talked about this
4 earlier. So, is it the total days' supply or
5 the total number of pills that is in the
6 measure?

7 I am asking for the developer,
8 when you do the collection, is it --

9 MR. CAMPBELL: Yes, so we looked
10 at both. We looked at the first prescription
11 within the measurement period to the last
12 prescription in the measurement period plus
13 the days supplied. Then it looks at the
14 number of days that are actually covered by
15 the medication, if you added up all those days
16 supplied across all the prescriptions.

17 CO-CHAIR GOLDEN: So my question
18 for you is if you prescribe something every
19 other day, would that fail or would that be
20 acceptable?

21 MR. CAMPBELL: It would be
22 acceptable, as long as the every other day was

1 indicated, in terms of the days supplied. And
2 in most cases, I believe that would be
3 correct, unless the patient were prescribed it
4 one way and the measure was still -- and it
5 was still one way versus what they were
6 actually told to by the physician. But if
7 they are following the instruction, it should
8 be captured.

9 CO-CHAIR GOLDEN: Jessie, do you
10 want to talk about reliability or talk about
11 validity?

12 MEMBER SULLIVAN: Well, this is
13 reliability.

14 CO-CHAIR GOLDEN: Okay.

15 MEMBER SULLIVAN: So I am
16 concerned about the cash and I don't
17 understand, if the developer could explain,
18 how you said that wasn't a problem. How did
19 you determine --

20 MEMBER BAILEY: I should just
21 clarify, too, that that falls under the
22 threats to validity section. So, this is the

1 appropriate --

2 MEMBER SULLIVAN: Oh, this is the
3 validity.

4 Okay, so I have several questions
5 about validity. One is the age. It seems to
6 me that we are saying that it is a good thing
7 that we have this measure. So, I don't
8 understand why it should start at 18 instead
9 of at 40, from what I have been hearing people
10 say. So, that concerns me.

11 I am concerned that the level of
12 accountability for this measure is at the
13 physician level but, as I understand the
14 measure, it doesn't take into account new
15 starts. So, if you start someone on the
16 medication, a new start in November, you are
17 going to get dinged because they wouldn't have
18 been on it for 80 percent of the measurement
19 year. And if they have an adverse reaction,
20 then you stop it because they had an adverse
21 reaction. That is going to count as a ding.

22 And if you are measuring at the

1 whole population level of the whole country,
2 that doesn't matter because it is trivial.
3 But if you are measuring in one practitioner's
4 practice, it can matter.

5 And then I am concerned about
6 patients with no pharmacy coverage who again,
7 if you are looking at the effect for patients,
8 it doesn't matter. Then we know that patients
9 don't have pharmacy coverage. But if you are
10 holding the physician accountable, that is
11 going to be an issue.

12 And then I particularly don't
13 understand about the missing data because I
14 know that Walmart doesn't contribute to
15 Surescripts. So, you are not going to get
16 fill data -- I mean if you go to CVS and pay
17 cash, it is still going to be in the
18 Surescripts data. But if you go to Walmart
19 and you pay cash, it is not. Right now that
20 is the case. So my patients at the community
21 health centers they -- those are all, I think,
22 threats to validity.

1 CO-CHAIR GOLDEN: We are having
2 some background noise on the phone, too. So,
3 please be careful with paper and what have
4 you.

5 So, the developers, can you
6 respond to some of those issues?

7 MR. CAMPBELL: Yes, absolutely.
8 So with regard to the age issue, I think again
9 it is important to note that in the
10 denominator the physician has prescribed the
11 medication and we do have evidence of a second
12 fill. And so for that reason, we would
13 suggest that this would be applicable to all
14 adult-aged patients greater than 18.

15 In terms of the level of
16 accountability, it is not at the individual
17 physician level but at the physician group
18 level. And in terms of new starts, if a
19 patient were, let's say they started in
20 October and they had fills in October,
21 November, and December, if they were adherent,
22 you would capture that because the follow-up

1 starts with the index event, which is their
2 first prescription. So, you will not be
3 dinged in the measure if the patient doesn't
4 start the medication until late.

5 In terms of the adverse reactions,
6 so again I think it was brought up the
7 potential for side effects with statins being
8 myalgia. While we do know that occurs, we
9 also know that the goal would be to try and
10 keep patients on statins. And so the
11 switching of patient from one statin to
12 another also is captured. So, you get credit
13 for if you start on let's say Lipitor and you
14 switch to Lovastatin, as long as the patient
15 is continually adherent, those count in the
16 total proportion of days covered and the
17 prescriptions are adjusted accordingly,
18 according to the algorithm.

19 And then as far as the cash
20 prescriptions go, we have done a limited
21 sensitivity analysis with regard to this,
22 where we tried to simulate what would happen

1 if patients didn't have claims for medications
2 on the discount formulary, what would happen
3 to measure rates. And we didn't see any
4 differences but we didn't have the ability to
5 test it with external data. However, I will
6 point out again that you are comparing
7 yourself to other providers' mean scores. And
8 so, therefore, if there are any issues with
9 cash prescriptions, you know those will be
10 similar across the board.

11 And as mentioned, we do know that
12 there is an effort to fill some of the gap
13 with the cash prescription information. But
14 it is not 100 percent and it won't be -- you
15 can probably never expect that it will be 100
16 percent perfect in terms of a measure but I
17 think it is the best we have and it certainly,
18 given the performance gap, ample room for
19 improvement that is not related to the use of
20 cash prescription.

21 MR. MATTKE: And one more comment,
22 Soeren Mattke from RAND, for the developers.

1 In order for the cash
2 prescriptions to have a big effect, you would
3 have to assume that a patient goes back and
4 forth between a claims recorded prescription
5 and a cash prescription because if they only
6 went to Walmart and got the four lovastatin,
7 we wouldn't pick them up in the denominators.
8 So we would really only pick them up if they
9 got two prescriptions through their benefit
10 and then rest of them through Walmart and then
11 potentially went back to the pharmacy in the
12 subsequent years.

13 So, we don't expect this to be a
14 large impact given how patients usually
15 behave, which is they fill all the
16 prescriptions in the same place and
17 repeatedly.

18 MEMBER SULLIVAN: I just want to
19 say that that is not true in the Medicaid
20 population.

21 So, people gain coverage, lose
22 coverage, they stay a patient of the doctor,

1 they go in and out of coverage on a plan. And
2 those patients are not randomly distributed
3 among doctors in the U.S. They are definitely
4 non-randomly distributed.

5 MR. MATTKE: No, but those would
6 fall, if they lose coverage, they fall out of
7 our denominator file.

8 MR. CAMPBELL: Yes, that is
9 correct. Just to clarify that point, this
10 measure requires 11 of 12 months continuous
11 eligibility. So, they have to be continuously
12 eligible for Part D, Medicare Part D, for them
13 to be considered in the denominator.

14 DR. PACE: How could it go to age
15 18 if it is only people on Medicare?

16 MR. CAMPBELL: Well there are dual
17 eligibles with Medicare. So, patients that
18 are not part of Medicare that are aged in.
19 So, this would include those dual eligible
20 Medicare/Medicaid patients.

21 CO-CHAIR GOLDEN: So, let's make
22 it clear. This is a Medicare-only measure?

1 MR. CAMPBELL: It would include
2 Medicare and Medicaid for Medicaid patients
3 that are dual eligible for both.

4 DR. PACE: Those patients enrolled
5 in Medicare Part D is what you said. Correct?

6 MR. CAMPBELL: That is correct.
7 Those patients that have continuous enrollment
8 in Part D that would have no more than a one-
9 month gap in coverage.

10 CO-CHAIR ROSENZWEIG: I just would
11 have an issue again with the specifications.
12 First of all, if you have patients, and as far
13 as I understand it if you have dual eligibles,
14 you will have patients who are under Medicare
15 who are younger than age 40, first of all the
16 measure indicates only a denominator exclusion
17 for gestational diabetes but does not specify
18 patients with preexisting diabetes who become
19 pregnant, which I think needs to be changed or
20 needs to be added.

21 Clearly, a woman who has
22 preexisting diabetes should not be on statins

1 if she becomes pregnant. Obviously, if they
2 are taken off of statins for pregnancy, it
3 would be considered to be nonadherence by the
4 way this measure is set up.

5 So, I think that is a potential
6 problem. The second problem is in the under
7 age 40 population, half of the patients that
8 you are dealing with in that population are
9 patients who are women. And I think this
10 measure might inadvertently increase the risk
11 of women with diabetes being on statins during
12 pregnancy. And I think that is a potential
13 problem with the measure as it is currently
14 constructed.

15 So, I would actually urge you to
16 actually move the age up to 40 for that basis.

17 CO-CHAIR GOLDEN: I guess the last
18 issue would be something with usability and
19 adverse consequences.

20 CO-CHAIR ROSENZWEIG: Correct but
21 we are talking about specifications here.

22 MEMBER BAILEY: And the other

1 consideration here is that the clinician and
2 the patient have already had the discussion
3 that the therapy is appropriate and therapy
4 has been initiated and we are looking at
5 continuation, not whether it is initiated.

6 DR. PACE: You have to keep in
7 mind the denominator are people that the
8 physician has already prescribed this, based
9 on guidelines, et cetera, in discussion with
10 the patient.

11 CO-CHAIR ROSENZWEIG: Correct but
12 the patient might become pregnant during the
13 period of time afterwards.

14 CO-CHAIR GOLDEN: Do we have other
15 comments or questions or are people almost
16 ready to vote?

17 MR. CAMPBELL: This is Kyle
18 Campbell again from FMQAI. Just a comment to
19 the pregnancy issue. This was something that
20 we did look into as part of the testing and
21 just the part is part of our ten-state data
22 sample for this population, the occurrence of

1 pregnancy, at least according to the
2 administrative claims data, was exceedingly
3 rare. And so for that reason, we did not
4 develop an exclusion specifically for
5 pregnancy.

6 CO-CHAIR GOLDEN: Jessie?

7 MEMBER SULLIVAN: Well, I guess I
8 did see the Part D thing, but it hadn't
9 clicked in my mind. And I think Helen is
10 right, someone who is dual eligible isn't
11 going to be on Part D. They are going to have
12 their drug coverage through Medicaid. So,
13 really we are just talking about the Medicare
14 population but it doesn't really say that.

15 And I guess my concern is that if
16 this gets endorsed by the NQF and it is
17 hanging out there, even though in the specs it
18 is intended just for the Medicare population,
19 it doesn't read that way. And I think that
20 there are risks in this, in the younger age
21 group that we have identified. I think it is
22 probably a good Medicare measure and I am not

1 sure that it is a good Medicaid measure for
2 young women in their 20s. I think it could do
3 harm.

4 DR. PACE: But the specifications
5 specifically say continuously enrolled in Part
6 D. So, that is part of the specifications.

7 MEMBER SULLIVAN: I know but I
8 think people won't necessarily read that.
9 When I am looking for a measure, if I am
10 thinking I want to do something about
11 adherence to statins and this looks like to me
12 the measure and that is not my population, I
13 might start using this measure. I understand
14 but people don't -- even the NCQA people
15 yesterday, they said we know the measures get
16 used in different ways for different
17 populations. And they do.

18 CO-CHAIR GOLDEN: Sue.

19 MEMBER KIRKMAN: But I don't think
20 this measure is going to push more people onto
21 statins. So, I don't really understand the
22 concern that this is going to make more child-

1 bearing potential women go on to statins. It
2 is really if you have decided that your
3 patient should be on a statin, whether they
4 are taking it or not.

5 So, am I missing something there?

6 MEMBER McDERMOTT: No. I was
7 going to say I think it is the women that
8 become pregnant, they have their two doses and
9 then they become pregnant. Now they are off
10 and they are going to look noncompliant
11 because that is a good thing for them to be
12 off.

13 MEMBER KIRKMAN: But again, I mean
14 --

15 MEMBER McDERMOTT: And they are
16 still continuously --

17 MEMBER KIRKMAN: -- if you talk
18 about the total universe of Medicare Part D
19 patients, that is going to be one in 50,000
20 people. And so, I mean again, you can't make
21 an exclusion for every single thing,
22 especially if it is really rare.

1 CO-CHAIR GOLDEN: So we might want
2 to change the title to adherence to statins
3 for Medicaid individuals with diabetes or
4 Medicaid recipients.

5 MEMBER KIRKMAN: Medicare or
6 Medicaid?

7 CO-CHAIR GOLDEN: Medicare.

8 MEMBER KIRKMAN: But I am
9 concerned that other people may adopt this,
10 other health plans and so forth. But I don't
11 think it is going to make more people go on
12 statins, necessarily. I think it is just
13 going to make people adhere better.

14 CO-CHAIR GOLDEN: I am getting
15 people antsy to vote. So, I am seeing people
16 who want to vote.

17 So, shall we vote? Let's vote.

18 MS. BAL: Voting is open.

19 CO-CHAIR GOLDEN: This will be an
20 interesting vote.

21 (Pause.)

22 MS. BAL: Okay, we have high

1 three; moderate 13; low one; insufficient,
2 two. And that passes.

3 CO-CHAIR GOLDEN: This is -- what
4 is this one here? Composite. Feasibility.

5 MEMBER BAILEY: So feasibility,
6 the data that is required here comes from
7 administrative claims data bases. So, with a
8 few exceptions that we already talked about,
9 specifically cash claims, that this data is
10 routinely generated during the course of care
11 because everyone wants to get paid and there
12 is no significant burden in terms of
13 collecting this information.

14 CO-CHAIR GOLDEN: -- a replay of
15 our last conversation but go ahead.

16 MEMBER TAYLOR: Just a point of
17 clarification. Our process is, if we did want
18 to suggest the name change that said for
19 Medicare-eligible patients or something, so it
20 is prominently displayed because that might
21 change the way some of us vote about these, we
22 ask the developer if they would find that

1 acceptable. Is that the process?

2 CO-CHAIR GOLDEN: That would be
3 fine. Did you have any objections to that,
4 changing the name? I will ask the developers.
5 I mean, it is not a specification change it is
6 just that it is a label.

7 MR. CAMPBELL: We can definitely
8 consider that in consultation with CMS.

9 CO-CHAIR GOLDEN: And CMS is not
10 here?

11 MS. RICKSECKER: This is the CMS
12 GTL for the contract. I would be agreeable to
13 changing the name of the measure to
14 accommodate that and including Medicare-
15 eligible individuals in the title.

16 CO-CHAIR GOLDEN: Great. Thank
17 you.

18 So, we are now feasibility. Any
19 other comments or do we want to vote? Okay.

20 MS. BAL: Voting is open.

21 (Pause.)

22 MS. BAL: Okay, we have high 14;

1 moderate four; low one.

2 CO-CHAIR GOLDEN: Usability and
3 issues of is the measure publicly reported.
4 This is I think where you get into adverse
5 consequences or unintended consequences.

6 So, currently this measure is not
7 in use. The goal is for public reporting of
8 the measure. And we have already talked about
9 some of the concerns about potential
10 unintended consequences but no other ones were
11 identified.

12 MEMBER KIRKMAN: So, I guess
13 somebody brought this up earlier and there was
14 some discussion yesterday, too, but I think if
15 you are talking about clinician reporting,
16 clinician-level reporting, I mean it is just
17 a concern that there is only -- there are
18 things that you can do to increase adherence
19 but Jessie may have a population of patients
20 that are just inherently going to be less
21 adherent than some Beverly Hills private
22 practice person.

1 So, I mean it is -- and again, I
2 think it kind of speaks to the quality of our
3 whole health system more than individual level
4 quality of care -- individual clinician-level
5 quality of care.

6 CO-CHAIR GOLDEN: To follow-up on
7 your comment, we have been going out dealing
8 with total cost of care and episodes of care
9 in Arkansas and I have been doing Town Halls.
10 And the first set of hands that go up will be
11 what about the patients? And what about --
12 they are component to this and why am I being
13 held accountable?

14 And we talked about a number of
15 ways to mitigate that but I can, to follow-up
16 on that, I would say that if we are not
17 careful with this measure and it is reported
18 in a way that clinicians are held accountable,
19 it will result in adverse patient selection
20 because the docs will hate it and they will
21 start making changes. Patients already in my
22 neighborhood do get fired, if you will, for

1 non-adherence and lawyers will tell them get
2 rid of folks for non-adherence.

3 So, if it is framed wrong or if it
4 is, in my community at least, there will be a
5 number of clinicians that will avoid patients.

6 MEMBER DUDL: Low adherence,
7 however, is workable. And if you don't
8 measure it and you don't go after it, it
9 doesn't improve. Low adherence can be helped
10 by looking at everybody that you treat because
11 you are looking at the percentage and finding
12 those that are actually easily moved but
13 didn't come in. It can be worked by learning
14 how to handle patient barriers and there are
15 four or five simple things. And we moved
16 adherence up from 50 percent to 85 percent in
17 three years. If you focus on it, you can do
18 it. I don't think there is that much adverse
19 selection. We did not find that much adverse
20 selection in our group. I'm sorry. We didn't
21 find people leaving. Nobody ever gets booted
22 out.

1 So, I think those are overly
2 worrisome things when you have a really big
3 potential for adhering.

4 MEMBER MAKAROFF: I just want to
5 echo what has been said about the adverse
6 selection. I think like in a place where you
7 have a pharmacy across the street or in the
8 building, it is going to probably incentivize
9 or those plans are going to look better.

10 And like a health center
11 population, Medicaid population, where I see
12 patients it is a bus ride to the pharmacy. My
13 patients are not adherent for a lot of
14 reasons. And a lot of things we do. I have
15 a case manager. I have a social worker. I
16 give them a bus token. But I don't know how
17 that is going to affect our performance as the
18 health center, who is really working hard. I
19 don't know if it is going to capture that
20 quality of care.

21 CO-CHAIR GOLDEN: To follow-up on
22 my comments well, not that you can't fix it,

1 it is a matter of how the measure is used.
2 So, I have seen useful measures used in a
3 punitive way. That is my concern.

4 MEMBER McCOLLISTER-SLIPP: And
5 that is sort of my question maybe for NQF on
6 that front is, I mean how -- I know that we
7 can't really predict how these measures are
8 going to be used. They will be used for some
9 things that we now about but others that we
10 won't.

11 I mean something like this is
12 absolutely something we should shoot for from
13 a compliance perspective, from a health
14 system. But I think this makes perfect sense
15 for like an Accountable Care Organization but
16 for an individual practitioner that is not
17 part of an Accountable Care Organization, that
18 might be slightly different.

19 DR. PACE: So, let's clarify. I
20 think Kyle said it is not for an individual
21 clinician. What is the smallest unit of
22 analysis?

1 MEMBER BAILEY: Physician groups.

2 MR. CAMPBELL: That is correct,
3 physician groups. And it would mostly likely
4 be limited to have a certain patient
5 population size within those groups.

6 MEMBER BAILEY: So a quick
7 question for you, Kyle. Was this first
8 intended use for the physician value-based
9 modifier program where it is physician groups
10 above a certain size?

11 MR. CAMPBELL: CMS hasn't made any
12 decisions with regard to its use at this
13 point. It was submitted in the measures under
14 consideration list at this point for the ACO
15 Shared Savings Program.

16 CO-CHAIR GOLDEN: Yes, actually I
17 think, and correct me if I am wrong, Kyle, but
18 I believe there is an adherence measure in the
19 CPCPI program that you have to -- that is used
20 in determining whether or not you get shared
21 savings.

22 MR. CAMPBELL: I'm not aware of an

1 adherence measure currently in the CMS ACO
2 Shared Savings Program. I can tell you that
3 our other measures are in use. This measure
4 NQF 0543 that looks at the coronary artery
5 disease population and measures adherence to
6 statins and is entirely harmonized with this
7 one is currently in use by the quality
8 resource use reporting program, which provides
9 individualized report to physician concerning
10 their patient population.

11 CO-CHAIR GOLDEN: Yes, I am pretty
12 certain they were all financial implications
13 with some of these measures.

14 Tracy?

15 MEMBER BREEN: I just want to say
16 this always comes down to this risk-benefit
17 ratio and I think there are potential risks of
18 patient dumping that are just going to be out
19 there. But when you look at the benefits, if
20 you don't start measuring something, you can't
21 make changes. And in fact, the places have
22 demonstrated that they can move, potentially,

1 adherence rates and we have already assessed
2 that adherence to these medications results in
3 better outcomes and lives saved. That is the
4 weight but I have the same concerns about the
5 avoidance of challenging patients. Although,
6 again, this measure Medicare-eligible
7 patients. We keep going back to who this is
8 specifically looking at, a slightly different
9 group of patients.

10 MEMBER BAILEY: And if I could
11 just expand upon that, so it is physician
12 groups that will be compared with physician
13 groups, ACOs compared with ACOs. So, you have
14 comparison with comparable groups and so you
15 have an idea of where you are performing with
16 respect to your peers and identify opportunity
17 because we all think we do well at everything
18 by nature of being physicians or healthcare
19 providers. But when you start to understand
20 what you are doing compared to your peers, it
21 incents behavior changes to improve outcomes.

22 MEMBER KIRKMAN: So not to belabor

1 this too much but I agree for quality
2 improvement, this is an incredibly important
3 measure but again, we are talking about public
4 reporting here. And even saying your peers,
5 so I work in an academic clinic at a state
6 university. We take all comers. I can tell
7 you the private practice endocrinologists are
8 very good at knowing that they can get rid of
9 people and that UNC won't refuse anyone.

10 So I just am concerned a little
11 bit about a publicly reported measure where
12 some things are within the physicians or the
13 group's control but a lot may be the patient
14 population. And I guess we will just have to
15 see what happens.

16 MEMBER BAILEY: And to address
17 that concern, it wasn't included in the
18 evidence provided but there was an analysis
19 that was presented at Academy Health a few
20 years ago that looked at whether changes in
21 performance against certain quality measures,
22 and the focus was on diabetes, whether it was

1 patient characteristic. So they controlled
2 for various patient aspects. And then they
3 did it at the physician level as well. And
4 performance actually tracked at the physician
5 level and not at the patient characteristic
6 level, suggesting that there are behavior
7 changes that occur when something is being
8 measured.

9 MS. BAL: Voting is open.

10 (Pause.)

11 MS. BAL: Okay, we have high five;
12 moderate ten; low four. So, it does go
13 through.

14 CO-CHAIR GOLDEN: And a global
15 picture.

16 CO-CHAIR ROSENZWEIG: I just want
17 to make one comment before we vote on this.
18 And that is I don't quite understand why if
19 gestational diabetes is listed as a
20 denominator exclusion, why diabetes and
21 pregnancy can't also be added as a safety
22 factor.

1 It affects the same population and
2 may involve very small numbers of people but
3 I think it is a reasonable thing to suggest
4 that the developers add that one additional
5 exclusion.

6 MR. CAMPBELL: This is Kyle
7 Campbell from FMQAI. Just the genesis of the
8 gestational diabetes was to harmonize the
9 diabetes identification algorithm with NCQA,
10 which has a number of diabetes measures.

11 But if the Steering Committee
12 feels strongly that pregnancy should be added
13 as a safety concern, we would be amenable to
14 adding that exclusion to the measure
15 specification.

16 CO-CHAIR GOLDEN: Yes?

17 MEMBER KIRKMAN: So again, I think
18 GDM is excluded not because it is bad to give
19 women with gestational diabetes statins but it
20 is because the denominator is sort of
21 everybody with diabetes. And that is sort of
22 not considered diabetes for a lot of these

1 measures.

2 So again, for pregnancy, I mean
3 the numbers are going to be so low, a Medicare
4 Part D patient with preexisting diabetes, that
5 gets a statin -- you know that gets a
6 prescription for a statin inappropriately,
7 that it is not -- I mean my understanding it
8 is not worth programming in exclusions for
9 incredibly rare events.

10 DR. PACE: And that is actually
11 part of the NQF guidance. And we ask
12 developers to really even when they do specify
13 exclusions, to do some analysis to see whether
14 it is sufficient enough to warrant data
15 collection and programming to do that.

16 And so I think the phrase that
17 Helen uses is decimal dust. So, we need to
18 think about whether that, you know first of
19 all, is that going to be kind of a random
20 event and as you said incredibly small versus
21 something that is really going to skew
22 performance results.

1 CO-CHAIR ROSENZWEIG: I'm not sure
2 this is decimal dust, frankly. And I am a
3 little concerned about the fact that the
4 measure might inadvertently be applied to
5 people outside of Medicare Part D.

6 MEMBER McDERMOTT: I was going to
7 say from someone that uses measures a lot and
8 we need to use external standards, this is the
9 kind of measure that one would like to use in
10 health plans. And we have ways of -- we have
11 adherence type measures today within our
12 building but they are not coming from an
13 external entity.

14 The thing that is wonderful is
15 that this has been standardized and harmonized
16 and so forth and so on. So, this is the kind
17 of thing that those of us that need to be
18 using standardized measures would love to be
19 able to grab onto.

20 So to me, to make the label that
21 is only for Medicare Part D is kind of
22 disappointing but that doesn't mean we

1 couldn't use it.

2 CO-CHAIR GOLDEN: So, I am going
3 to try to corral us here. We have just gone
4 through a series of votes. And a lot of the
5 issues being raised here were incorporated in
6 those series of votes on usability and
7 reliability.

8 So, my suggestion here is this is
9 a yes or a no. Most of the folks in the room
10 have been saying things are okay. I mean you
11 are free to vote yes or no. If we vote it
12 down, we might revisit some things to find out
13 okay what was the no all about. But I think
14 continuing this conversation at this stage is
15 not going to result in any significant change.

16 So unless using my prerogative --
17 I see people raising their hands to vote. But
18 unless people want to object, I would suggest
19 we vote on the overall measure.

20 MS. BAL: Voting is open.

21 (Pause.)

22 MS. BAL: Okay, we have yes, 15;

1 no, four. The measure passes.

2 CO-CHAIR GOLDEN: Okay. It is
3 about lunch time but we have public
4 commentary. So, we are going to let the non-
5 committee members discuss anything of their
6 choosing.

7 MS. TIGHE: Operator, if you could
8 see if anyone on the line has a comment and
9 anyone in the -- no one in the room.

10 OPERATOR: At this time, if you
11 have a question or a comment, please * then
12 the number one on your telephone keypad.

13 And there are no questions or
14 comments at this time.

15 CO-CHAIR GOLDEN: Okay. We are
16 inching our way forward. I am going to
17 suggest that we take ten or 15 minutes but eat
18 during the next discussions, so we keep things
19 moving.

20 So, is lunch here?

21 MS. TIGHE: It is.

22 CO-CHAIR GOLDEN: All right. So,

1 folks can gather about and let's say about
2 quarter of, we will reconvene.

3 (Whereupon, the above-entitled
4 matter went off the record at 12:31 p.m. and
5 resumed at 12:48 p.m.)

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(12:48 p.m.)

CO-CHAIR GOLDEN: So, if we get people's attention, we will move along.

So, we are talking about adherence to what? Adherence to a blue box.

MEMBER DUDL: ACEI/ARBS.

CO-CHAIR GOLDEN: ACEI and ARBs, okay. I think that we heard the developer talk in general about these. Does the developer want to make specific comments related to ACEIs and ARBs or shall we just go straight to discussing the evidence?

MR. CAMPBELL: I think it would be fine to go straight to discussing the evidence. These measures are structured in exactly the same way and harmonized.

MEMBER DUDL: These are Siamese twins joined at the hip. So, thank you, Bob, for doing all that heavy lifting. This should go fairly simply.

Just quickly, this is a process

1 measure which takes us from Box 1 to 3, 80
2 percent adherence to ACEI/ARBs in people with
3 diabetes where the use of ACEIs has already
4 been shown and systematic reviews, three of
5 them, but there is at least moderate evidence
6 of decreased CVD events with their use.

7 Clearly, if the issue is just
8 should we measure it, the evidence is high or
9 moderate. However, the proposal is way to
10 measure and it is the 80 percent adherence as
11 target, which is a distal step, which takes us
12 down to box 7.

13 There were three articles then
14 submitted or there are three articles that
15 suggest adherence makes a CVD difference. Two
16 submitted by the submitter, which adds
17 empirical evidence. There was an AJMC article
18 a little bit older showing that high adherence
19 at 67 percent produced at 23 per thousand
20 versus a low adherence of 15 per thousand
21 difference at hospital MIs and strokes after
22 three years. So, that was good circumstantial

1 evidence. Not the 80 percent but there were
2 two other articles at 80 percent that I did
3 find that do speak to this. And these are
4 mixtures of diabetics and CVD because they
5 were all looking at higher CVD risk people.

6 And the first was very good. It
7 was an Aetna study with Harvard Brigham, the
8 MI FREEE trial, where they did secondary
9 analysis and they looked at 80 percent of
10 proportion of days covered, exactly what we
11 are looking at with ACEI/ARBs and showed a 24
12 percent difference from partial adherence, 40
13 to 80 percent, which was no bigger than
14 placebo. So, this would suggest the 80
15 percent was a really important cut point.

16 A second study -- however, they
17 were not all diabetic so we had to move on to
18 a second study, which was all diabetics with
19 heart disease by Ho in BMC Cardiovascular
20 Disorders, 4,000 patient retrospective cohort
21 studies with ACEIs and statins. The greater
22 than 80 percent adherence, same proportion of

1 days covered had a 45 percent drop in all-
2 cause mortality compared to low adherence.
3 But here they had a proportionate drop down to
4 50 percent, rather than the sudden drop off.

5 However, there were no studies
6 that were submitted that said that it wasn't
7 important and the group, I believe, thought
8 that this worked through to rating this -- oh,
9 and the other thing, of course, is fairly high
10 certainty of clear benefit versus non in box
11 9, gives us a moderate rating.

12 And I wonder if Anne or anybody
13 else who is on the call want to speak about
14 that.

15 CO-CHAIR GOLDEN: I have a
16 question for you. So, you have some data that
17 shows adherence is associated with some better
18 outcomes. But could that be because you have
19 blood pressure control, so you are just
20 measuring something twice?

21 MEMBER DUDL: That could be. In
22 fact, probably is. They probably do work

1 through blood pressure control but that is not
2 the question. It is actually, in a way,
3 easier to measure adherence in some ways than
4 it is to try to get repeat blood pressures, if
5 we have the data.

6 So, I think the question in front
7 of us for adherence is a very good one.
8 Clearly, as you point out, maybe they would
9 work better with DASH diet or do some other
10 lifestyle things that would drop blood
11 pressure and make a difference. But these
12 three studies really looked at it this way and
13 their evidence was pretty good.

14 CO-CHAIR GOLDEN: Everybody is
15 eating or they are ready to vote.

16 MEMBER DUDL: This is the perfect
17 time to talk.

18 CO-CHAIR GOLDEN: Ready to vote?

19 MS. BAL: Voting is open. You
20 have 38 seconds to vote.

21 CO-CHAIR GOLDEN: Are we missing
22 anybody? Is everybody here?

1 (Pause.)

2 MS. BAL: Okay, we have high six;
3 moderate 12.

4 MEMBER DUDL: Are we at gaps in
5 care? They clearly demonstrated gaps in care
6 as was presented earlier. The same data.

7 And there was a disparity gap in
8 care with Hispanics.

9 The priority, again, this would be
10 high prevalence, high severity, high cost,
11 high priority.

12 MS. BAL: So, are we ready to
13 vote? Okay, voting is open.

14 (Pause.)

15 MS. BAL: Okay, we have high 15;
16 moderate three; low one.

17 MEMBER DUDL: And then we go on to
18 reliability.

19 CO-CHAIR GOLDEN: No, I think we
20 are doing priority.

21 MEMBER DUDL: Oh, I'm sorry,
22 priority.

1 Okay, I covered priority. It was
2 high cost, high severity, high prevalence,
3 high priority.

4 MS. BAL: So, is everybody ready
5 to vote?

6 MEMBER DUDL: I'm sorry.

7 MS. BAL: Is everybody ready to
8 vote? Voting is open.

9 (Pause.)

10 MS. BAL: Okay, we have high 14;
11 moderate three.

12 MEMBER DUDL: Reliability, the
13 same studies were presented, I think, earlier.
14 The reliability test 0.82 for states is very
15 high; physician groups, 0.74; drug plans,
16 0.76. So, they were all of at least moderate
17 reliability.

18 MEMBER SULLIVAN: So, I would be
19 more comfortable with the precision of the
20 specifications, if we stated that the title of
21 the measure would also include Medicare, as
22 for the previous one. I do understand it is

1 in the details but I think it calls it out.

2 CO-CHAIR GOLDEN: Yes, so we have
3 a series of measures from CMS. So the request
4 to CMS would be to change all of them to a
5 Medicare measure. Okay, thank you. I would
6 assume that would be reasonable, if they have
7 already agreed to the first one.

8 MS. RICKSECKER: This is Elizabeth
9 Ricksecker, the GTO from CMS working on this
10 contract with FMQAI. And CMS would certainly
11 be agreeable to adding Medicare-eligible to
12 the title of all of these measures. Thank
13 you.

14 CO-CHAIR GOLDEN: Thank you.

15 MEMBER DUDL: Good point, thanks.

16

17 MS. BAL: Voting is open.

18 (Pause.)

19 MS. BAL: Okay, we have high ten;
20 moderate nine.

21 MEMBER DUDL: We are at validity.

22 Face validity was strong, 77.8 percent

1 together exclusions were as noted. Scientific
2 acceptability was clear. No problems with
3 code definitions or specifications. Elements
4 were clearly defined. Logic calculation is
5 good and could likely be implemented.

6 I think we found that it would be
7 at last moderate.

8 CO-CHAIR GOLDEN: Comments,
9 questions? Open the pools.

10 MS. BAL: Voting is open.

11 (Pause.)

12 MS. BAL: Okay, we have high five;
13 moderate 13; low one.

14 MEMBER DUDL: Next, I think is
15 feasibility. Pharmacy claims are used and it
16 is deemed high feasibility.

17 CO-CHAIR GOLDEN: Ready to vote?

18 MS. BAL: Polls are open.

19 (Pause.)

20 CO-CHAIR GOLDEN: So, I don't
21 know, Jim. I think that we either have to
22 have you do all the measures or we have to be

1 fed earlier.

2 (Laughter.)

3 MEMBER DUDL: And I have to come
4 after Bob every time. He had three years to
5 come back.

6 MS. BAL: Okay, we have high 16;
7 moderate three.

8 MEMBER KIRKMAN: So, I think part
9 of it is that the measures are so similar,
10 this one and the last one and the next one.
11 The issues are really the same that we have
12 already discussed, but it is also that Jim is
13 wonderful.

14 (Laughter.)

15 MEMBER DUDL: Thank you but I
16 think that it is that they are the same. The
17 evidence is there.

18 CO-CHAIR ROSENZWEIG: The one
19 issue here I think -- I don't think it makes
20 a difference in terms of the measure but there
21 are more options to ACEI/ARBs with respect to
22 treatment than there are with respect to the

1 statins. I mean, you --

2 MEMBER DUDL: Well, do you mean
3 between many different drugs or do you mean
4 other anti-hypertensive agents, like
5 hydrochlorothiazide?

6 CO-CHAIR ROSENZWEIG: Agents, yes.

7 MEMBER DUDL: Hydrochlorothiazide
8 and beta blockers -- well not beta blockers
9 too much, but beta blockers actually with CVD
10 and calcium channels. They all drop CVD a
11 lot. So, you know I think there is a good
12 point there.

13 CO-CHAIR ROSENZWEIG: And the
14 evidence of the ACEI and ARBs in African
15 Americans is less solid than it is in the
16 other populations --

17 MEMBER DUDL: Correct.

18 CO-CHAIR ROSENZWEIG: -- for
19 preferential drugs.

20 MEMBER DUDL: That is correct.

21 MEMBER KIRKMAN: But again, this
22 isn't a measure to move more people to these

1 drugs. This is a measure to say that if you
2 thought your patient should be on the drug,
3 are they adhering?

4 CO-CHAIR ROSENZWEIG: Correct. I
5 fully understand that.

6 MEMBER DUDL: That is correct.
7 And so the drugs have been shown to be very
8 powerful when used as indicated and adherence
9 seems to be important in that group. And that
10 is what we are after.

11 Usability, I think that, again, as
12 planned use and not in-use, but I think the
13 discussion last time carried the data. It is
14 at least moderately usable.

15 CO-CHAIR GOLDEN: Other comments?
16 All right.

17 MS. BAL: The polls are open.

18 (Pause.)

19 MS. BAL: High eight; moderate
20 ten; low one.

21 Do we want to vote or talk?

22 CO-CHAIR GOLDEN: Time to vote.

1 (Laughter.)

2 MS. BAL: Okay, polls are open.

3 (Pause.)

4 MS. BAL: We have yes 18 and no
5 one, passing this measure.

6 CO-CHAIR GOLDEN: Okay. So, we go
7 to 2468 and Grace is the presenter. You have
8 a high bar to meet.

9 MEMBER LEE: I can only try to
10 aspire to decrease my time to Jim's time.

11 The title measure is adherence to
12 oral diabetes agents for individuals with
13 diabetes. A brief description, at least two
14 prescriptions in a diabetic for a single oral
15 diabetes agent or at least two prescriptions
16 for multiple agents with a diabetes drug class
17 and who have a PDC, as we had previously
18 discussed of 0.8.

19 So, just to go into some
20 definitions, the numerator is in patients with
21 at least two prescriptions for oral diabetes
22 agents in any diabetes agents in any diabetes

1 drug class with a PDC of at least 0.8 for at
2 least one diabetes drug class. And the
3 denominator does include 18 years of age or
4 older. These are for the Medicare Part D
5 patients.

6 As of the beginning of the
7 measurement period with diabetes and at least
8 two prescriptions for a single oral diabetes
9 agent or at least two prescriptions for
10 multiple agents within a diabetes drug class
11 during the measurement period.

12 So, to move on to the evidence,
13 they --

14 MEMBER BREEN: I have a question
15 about the measure. I'm confused about the
16 numerator and denominator a little bit. So,
17 does this mean -- sorry, can you just go back
18 up? It said in the numerator patients who
19 receive any type of an oral diabetes drug or
20 any class of diabetes drug. I am just curious
21 where insulin plays into this and if patients
22 who are suddenly switched from orals to

1 insulin drop out of this and how you would
2 find that out. Because unlike the statins and
3 the hypertensive agents, there is a lot more
4 movement in therapy in the anti-glycemic
5 arena. So, I just didn't understand the
6 details of that. Maybe the developer can
7 comment?

8 MR. CAMPBELL: Sure, this is Kyle
9 Campbell again from FMQAI.

10 Due to the nature of the
11 administrative claims data, we weren't able to
12 operationalize a measure for insulin in the
13 same way that we are for the oral medications.
14 So, this measure is limited to adherence to
15 oral diabetes agents.

16 In this case with this particular
17 measure, a patient only needs to achieve a 0.8
18 on any of the classes for which they would be
19 taking. So for example, if they had like
20 let's say metformin and they also had
21 glipizide, if they were adherent at 0.8 to
22 their metformin but not adherent to their

1 glipizide, they would still be counted as a
2 numerator-positive case.

3 MEMBER BREEN: But my question is
4 someone who is on multiple oral therapies in
5 May. And in June, their provider decides to
6 drop the whole oral shebang and switch to an
7 insulin basal-bolus form. They are going to
8 come out as a numerator fail, if you can
9 exclude patients switching to insulin.

10 MR. CAMPBELL: Yes, at this time
11 we have not excluded patients with insulin.
12 At this time, we have only limited the
13 inclusion to patients who have two
14 prescriptions for multiple oral agents within
15 the class.

16 CO-CHAIR GOLDEN: So just to be
17 clear also because this is where you start
18 getting into some brand names and copays,
19 which can be all over the place.

20 So, if somebody is on metformin
21 and Actos and intermittently misses the Actos
22 because of co-pay issues, as long as they stay

1 on the metformin, they would meet the
2 requirements?

3 MR. CAMPBELL: Yes.

4 CO-CHAIR GOLDEN: Okay.

5 MEMBER SULLIVAN: I just wanted to
6 clarify. So, this could incent physicians to
7 leave people on oral agents instead of
8 converting them to insulin.

9 I have a feeling there is going to
10 be a lot more discussion later on in other
11 sections.

12 CO-CHAIR GOLDEN: All right, so
13 evidence. Let's go back to discussing the
14 evidence, since now we understand the measure.

15 MEMBER LEE: So the evidence
16 presented included clinical practice
17 guidelines from the ADA from 2013. However,
18 the guidelines did not directly address the
19 topic of medication adherence directly. Then,
20 the developers presented the results, a review
21 of ten studies, which was quite extensive,
22 looking at adherence, including the measure

1 PDC but other measures, including medication
2 possession ratio and found that all of the
3 studies showed that adherence was associated
4 with improved outcomes, other intermediary
5 hemoglobin A1c or hospitalization rates.

6 And so based on the algorithm, the
7 workgroup recommended this be a moderate.

8 CO-CHAIR GOLDEN: I see no
9 comments or questions.

10 MS. BAL: Voting is open.

11 (Pause.)

12 MS. BAL: Okay, the final results
13 are high four; moderate 15. And we will
14 continue on.

15 MEMBER LEE: So, a performance gap
16 was identified as to the previous two
17 measures. The mean state was 73 percent or 74
18 percent, with a 15 percent spread, contrasting
19 the physicians a 73 percent mean, with
20 approximately 40 percent spread. So, there
21 was a gap.

22 CO-CHAIR GOLDEN: Okay, let's

1 vote.

2 MS. BAL: Voting is open.

3 (Pause.)

4 MS. BAL: Okay, we have high 14;
5 moderate five.

6 MEMBER LEE: So, priority. The
7 working group felt that this was high priority
8 because based on diabetes morbidity/mortality
9 and based on the studies and their outcomes
10 that were reported.

11 CO-CHAIR GOLDEN: Time to vote.

12 MS. BAL: Voting is open.

13 (Pause.)

14 MS. BAL: Okay, we have high 13;
15 moderate six.

16 So reliability. Again, looking at
17 the signal to noise ratio for states, drug
18 plans, and physician groups, reliability
19 testing was met at acceptable ranges for 0.98
20 for states down to 0.71 for physician groups.

21 So, it is recommended to be
22 moderate.

1 CO-CHAIR GOLDEN: I have a
2 question for the developer.

3 I have heard there are some plans
4 or some activities they actually provide the
5 drugs to patients to try and create adherence.
6 So they either get rid of co-pays or they
7 actually supply the drugs. But I was just
8 curious. Does your mechanism capture that, if
9 that is something that they do or is that so
10 rare not to be even considered?

11 MR. CAMPBELL: Unfortunately, I
12 don't have any data with regard to that. If
13 it was covered by the plan itself, presumably
14 it would be captured but we would have to
15 investigate that a little further to get any
16 answer to that question and I don't have an
17 answer readily available.

18 MEMBER HAYDON-GREATTING: Hi, this
19 is Starlin. I do this in our plan and
20 everything, even though it is free to the
21 patient, is still ran through the pharmacy
22 benefit computer process so we can capture it

1 because we are still collecting the same
2 adherence medication to make sure they are
3 still filling when we only see them every
4 other quarter. So, we want to know that same
5 information.

6 So, Medicaid and Medicare would
7 still be capturing that.

8 MEMBER DUDL: The Aetna study
9 speaks to that. Giving the drugs free in a
10 controlled trial only produced about a five,
11 ten percent better improvement, showing that
12 adherence is multifactorial.

13 CO-CHAIR ROSENZWEIG: Just a
14 clarification. If a patient is on, let's say
15 metformin and is switched to another oral
16 agent and the patient is adherent to the new
17 agent, then they are not -- there is no way
18 that they get dinged for stopping the
19 metformin, is there?

20 MR. CAMPBELL: That is correct.

21 CO-CHAIR GOLDEN: All right, I
22 think it is time to open the polls.

1 MS. BAL: Okay, voting is open.

2 (Pause.)

3 MS. BAL: Okay, we have high
4 eight; moderate 11.

5 MEMBER LEE: So, moving on to
6 validity, they again looked at face validity
7 and had the exact same members saying exactly
8 78 percent potential threats to validity.
9 Again, we had discussed that they had done
10 extensive research on cash prescriptions at
11 discount pharmacies.

12 So given that it was face
13 validity, the working group recommended
14 moderate.

15 CO-CHAIR GOLDEN: Do you want to
16 make a comment or are you -- okay, Tracy.

17 MEMBER BREEN: I tried to save my
18 comments for the right box. I am learning
19 this whole NQF process.

20 CO-CHAIR GOLDEN: And when you
21 learn, it will be time to go home.

22 MEMBER BREEN: I know!

1 (Laughter.)

2 MEMBER BREEN: So my concerns
3 about this measure, as opposed to the prior
4 two, relate back to what I said about the
5 change, the dynamic of therapy. And when we
6 think about and again now it becomes very
7 important that this is a Medicare-eligible
8 population because now it is an older
9 population, and the natural history of Type 2
10 disease is to become, at some point, insulin
11 deficient. And we are going to see large
12 numbers of older patients transitioning off
13 oral therapies onto insulin. And in the
14 interest of simplifying regimen and avoiding
15 poly-pharmacy in older patients, we hope that
16 many of these orals will be discontinued.

17 So, I am concerned that there is a
18 big chunk of patients who are going to show up
19 as a ding, as a numerator fail, when they are
20 having their regimens appropriately changes or
21 disease changes but the measure hasn't figured
22 out a way to operationalize having patients

1 who are insulin fallout. So, that is my
2 concern about the specifications of this
3 measure, as opposed to the other two.

4 MR. CAMPBELL: This is Kyle
5 Campbell from FMQAI. I think that is a really
6 good point and I think we could evaluate an
7 exclusion for patients receiving prescriptions
8 for insulin. We would need to look exactly at
9 how it would be operationalized. But I think
10 operationalizing an exclusion would be
11 feasible; whereas, actually measuring
12 adherence of insulin patients would probably
13 require a different measure and a different
14 algorithm.

15 MEMBER MILLER: The other thing
16 that may change is not just even the natural
17 history of the disease but also in that
18 specific population, we are also going to see
19 their GFR dropping and medication regimens
20 changing as a result of renal function.

21 MEMBER HAYDON-GREATTING: Yes,
22 Kyle, I have a question. Some of the dual

1 eligibles in the Medicaid population in some
2 states are being required to do a four
3 prescription per month limit. So, they are
4 having to take a three-month fill time and
5 spread if they are on 12 drugs. Have you
6 considered this that maybe down the road as
7 one of things that will threaten validity?

8 PARTICIPANT: Yes, it is happening
9 in the Medicaid population, unfortunately.

10 MEMBER HAYDON-GREATTING: They can
11 only fill four prescriptions per month. So if
12 they are on 12 chronic meds, they have to --
13 like January they get four for 90 days,
14 February they get four for 90 days and so
15 forth. And so they are having to --

16 CO-CHAIR GOLDEN: There are many
17 states, again, this is a Medicare measure.
18 There are many states where Medicaid limits
19 the number of scripts. So, I can tell you
20 that I have had patients in my office I say
21 these are your expensive ones. These are your
22 cheap ones. Pay cash for these. Use your

1 card for those. So, that gets into the whole
2 cash issue. So, it is a strategy.

3 MEMBER HAYDON-GREATTING: And it
4 is affecting the dual eligibles in Illinois.
5 I just want to make that point. So, when you
6 are out there looking at the data, which you
7 will be, you might want to consider those
8 states that are making their dual eligibles
9 fall into that four prescription limit.

10 MR. CAMPBELL: Okay, we will
11 definitely take a look at that. I mean the
12 measure would definitely capture the 90-day
13 supply and give credit for a 90-day supply.
14 But I understand with regard to the four
15 prescription limit, if that is, indeed, the
16 case in some states, for dual eligibles is
17 something that we should be aware of. It is
18 not something we investigated.

19 CO-CHAIR GOLDEN: Sue.

20 MEMBER KIRKMAN: But I guess I am
21 confused now because if this measure
22 specifically is for Medicare Part D, so that

1 wouldn't apply. I mean I understand that if
2 somebody else --

3 MEMBER HAYDON-GREATTING: There
4 are dual eligibles that some of the services
5 for Medicaid you get your prescription filled
6 through Medicare Part D and so --

7 MEMBER KIRKMAN: But would they be
8 held to that same four prescription a month
9 rule? It seems like that would be only if
10 Medicaid is their prescription coverage.

11 MEMBER HAYDON-GREATTING: They are
12 putting them in a managed care. What they are
13 doing in Illinois is they are bidding them out
14 into a managed care population and they are
15 doing some limits because of the funding that
16 is -- because the thought was we could move
17 everybody to Medicare Part D and that would be
18 great for the patient in particular. But
19 because of their living arrangements and
20 getting disability under Medicaid, it is
21 split. So, under their split, they are
22 getting some care.

1 And if you are a bipolar
2 schizophrenic that is on all these medications
3 and have diabetes because of the medications
4 for all those kind of -- I just wanted to make
5 Kyle aware that some of those might be
6 something that would affect the validity.

7 Don't do it on Illinois. So,
8 leave our state out of it. It's not good
9 data.

10 CO-CHAIR GOLDEN: I think another
11 state is don't tread on me but that is neither
12 here nor there.

13 Anybody else with comments? Bill.

14 MEMBER CURRY: A procedural
15 question. If we feel strongly that there
16 should be an insulin exclusion, where do we go
17 with the process?

18 CO-CHAIR GOLDEN: So, we have a
19 measure before us as specified. If you want
20 a change to the specs, you would basically
21 give this a low number or, at some point,
22 reject the measure and ask for revision.

1 So but we cannot make a revision
2 today. I don't think we can do it on the fly.
3 It is a substantive change. So, if you really
4 feel like you want that to be done, then you
5 would give this a low score and at some point
6 vote no on the -- this is not a must pass --
7 this is a must pass. Excuse me. It is a must
8 pass.

9 So, if the group votes against it
10 or doesn't like it, then we can ask for
11 revisions.

12 MR. MATTKE: One question on that.
13 Soeren Mattke for the developers. In my
14 experience, isn't it the case that even if you
15 go from orals to insulin that initially you
16 keep patients on some dose of oral so that you
17 don't have to dose the insulin side?

18 CO-CHAIR GOLDEN: In looking at
19 the room, I see lots of faces saying it ain't
20 necessarily so.

21 MR. MATTKE: Okay.

22 CO-CHAIR GOLDEN: Are we ready to

1 vote? Okay.

2 MS. BAL: Voting is open.

3 (Pause.)

4 MS. BAL: Okay, we have high one;
5 moderate four; low nine; insufficient five.

6 And so this does not pass.

7 CO-CHAIR GOLDEN: So, the
8 committee decided that we would like some
9 revisions or some rethinking.

10 You got two out of three, guys.

11 MEMBER KIRKMAN: So, is the issue
12 this insulin issue primarily?

13 MEMBER BREEN: I think it is a
14 good tool to get at medication adherence. The
15 concern is, I think, there are going to be too
16 many people tagged as being non-adherent
17 because you are not accurately capturing
18 therapeutic change. So, if you just pull out
19 the patients who have some insulin
20 prescription, then you get to the nut of
21 people who are strictly on orals. And then if
22 they are falling out, then you are sure that

1 it is because of non-adherence, as opposed to
2 the way it is set up now you are not sure what
3 is measuring adherence versus what is
4 trickling in from therapeutic change. Because
5 there is a lot of insulin being used,
6 especially in that population. As the insulin
7 rates go up, if you are not pulling those out,
8 I think it is a dirty number. I don't know
9 how --

10 MEMBER BREEN: I mean it would be
11 interesting for them to actually look at the
12 data because in the older population, there is
13 a lot of incident diabetes, too. So, it is
14 not necessarily the case that everybody has
15 got long-standing diabetes. And I think if
16 you look at the NHANES data, insulin use is
17 actually lower in older patients than in
18 middle-aged patients.

19 So it just might be worth them
20 looking at the data and if they find that most
21 people that switch to insulin that do stay on
22 an oral agent or whatever.

1 CO-CHAIR GOLDEN: So, Helen --

2 MEMBER KIRKMAN: But that would
3 mean that if they went back and looked at the
4 measure and did that math for us and presented
5 it again and say we have looked at this and we
6 found that it was a negligible difference, I
7 would at least feel more comfortable. But now
8 I don't know what that difference is.

9 CO-CHAIR GOLDEN: So, Helen, I
10 have a question for you, since we are a new
11 standing committee with a whole different
12 framework. We have only two measures that
13 have gone down but this one went down.

14 Can the developer contact the
15 committee for just some insight? Do you have
16 any process for that? Is it they are on their
17 own? I am just thinking through here how to
18 make this constructive, if people wanted
19 revisions.

20 DR. BURSTIN: I think that is a
21 good question. And again, we are just
22 starting on standing committee. This is

1 somewhat new ground for us. But either way,
2 it is very appropriate at this point if the
3 developer wants to give you the additional
4 analyses that you just raised for you to
5 consider it in a follow-up discussion and you
6 can just stop the analysis here for today and
7 potentially return to it.

8 Does that sound reasonable, Karen
9 or Lindsey?

10 CO-CHAIR GOLDEN: Yes, I guess one
11 of my thoughts was after this meeting we all
12 go home. Do you want to have some -- if
13 people are willing to send comments or
14 something, is that something of value or even
15 appropriate?

16 MS. TIGHE: I will just jump in.
17 Actually, during the commenting period, if a
18 developer wants to investigate this potential
19 exclusion and see whether or not it actually
20 impacts the measure, there will be sufficient
21 time for them to do that. And then we have a
22 call scheduled after the comment period where

1 they could share that information with you
2 all.

3 Because the endorsement
4 recommendation, though we ask you to vote here
5 now, we put it out for a comment and then you
6 do have the opportunity to reconsider, based
7 on the comments received and then this
8 potential additional information that you are
9 requesting from the developer.

10 So this is not necessarily your
11 final, final vote.

12 CO-CHAIR GOLDEN: So just to get
13 the committee oriented, so as we finish today,
14 everything we did goes on the web. There is
15 a public comment period. The comments come
16 back to us.

17 And so the CSAC, the higher
18 committee, doesn't see material from this
19 committee until we see the comments and review
20 our previous actions.

21 PARTICIPANT: Now do we then do an
22 up or down vote after that or do we have to go

1 through each of these individual --

2 MS. TIGHE: For this measure,
3 because we stop at validity, we would have to
4 finish the vote on this measure so that we
5 could have that information.

6 PARTICIPANT: What about the ones
7 we have already approved?

8 MS. TIGHE: Those, if you see the
9 comments and it causes you to reconsider your
10 initial recommendation, you can request to
11 vote again. But it is not, by any means
12 mandatory.

13 MEMBER BREEN: So, I guess my
14 question is, is there a way to vote like an
15 asterisk? So it seems like on this one
16 measure we have a very specific question where
17 I assume that the rest of the vote will
18 probably, for the other measures, will be
19 similar to the last two measures. So, I am
20 just -- I don't understand the process.

21 MS. TIGHE: We will reflect that
22 in the draft report when we post it for

1 comment that if this one specific issue that
2 the committee is seeking comments on this
3 measure and provide all of that to you.

4 Because this won't be, by any means a final.

5 CO-CHAIR GOLDEN: So in terms of
6 time line, we will be seeing the results of
7 the comments about June, July?

8 MEMBER McCOLLISTER-SLIPP: So just
9 a procedural question. So, is this sort of
10 like an FDA advisory committee, where we
11 provide advice and then ultimately NQF and
12 like the master committee or whatever decides
13 whether or not it actually gets approved?

14 MS. TIGHE: So you do provide
15 these initial recommendations and then revise
16 them, potentially, based on the comments
17 received. We will then put it out for NQF
18 member vote. All of this information is taken
19 as an input to our Consensus Standards
20 Approval Committee. And they have specific
21 criteria that they are evaluating at that
22 point in time. I am looking to Helen now but

1 it is whether the process was followed,
2 whether there was sufficient consensus
3 achieved at the committee level and at the
4 member vote level. I think potentially a
5 change to evidence in the time between.

6 Yes, so they are looking for
7 specific things where they may reverse the
8 decision of the standing committee but the
9 work that you are doing now goes forward,
10 unless one of those issues arises.

11 CO-CHAIR ROSENZWEIG: The measures
12 that have been waived by the developers for a
13 later time, can we fully vote and approve them
14 on a conference call or do we have to wait for
15 another meeting like this?

16 MS. TIGHE: I will actually let
17 Katie talk about the timeline more but I will
18 say there won't be any more in-person meetings
19 scheduled at this point.

20 DR. PACE: But your question is
21 the two measures that you didn't get to, you
22 will finish those and that will be included in

1 the recommendations that go out for comment.

2 So, you will vote on them, yes.

3 MEMBER KIRKMAN: Sorry. The ones
4 we didn't finish because we didn't get all the
5 way through them here or the two that we
6 haven't talked about at all?

7 CO-CHAIR GOLDEN: The podiatry
8 ones.

9 MEMBER KIRKMAN: Okay, so for this
10 measure, I guess I am still confused. We
11 didn't actually get to the end and vote it
12 down. We just stopped the process in the
13 middle. So, is it -- so, we will get more
14 evidence from the developer, presumably, and
15 then complete the vote by phone. Is that
16 right?

17 MS. JOHNSON: So, this is a must-
18 pass criterion. So right now you have voted
19 down this measure. If the developer chooses
20 to, and I imagine that they will, they can
21 bring you back more information. And when
22 they do that, then you can decide if you want

1 to revote. If you do revote this criterion
2 and it goes forward, based on what they give
3 you, then we would finish out the voting for
4 this measure and then it would go forward.

5 CO-CHAIR GOLDEN: Is the voting
6 based on a quorum attendance or is it based
7 upon a percentage of the total committee
8 members?

9 MS. TIGHE: Yes, so we require a
10 minimum of 75 percent of the committee to vote
11 on a measure. If we get 75 percent of the
12 votes back from the committee on the measure
13 and we realize that the remaining votes could
14 still change the decision, then we will go out
15 and seek the rest of the votes.

16 MS. STREETER: As far as the time
17 line, over the next several weeks, staff will
18 be preparing a draft report that does
19 summarize all your recommendations from today,
20 as well as from the March 12th call and you
21 evaluate the two APMA measures.

22 We will be putting the draft

1 report out for comment the first week of April
2 and that is a 30-day period. We will then be
3 asking you to meet via webinar to review the
4 comments. I believe it is -- I don't remember
5 the exact date. I think it is the third week
6 of May. And then that is when you will review
7 and respond to the comments, decide if you
8 want to reconsider any of the measures. And
9 then in June, that is when we will hold the
10 15-day NQF member voting.

11 Eventually, your recommendations
12 will be put forth to CSAC in September.

13 MEMBER SULLIVAN: So, one of the
14 procedural things. So, I think I understand
15 if CMS does the analysis, they present it to
16 us on the call, the insulin impact is
17 negligible, we could vote on the measure as it
18 stands with that impact being negligible.

19 Suppose they do the analysis and
20 then insulin impact is not negligible. Is it
21 an option that CMS could say and we have
22 quickly figured out how to do an insulin

1 exclusion and that they could present it and
2 then we could vote on the revised measure?

3 MS. JOHNSON: I think so, yes.
4 So, it may not be possible for them to do that
5 but I would think that if they did, you could
6 potentially vote on it.

7 MS. TIGHE: And I know you were
8 asking if CSAC is the Consensus Standards
9 Approval Committee that I referenced earlier.

10 CO-CHAIR ROSENZWEIG: What is the
11 earliest time in which measures that we
12 officially approve here can they be
13 implemented?

14 MS. STREETER: The Board approval
15 period is in October. So, the Board would
16 approve endorsed -- if we are still doing
17 that. Okay. So, it would be October.

18 CO-CHAIR GOLDEN: Okay. So we
19 finished the measures. Where do you want to
20 go from here? We have a number of items here
21 on the agenda. Time is starting to get
22 tighter.

1 And so I will leave it to NQF
2 staff to decide which of these items you would
3 like to -- and it might not have been the
4 presenters or the lunch. It could have been
5 the cookies, Tracy.

6 Which area do you want to go next?

7 MS. JOHNSON: Okay, so we are not
8 going to do a harmonization discussion this
9 afternoon. One main reason for that is there
10 would be a pretty definite discussion of that
11 after you do the podiatry measures.

12 CO-CHAIR GOLDEN: If we do the
13 podiatry --

14 MS. JOHNSON: The podiatry
15 measures, right.

16 So, we will push off the
17 harmonization discussion until the call on the
18 12th of March. So, you should already have
19 that on your calendars. We will do all of
20 that then, evaluate the two measures and
21 discuss harmonization at that point.

22 So, what we were hoping to get

1 from you guys today is some feedback. So, we
2 have -- this is a pilot project and as part of
3 the pilot and then as part of just regular
4 improvements that we try to do with our
5 process, we have actually instituted a lot of
6 new things that you guys are the first ones to
7 really try out.

8 So, we were hoping to get from you
9 quantitatively through the survey that we sent
10 you out this morning but also a little more
11 qualitatively this afternoon, any feedback
12 that you want to give us.

13 And I will just give you the
14 overall pieces that we are interested in
15 feedback about. And I will just let you guys
16 discuss.

17 So, I want you to think about the
18 orientation call that we provided and the
19 information that we gave you on that, as well
20 as the Steering Committee guidebook that we
21 gave you, and a tool called the "What Good
22 Looks Like." I don't know if you -- so we are

1 interested did you even take a look at those
2 things. Were they helpful? That sort of
3 thing.

4 We had two Q and A calls that you
5 had the option to attend. So, we are
6 interested in did you attend and was it
7 helpful to you.

8 We had workgroup calls. And on
9 the workgroup calls, I think one of the
10 problems that we already know about is we
11 didn't get through all of the measures. So,
12 some of the measures got a very short shrift
13 in the workgroup calls. But let's talk about
14 what you thought about workgroups and what
15 would be most helpful to you, if that is not
16 it.

17 And then finally, we, as part of
18 your submission materials that we gave you, we
19 did this staff review piece that we kind of
20 placed on top. So, we want your feedback
21 about was that helpful at all or not? If part
22 of it was, which parts? And then as part not

1 just the staff review part but even the
2 formatting, what it looked like, was it
3 helpful to have it stuck with the submission
4 materials, with the hyperlinks? So it is
5 basically a free for all for you guys to give
6 us input so that we can improve our process.

7 So with that, I will ask you guys
8 to start.

9 CO-CHAIR GOLDEN: I just want to
10 make a quick comment as the chair, just that
11 I think that the fact that most of you, or
12 most all of you, have never done this before,
13 I think people did real well. But I think
14 that the workgroup calls, which could have
15 been great, had a certain amount of chaos to
16 them because nobody had done this before. And
17 now that you have been through this meeting,
18 I think they would be a lot more useful.

19 I hate to say it but the
20 workgroups could have been a really high-risk
21 venture, given the inexperience of everybody
22 in this process.

1 Sue?

2 MEMBER KIRKMAN: I just had one
3 comment about I think everything that the
4 staff did, to me, was very helpful. But one
5 thing is the big document with all the
6 information, like by the time of the meeting,
7 it was sort of overwhelming. It is just kind
8 of hard because you have got what the
9 developer put in there and then you still have
10 the staff comments in there. And then you
11 have comments in there. And then you have red
12 highlighted comments in there and they are not
13 always kind of in the same place.

14 I don't really know what a better
15 way to do it is but maybe if the final
16 document could be sort of pared down to just
17 sort of what we would need at the meeting. I
18 mean I don't think it is good to have it in
19 multiple different documents but that was just
20 my gestalt was the document just sort of
21 becomes very hard to plow through and figure
22 things out.

1 But I thought the staff comments
2 were helpful in the beginning, I mean
3 especially as a newbie, because it did sort of
4 help orient us.

5 CO-CHAIR GOLDEN: A question for
6 you, Sue. In terms of the formatting of the
7 document, would it be more useful to have
8 staff and workgroup comments separate from the
9 big document for easier reference or do you
10 want everything all in one big document?

11 MEMBER McCOLLISTER-SLIPP: I would
12 say yes. I mean, as somebody still has no
13 idea where the workgroup comments were that I
14 was looking for yesterday. I mean I found
15 that really hard to navigate. And if I would
16 have brought my marked up version instead of
17 leaving it at home, it would have been a lot
18 easier.

19 But I think formatting in one way
20 or another, I don't know if you have a graphic
21 designer or whatever the case may be, could be
22 really helpful, just using color or different

1 kinds of section headers or something.

2 MEMBER KIRKMAN: Yes, I don't know
3 whether a different document is better or
4 worse but maybe just paring down something.
5 Like, I don't know that we still needed the
6 staff comments today, for example. So, maybe
7 just cutting them out.

8 DR. PACE: I guess one of the
9 questions because you were in your small
10 workgroups, but people at this meeting had to
11 review all the measures. So, I guess that was
12 part of our thinking is that those who hadn't
13 reviewed those initially, would that be useful
14 to still have that.

15 So, I hear what you are saying for
16 the people who had already focused on those.
17 But I guess that was part of the balance. But
18 definitely, we will continue to work with
19 that.

20 MEMBER SHWIDE-SLAVIN: I liked
21 that you kept the staff comments there. It
22 was helpful today to be able to look at those

1 as we were going through these.

2 But I think the placement of the
3 committee comments and all of the information,
4 instead of putting it at the very end where
5 you had to figure out we are talking about
6 reliability now but all the comments are after
7 validity and which goes with what, you had to
8 constantly go back and forth.

9 So, if they were really placed in
10 the right place, it would mean creating new
11 boxes in the document but I think you need to.
12 I think they need to go there.

13 MEMBER KEARNS: Yes, I just want
14 to say that once I figured out how the
15 hyperlinks worked, it was really good.

16 I liked the staff comments because
17 they kind of gave me direction for what I was
18 looking for and what I was doing. So, once I
19 figured out how the hyperlinks worked and I
20 could go back and forth, I found that very
21 helpful because I think the original document
22 just plunked down to me would have been kind

1 of overwhelming without that.

2 But yet, as I got more familiar
3 and looked at it more and more, I did go back
4 to the original document more and more to see
5 what I thought about it.

6 So, I thought that system worked.
7 I would echo about where the comments are
8 placed but that has already been spoken to.

9 MEMBER BREEN: I agree with the
10 comments about having the staff comments for
11 other measures that I didn't look at so
12 closely. I think that is helpful.

13 But I think what we are really
14 asking for is two different things; one very
15 robust document that has everything and almost
16 maybe like a cheat sheet, something I can
17 refer to with like just the meat of it.
18 Either just the meat of the staff of comments
19 or just the meat of the workgroup comments
20 that I could almost have side-by-side. So, I
21 am looking at the very detailed measure but
22 then I see kind of right next to it what some

1 of the key topics are. I think that would
2 move the reading along faster.

3 And in terms of the learning curve
4 on this, I am very new to this process, I
5 thought the learning curve was incredibly
6 steep and where we were today is very
7 different than where we were yesterday. I
8 almost want to do my workgroup over. I think
9 it would be a much better workgroup. But I
10 don't know how to make that learning curve
11 steeper. Because until you see it in process,
12 I don't know how I could have learned how to
13 do it better, other than to sit through this
14 whole thing yesterday. So that is the
15 challenge for those initial workgroups, for
16 those of us who are new. And I don't have any
17 suggestions how to make that better. But I
18 think that we could have used that time much
19 more effectively if we somehow understood the
20 process.

21 And I was on the Q and A call kind
22 of listening in and I did all the good things

1 and I still didn't get it. And I don't think
2 until I sat here I really got it. Not for
3 lack of your trying. Very good job but I had
4 no idea what you were talking about.

5 (Laughter.)

6 CO-CHAIR GOLDEN: It may be that
7 when you have -- you know we had a large
8 volume of stuff to do. And it might be,
9 honestly, if you have especially a new group,
10 it might be good to do a measure on a phone
11 call. Have somebody walk through it and
12 actually walk through one, so that everybody
13 can follow what --

14 MEMBER CURRY: They did do that
15 and it was very helpful.

16 CO-CHAIR GOLDEN: Okay, maybe I
17 wasn't on that call.

18 MEMBER CURRY: But it took such a
19 long time, we didn't have time to do the
20 others.

21 MEMBER BREEN: And we weren't
22 invested in it yet.

1 CO-CHAIR GOLDEN: Never mind.

2 Ingrid?

3 MEMBER DUVA: I liked the staff
4 comments and I agree with the executive
5 summary for today. Since we have all done our
6 workgroup, it would be nice to look back and
7 see at a quick glance what the other
8 workgroups had kind of decided.

9 But from a logistics standpoint, I
10 thought it would be very helpful to have two
11 separate documents where the developer has
12 their document and then the staff, whose
13 comments were helpful and it helped us kind of
14 orient to where we were in the process on the
15 workgroup, especially I was stuck because you
16 can't go into the NQF site twice. I tried to
17 pull up the document twice so that I could be
18 at different points in the document and
19 compare but you can't go in. Your access gets
20 blocked.

21 So, that is why I thought if we
22 had two -- you know, then you download both

1 documents or whatever. But if you have the
2 two documents, you can also split screen and
3 put them up side-by-side. And I just thought
4 that would facilitate the work really for me
5 that was my perspective. Because that
6 workgroup call is so important to kind of
7 guide everybody through what you have already
8 done to make it efficient.

9 And then the staff comments were
10 so helpful, you kind of wanted to have them up
11 so you could say well this is what I saw.
12 This is what the staff saw, just to make it
13 more efficient. And then the executive
14 summary today, I thought that was a great
15 idea.

16 MEMBER McCOLLISTER-SLIPP: I would
17 agree with that. I found it, and I don't know
18 if it was just me, but I found it really hard
19 to sort of sort through the whole document
20 when you are originally reviewing the measure.
21 And I ended up like wasting, or not wasting
22 but using tons and tons of toner printing

1 things out so that I could see this is the
2 section, this is this section, this is this
3 section.

4 So, anyway, I mean I don't know.
5 I mean I hate to kill trees by having you guys
6 print all this stuff and send it out to
7 everybody. But on the other hand, I mean it
8 is much easier to review it sort of logically
9 if you have got one section here, one section
10 here and you can sort of cross-reference back
11 and forth. Because when you go through and
12 answer the questions, you are sort of going
13 from one question to the other to the other.
14 So, you end up flipping sort of.

15 And for me, the hyperlinks didn't
16 work. So, it was kind of cumbersome,
17 especially if you are doing it while you are
18 traveling and your laptop screen is this big.

19 MEMBER KEARNS: I really think
20 once the hyperlinks worked, that saved that
21 problem for me because I was having a lot of
22 that. And once I figured out -- and I don't

1 know what your issue was -- but once I figured
2 that out, it was essentially like having them
3 side-by-side because you can easily go back
4 and forth. And that saved me a lot. A lot.

5 I didn't figure that out until
6 yesterday.

7 CO-CHAIR ROSENZWEIG: Yes, I had a
8 big learning curve with respect to that as
9 well. It was not easy.

10 MS. JOHNSON: So let me ask, what
11 do you mean about they didn't work? Do you
12 mean they actually didn't work or you didn't
13 know how to go back?

14 MEMBER KEARNS: I didn't know how
15 to go back and forth very well.

16 MS. JOHNSON: Okay.

17 MEMBER KEARNS: And I kept ending
18 up in the wrong section in one or the other.
19 And it was confusing until I figured out that
20 they were actually one big document, I was
21 jumping back and forth.

22 But yesterday I think someone

1 helped me figure out how to really go toggle
2 back and forth. And then it was like a light
3 bulb went off. It was a lot simpler.
4 Otherwise, it was kind of very I am scrolling
5 way down, I am scrolling way up. Where is it?
6 Where did I start? But they hyperlinks, once
7 I figured it out was like wow, that was a
8 really good idea.

9 CO-CHAIR ROSENZWEIG: Yes, I kept
10 logging out accidentally because of not being
11 able to switch and staying within the
12 document.

13 MS. JOHNSON: We will send
14 instructions.

15 CO-CHAIR ROSENZWEIG: I have a
16 couple of questions for the committee as a
17 whole. What about, this may be specifically
18 NQF policy but the process of having the
19 measure developers in the room the entire time
20 we consider the measure, is this cast in -- is
21 this a policy that NQF has fully decided on?

22 Because to me, that can be a

1 little intimidating for the group as a whole.
2 And sometimes people may want to -- the
3 committee may want to raise issues related to
4 the overall consideration of the measures in
5 private. Has that been discussed at all? I
6 mean especially at the very end when we decide
7 to vote on the measure. There is a certain
8 amount of inhibition of criticism to a certain
9 extent that is implicit in this process.

10 MS. TIGHE: Yes, NQF generally is
11 extremely committed to transparency and so all
12 of our documents are available on our website.
13 All of our calls are publicly available. We
14 provide transcripts to every meeting publicly.
15 And so, it is a stance that we have taken as
16 an organization to be as transparent as
17 possible.

18 That said, I certainly do
19 understand your concerns.

20 I am kind of looking to Helen now.
21 I am not sure if we really have or even could
22 have a process to get at that, other than

1 perhaps email amongst the committee.

2 DR. BURSTIN: Yes, it is really
3 complex. I mean again, so much of our
4 hallmark is transparency. So, we try to be
5 transparent. That being said, there is
6 nothing that would prevent you from, at some
7 point, often at the end of a meeting, going
8 into an executive session and having a chance
9 to freely air any concerns you want to talk
10 about that are not directly related to
11 individual measure evaluation, in which case
12 you want the public and everybody there open.
13 But I do think there may be conversations
14 about specific issues that came up over the
15 meeting where we could do that in executive
16 session.

17 Is that fair?

18 MEMBER KIRKMAN: Something related
19 to that, so on the workgroup call, I was
20 actually kind of -- I guess it didn't sink in
21 to me that the developers were on the call
22 until they started to speak up. So, at first,

1 I was a little taken aback by that.

2 But once I realized it was, I
3 actually think it was really good because, for
4 example, the APMA measures. I mean we had a
5 lot of criticism of them and I think the
6 developer sent some things in afterwards and
7 there was a little bit of defensiveness on
8 their part as well. But I just think if they
9 hadn't been on the call and if they weren't on
10 the call where we actually approve or don't
11 approve the measure, then I think they are
12 just going to say oh, you know, they just
13 didn't understand it. We got screwed,
14 whatever.

15 And so I mean I actually think
16 once you sort of realize they are going to be
17 here, I think it is better. I think it is
18 better for us and for them.

19 And so for example, the
20 osteoporosis measures, I mean one of them
21 didn't go forward. And I mean I don't think
22 it was that hard for --

1 MEMBER SHWIDE-SLAVIN: Yes, but I
2 also heard them talking that they didn't
3 expect that one to go forward.

4 That was interesting.

5 MEMBER KIRKMAN: I mean I did feel
6 like -- are they still on the call? Are
7 people still on the call?

8 MS. TIGHE: We are not in an
9 executive session.

10 MEMBER KIRKMAN: Okay. So there
11 was some eye rolling going on for one of the
12 measure developer groups yesterday. But you
13 know I think you just deal with it.

14 MEMBER BREEN: I think that is
15 okay. I think that is good communication and
16 there is very powerful communication when you
17 have people in the room, which is why I think
18 is more effective than being on that isolated
19 workgroup call.

20 So, I think for me having
21 developers sitting right in front, being able
22 to speak to the details or even on the phone,

1 it is very helpful. And I think you learn
2 more. I think it informs their process. I
3 think it is good. I think we can be
4 professionally candid about the things and
5 deficits that we see, that they have to be
6 addressed.

7 CO-CHAIR GOLDEN: Bill?

8 MEMBER TAYLOR: I think that there
9 is a difference in how some of the measure
10 developers, though, interacted with the group.
11 And I really appreciated yesterday when you
12 guys, as the chairs, would interrupt their
13 interruptions of the workgroup's conversation.

14 I think that there are times we
15 need to hear from them but I think there are
16 times that our conversation needs to come
17 first.

18 So, I think that is important that
19 you set that tone yesterday. And I don't
20 think that we were intimidated by their
21 presence. I think there was one group that
22 was pretty forward in their arguments. And

1 that is okay but I think by setting the tone
2 that our conversation needs to happen first I
3 think was really important.

4 CO-CHAIR ROSENZWEIG: Well, I do
5 recall one incidence in which you were
6 presenting a case in which your former boss
7 was sitting over here looking directly at
8 your.

9 MEMBER BREEN: Yes, good stuff. I
10 like that.

11 (Laughter.)

12 CO-CHAIR ROSENZWEIG: And I'm not
13 saying it was --

14 MEMBER BREEN: No, good stuff.
15 But anyway, this is what we all have to do.
16 And I think the moderators handled it very
17 well. I think groups this big and bulky have
18 to be well moderated.

19 And I think you said yesterday
20 don't panic if it takes us a gazillion hours
21 on the first measure because we will get
22 through it. So, at the time I was thinking

1 oh, maybe this needs to be more aggressively
2 moderated but I think we needed to go through
3 that process.

4 So, thank you for saying it will
5 take so long because it did.

6 CO-CHAIR ROSENZWEIG: One other
7 issue I would like to bring up is that we are
8 kind of in an age now when there is going to
9 be progressive proliferation of measure sets
10 to a certain extent. And a lot of these are
11 going to be very similar to each other or
12 overlapping in a lot of different ways.

13 Does the committee have the right
14 to kind of screen the measures? Let's say if
15 there is another measure set that is basically
16 very similar, only with slightly different
17 language to the other set, do we have the
18 ability to kind of screen them and say well,
19 we have already covered this in another
20 measure set?

21 MS. TIGHE: Yes, so we have moved
22 to standing committees for several reasons.

1 One is the steep learning curve that you have
2 described in applying the criteria to the
3 measures. Another is the idea that we would
4 like you to take ownership of the portfolio.
5 And so to understand where there are measures
6 that are potentially competing with each other
7 or very highly related to evaluate them
8 independently against the criteria and then
9 really to make an overall assessment of
10 whether we need both of these measures and if
11 not, which one we don't need.

12 So we do want to make sure, of
13 course, that they both meet the criteria. It
14 wouldn't be the first one in is the one that
15 we keep necessarily. But yes, we would want
16 you to make that determination.

17 CO-CHAIR ROSENZWEIG: Okay, thank
18 you.

19 MEMBER DUDL: I'm going to make a
20 statement that I think might make this meeting
21 flow better. We could -- could it be possible
22 that once we are assigned what we are supposed

1 to do, we get a template from you about the
2 exact items we are to present?

3 For example, the issue was well,
4 give us a quick review. Well what does a
5 quick review mean? And when we go into each
6 section, how much is that that we would fill
7 that out, send it back to the staff, and like
8 Karen Johnson was fantastically helping me
9 because it was interesting, we use grade for
10 implementation and you don't. And I was going
11 to present grade until she explained how
12 everything works out. And then you send it
13 back.

14 And I think the whole thing might
15 just go a little quicker. We won't lose our
16 place and that kind of thing.

17 MEMBER MILLER: I had made up my
18 own little cheat sheet template as I went
19 through this when I started out because for
20 the first measure, I had no idea what I was
21 doing. So, I just thought make up a little
22 cheat sheet template that I could use then for

1 each of the measures.

2 I will say, too, just addressing
3 the NQF process, I was very impressed with the
4 amount of data that you provided to us that
5 the measure developers had provided to you.
6 I thought your system was very easy to
7 navigate, once we had that phone call.

8 I know Reva said at first that it
9 was going to be her default process to go
10 through a measure but I think that was one of
11 the most helpful things.

12 I also think that going forward
13 for other standing committees, before you have
14 that first call, the orientation call, I think
15 one of the reasons it was easier for me with
16 the orientation call was I had about a little
17 time, like half an hour or so that I looked
18 through the website and the home site of the
19 SharePoint to really look at some of the
20 documents.

21 So, I think if people have an
22 opportunity to encourage people to take an

1 opportunity to do that before the orientation
2 call.

3 MS. TIGHE: I'm going to just jump
4 in on your first comment. If you wouldn't
5 mind sending the document that you used to
6 prepare, that would be really helpful so we
7 can see where it matches and differs from our
8 own.

9 MEMBER MILLER: Sure. It is very
10 informal. You may be underwhelmed but I will
11 be happy to send it to you.

12 (Laughter.)

13 CO-CHAIR ROSENZWEIG: One other
14 thing. Can we assume that prevention of
15 diabetes is within the purview of this
16 committee or is that not within our --

17 MS. TIGHE: I think it falls under
18 our Population Health Committee but that
19 shouldn't restrict you all from certainly
20 identifying it as an area where we need
21 measures.

22 DR. BURSTIN: And if you look at

1 the bubble diagram, that sort of longitudinal
2 framework, it begins with prevention. So if
3 you think that there are important areas to
4 bring in, really like we sort of did with
5 osteoporosis yesterday, I think that is fair
6 game.

7 We do have a Population Health
8 Committee that does look more at sort of
9 general population screening. But again, if
10 it comes up and it is diabetes, because you
11 are a standing committee, we would likely
12 bring it to you for your input as well.

13 CO-CHAIR ROSENZWEIG: Another
14 thing is that I was really extremely impressed
15 with the expertise and diversity that was
16 represented in this committee.

17 I would hope that in the future
18 that as people turn over that they continue to
19 have certainly the diversity that is implied
20 here. I think we always have at least one
21 person who is a methodologist and one person
22 who has diabetes, who can represent people who

1 have diabetes and also, a pediatric person.

2 So, I just think that that is very
3 important. I didn't know if when you created,
4 when you selected the members, whether or not
5 you had all of that in mind but I assume that
6 you did.

7 DR. BURSTIN: Yes, when we do our
8 slates, we very much think about it as a bit
9 of a Noah's Ark. We need some of those, and
10 some of those, and some of those to really get
11 the fully multi-stakeholders. And again, a
12 special thanks to NI. I think it is again,
13 just so important to have the voice of the
14 patient here. The purchaser, the health
15 plans, all of you together makes it a dialogue
16 that, on our own, we just tend not to get
17 quite that rich a dialogue.

18 MS. TIGHE: Maybe we can make a
19 policy for when you go off the committee, you
20 find your replacement.

21 (Laughter.)

22 MEMBER SHWIDE-SLAVIN: I wanted to

1 make a suggestion that maybe if you had a
2 tutorial available on a 24-hour basis with
3 that sample measure and a lesson how to go
4 through it. That would also be a way that
5 would sort of help the learning curve.

6 MEMBER McCOLLISTER-SLIPP: Or just
7 maybe like the objective of a particular
8 section. I mean I am glad that everybody else
9 was a little confused as they went through it.

10 One thing that I think that would
11 be really helpful, and maybe this is more
12 obvious to the others in the room, but what is
13 the intended objective of each measure?
14 Because that will determine a lot about how
15 you think about the evidence presented and the
16 specificity presented.

17 So, I mean I found that to be
18 confusing because I wasn't sure if I was
19 judging -- if I was creating a measure for a
20 hospital like for uses or a group of
21 physicians who may be, as part of an ACO, if
22 it would be for an individual physician, if it

1 would be for a health plan. And I understand
2 that once we decide on something and it gets
3 ratified, et cetera, that it can be used for
4 lots of different things. But in terms of
5 your framing of the issue, it would be really
6 helpful to know what the intended objective
7 is.

8 And I can follow most of the
9 acronyms because I am in D.C. and a nerd and
10 have all the complications but it would be
11 helpful to have at least one reference to what
12 the full acronym means as well.

13 CO-CHAIR ROSENZWEIG: I think that
14 is an excellent point. Most templates for
15 measure sets usually have like a rationale at
16 the beginning, especially if you require that
17 it be in lay language as well, I think that
18 would be helpful.

19 MS. JOHNSON: Right. And just to
20 make sure that you get some of our jargon
21 here, we use the term level of analysis to
22 signify if it is a health plan measure versus

1 a facility measure, versus a clinician
2 measure. And that is actually, if you go back
3 and look at your first page that has that kind
4 of brief description of the measure, that is
5 on there toward the bottom. It is called
6 level of analysis. So, that is where that is
7 located.

8 MEMBER MCCOLLISTER-SLIPP: Maybe
9 if -- and again, maybe this is impossible.
10 Maybe it is an unknown at this point. But I
11 mean I saw that part of it and I certainly
12 thought of that, which was helpful. But like
13 is this a reimbursement issue? Is it an
14 incentive issue? Is it a readmission? I
15 mean, we didn't get into any of that stuff
16 today. But how will this actually be used on
17 the field, once it is ratified? I mean how
18 are we measuring? How is this going to be
19 used and implemented?

20 MS. TIGHE: I know Helen spoke to
21 this a bit yesterday, so maybe she will speak
22 to it again more. But we are certainly, we do

1 understand that it is hard to divorce the
2 intended use of the measure from the
3 endorsement of the measure. And so, it is
4 something that we are, as an organization,
5 trying to visit and understand how we can link
6 the use of the measure to the endorsement of
7 the measure. Right now, it is endorsed just
8 generally for all of the purposes under the
9 sun. And then our MAP team takes it and looks
10 at it for use in specific federal programs.

11 Our Board has certainly indicated
12 that we need to move in this direction. And
13 so that is something that we are continuing to
14 explore.

15 MEMBER KIRKMAN: Just to make it
16 clear, it is not up to NQF to say this can't
17 be used this way or can be used or should be
18 used this way or whatever. Right? It is just
19 sort of the developer presents it and they
20 sort of say in general this is why they want
21 it and what it might be used for, but after
22 that, it is not really up to you all or we

1 all.

2 DR. PACE: Well, we endorse the
3 measure as specified. And under the premise
4 that the measures that we endorse are suitable
5 for accountability applications, in addition
6 to improvement, I mean that is the whole goal
7 of any of these performance measures, but
8 beyond on that -- so, we, from an endorsement
9 standpoint, we would expect it to be used as
10 specified and endorsed. But we don't have
11 control when it gets implemented.

12 DR. BURSTIN: Although in some
13 ways, it does present a bit of a backstop for
14 end users to be able to push back and say
15 well, this was really endorsed at the health
16 plan level. Why is it being applied at the
17 clinician level? And then to go back to the
18 evidence to say there was an evidence support.

19 So, I think some of this it can be
20 used in that way. And that is why I think the
21 more we would like to see those decisions
22 about use is really driven by science. And

1 what you guys have spent a lot of time talking
2 about over the last couple of days of when
3 does a measure logically fit at the clinician
4 level, for example. When is it appropriate
5 for payment, for example, versus quality
6 improvement.

7 So, more on that to follow. We
8 will definitely be reaching out to you as we
9 kind of think through those next steps.

10 CO-CHAIR ROSENZWEIG: So, once a
11 measure set is approved and is implemented,
12 the measure developer doesn't have to come
13 back to you with outcomes until they present
14 the measure again for renewal?

15 DR. BURSTIN: That is correct.
16 They come back in three-year maintenance.

17 Now, we do have something called
18 our ad hoc process, which at any point during
19 the time when a measure is endorsed, if there
20 is either a change in the evidence that would
21 substantially affect the measure or any
22 evidence of unintended consequences, we would

1 immediately re-review the measure. So, we do
2 have that as our sort of backup, particularly
3 for changes in evidence, which happen, as we
4 all know. That is why we have delayed the
5 lipid measures a fair amount.

6 So, we recognize that it is just
7 not static to assume that this won't change.
8 And three years was the number we picked,
9 frankly, because it mirrors the usual
10 periodicity of guideline development as well.
11 So, it seemed like the logical number. But if
12 something happens more acutely or there is
13 evidence of unintended consequences, we will
14 review it again.

15 CO-CHAIR ROSENZWEIG: Any other
16 comments?

17 MEMBER KEARNS: I just had another
18 comment on a different topic, we are okay with
19 that.

20 I found that I had a hard time
21 finding the SharePoint site. What I wanted
22 was to be able to log in to NQF, go to my

1 dashboard, boom there is the SharePoint. I
2 click on it. Instead of that, I had to kind
3 of keep that link separate because I didn't
4 really know how to find it. I looked all
5 over.

6 So that is kind of a technical
7 thing. I wanted to have my dashboard really
8 drive everything and I don't know what the
9 answer to that is.

10 The second comment is I thought
11 the travel arrangements were fantastic. It
12 was very easy to make the reservations for the
13 flight, the hotel. All of that was very easy
14 from my end. Thank you.

15 MEMBER BREEN: I enjoyed the
16 cookies. Thank you very much.

17 (Laughter.)

18 CO-CHAIR ROSENZWEIG: Yes, Bill?

19 MEMBER TAYLOR: I also really
20 appreciate how much staff support there was
21 that I felt very well taken care of. I also
22 felt very lost at the beginning and sort of

1 mired in jargon that I was unfamiliar with
2 about what the process was. I'm not sure how
3 to do it better to get us up to speed because
4 I think we all got there but the start is
5 hard.

6 But the amount of help, whenever I
7 needed it, was unbelievable. And the
8 responsiveness of anybody that I got in touch
9 with I'm looking especially at the Board was
10 just phenomenal. So, I deeply appreciate
11 that.

12 I also appreciated that we started
13 with the attention to conflict of interest
14 about all of us and were explicit about that.

15 I am still a little lost about I
16 have a sense of all of us, of where we are and
17 where we come from. I have less of a sense of
18 NQF and where does it come from. And now that
19 we have all been in the midst of it, maybe
20 everybody else is more sophisticated about
21 that. But where does the money flow? Who
22 paid for our salmon and all of that and our

1 plane tickets and so on is now of more
2 interest to me, having participated and being
3 a part of this.

4 But I am extremely impressed by
5 how well-run the whole operation is from what
6 I have seen of it.

7 DR. BURSTIN: Well, thank you. We
8 have great staff, certainly, and appreciate
9 the comments.

10 At this point, the overwhelming
11 majority of all of our endorsement work is
12 funded by the federal government. It is
13 funded through a contract with CMS. We do
14 still have some dollars from foundations and
15 from our membership dues, from our
16 organizational members but, overwhelmingly, it
17 is funded through CMS.

18 So, I think we actually buy the
19 cookies and things. The salmon is ours, which
20 is why it is all family style. When we moved
21 to this building, we intentionally set up this
22 room so that we could avoid all the hotel

1 lunches for \$45 for a sandwich and so we can
2 use local caterers and get good meals and good
3 deals. And it is just a lot more comfortable.

4 So, thanks.

5 MEMBER McCOLLISTER-SLIPP: I guess
6 Bill has left, so we are not going to get the
7 brandy.

8 (Laughter.)

9 MEMBER McCOLLISTER-SLIPP: But
10 just from a philosophical -- I mean this is
11 more of a philosophical -- maybe this isn't
12 the best form for it but from a patient
13 perspective who thinks that we have a long way
14 to go in terms of establishing good meaningful
15 quality measures, especially for those of us
16 with Type 1, I found it slightly depressing
17 when I looked at all the documentation
18 required. And I know that sounds kind of
19 silly because you do want this to be science-
20 based and you do want -- I mean I understand
21 the need for all of it. But I think and maybe
22 this will be answered in the incubator thing

1 that you were referencing yesterday, Helen, I
2 think it would be great and I feel some sort
3 of a need of this committee or some forum to
4 be able to articulate a path forward for new
5 measures. Because I mean hemoglobin A1c is
6 based on the science from what, 40 years ago.
7 It was endorsed 20 years ago. And we need to
8 have a way of encouraging, directing,
9 incentivizing, whatever, the development of
10 new measures that take into account all of the
11 things that we have learned with the great
12 science that has been done, with all the
13 studies that we do have, and with new
14 technologies like continuous glucose monitors
15 as a mechanism for doing different types of
16 measures.

17 I don't know what the answer is.

18 DR. BURSTIN: It's a great point.

19 And actually one other issue I will raise
20 because this is a committee where we do have
21 periodic opportunities for submission. The
22 other thing is we often don't get, for

1 example, some of the measures some of you and
2 your health systems are using on the ground
3 that you have found incredibly valuable or
4 that patient groups have come up with. So,
5 the question is really how do we work with
6 those.

7 And so that is part of the idea of
8 the incubator as well. So, for example, if
9 Kaiser or UNC has a great measure that works
10 perfectly well in their system, can we bring
11 that to the incubator, bring the right
12 resources together to create, to pull it into
13 a national standard and get all the rest of
14 that work done. Because we do recognize there
15 is a lot of innovation out there that is just
16 not coming our way and some of that is because
17 of the burden.

18 And I see Patricia's card is going
19 up. There is a fair amount of burden
20 associated with being a measure developer and
21 submitting to NQF, which is why we want to try
22 to create those partnerships.

1 DR. PACE: But I think that leads
2 to a question. Would you drop any of the
3 criteria that we have, thinking about these
4 being used in an accountability application?
5 Because it is a question that we get about,
6 you know our discussion about the burden.

7 And so basically, to reduce --
8 sometimes developers provide more information
9 than we ask for. If you looked at our
10 examples of what good looks like, we really do
11 have examples of concisely providing the
12 information we want. So, that is part of it.

13 But in general, in order to reduce
14 what we ask for submission is to maybe
15 eliminate some of our criteria.

16 So, I am just curious after having
17 gone through this if there is something that
18 you think is well, maybe not that necessary
19 that we should at least be thinking about.

20 CO-CHAIR ROSENZWEIG: Yes, Bob?

21 MEMBER BAILEY: I would advocate
22 that the criteria that you have are good.

1 Coming from a consumer standpoint as well,
2 very often implementing these measures at a
3 large scale are not unlike a controlled
4 clinical trial, where it needs to go through
5 an IRB to make sure that the evidence suggests
6 that there may be a benefit. You talk about
7 the potential threats, the unintended harms.
8 It is very comforting to know that this is the
9 case. But I can't think of anything that I
10 would eliminate here.

11 CO-CHAIR ROSENZWEIG: Janice?

12 MEMBER MILLER: I would like to
13 just say that I really liked that this morning
14 when we were talking about the diabetes
15 education for the foot exam, we didn't have a
16 really strong body of evidence. But I really
17 liked that we could say it was insufficient
18 evidence with an exclusion. And I just think
19 that that is also the path to go for overall
20 diabetes education measures, that it may be a
21 long time until we have a very homogeneous
22 type of education that we can evaluate.

1 But if we can have something like
2 that, it is very intuitive but we just don't
3 have evidence. So, I think if we could do
4 that with an exclusion, that would be superb.

5 MEMBER McCOLLISTER-SLIPP: Yes, or
6 some way of just appending things, so that it
7 is not just an up or a down. I mean, some of
8 this stuff is like yes, I want everyone to
9 have a retinal exam but I mean that is how I
10 probably kept a large part of the sight of my
11 right eye, just a regular retinal exam.

12 But we need to come up with better
13 ways of tracking it or what exactly -- just
14 some of those questions, I think if there is
15 a way of incorporating either nuance or
16 further recommendation or perhaps even a
17 provisional recommendation or a provisional
18 approval with a recommendation for additional
19 studies or additional clarification because I
20 don't want to be a progress to encouraging and
21 incentivizing good care. I don't want to get
22 in the way of that. But at the same time, I

1 would be a little uncomfortable on some of the
2 stuff just pushing forward with the way that
3 is stipulated.

4 CO-CHAIR ROSENZWEIG: Patricia,
5 did you have a comment?

6 MEMBER McDERMOTT: I was just
7 going to comment on you require a great deal
8 of due diligence in order to present a
9 measure. Within Aetna, we have developed lots
10 of measures that are truly Aetna-defined. We
11 are using clinical evidence and we are using
12 valid reasons and good code.

13 One of the other things that
14 didn't come up here was maintenance of code.
15 Now, the measures that we have talked about
16 don't have a whole lot of -- if you are
17 looking at the class of a drug, you don't have
18 to worry about individual NDC codes or CPT-4
19 codes for example. But that is another thing
20 that is important is the maintenance of those
21 measures.

22 But going back to the concept of

1 submitting a measure, I mean I need to have a
2 whole PhD staff in order to present all the
3 documentation that would demonstrate to all of
4 you that the things that we have done are
5 valid.

6 We have done our due diligence to
7 look at variability. We have put them out in
8 the market. We know how our doctors respond.
9 It has been positive. We know we are showing
10 differences. But for me to bring those things
11 and present them here, again, I need a staff
12 to be able to do that.

13 So, I don't know how you change
14 that paradigm. The only the other thing that
15 I would say about some of the measures we have
16 talked about today that are only for a
17 specific population but they are obviously
18 generalizable to a very large population. The
19 only thing that I would encourage is that when
20 we do get a measure that we know has been only
21 researched on a small population but is valid
22 for that larger population, that we try to

1 figure out a way to get that in the
2 specification. Because, unfortunately, we
3 also have people that if we take the measure
4 and we take it slightly -- it is only supposed
5 to be for this or it is only supposed to be
6 for that, if we add that pregnancy exclusion,
7 for example, or say if it is 40 and above,
8 then the measure is valid. But then we have
9 deviated from the NQF standard that has been
10 approved, so we get a slap on the hand.

11 So, it is an interesting paradigm
12 what is going on within measurement. And you
13 are a very powerful organization, very
14 powerful.

15 MEMBER LEE: I had a question on
16 how the developers actually developed the
17 measurement. Is there sort of a letter of
18 intent or is there an intermediary feedback
19 process, for example, the measure I had, in
20 terms of getting voted on, the insulin was
21 sort of the point at which it got halted and
22 perhaps could have pre-screening or some sort

1 of mechanism could speed along the efficiency
2 of which we are able to evaluate these
3 measures?

4 MS. TIGHE: Yes, so I can speak
5 briefly to that. And we are trying to figure
6 out ways where we can get the right measures
7 that are going to meet our criteria into our
8 process. And so part of this we held an event
9 in September. It was collaborative. It
10 involved our developer colleagues, federal
11 partners and our staff. And we asked that
12 exact question. How can we get this feedback
13 while the measure is being developed, so that
14 when it comes to NQF for endorsement, it is
15 meeting our criteria and then can be put out
16 into use pretty quickly.

17 So, Karen actually probably can
18 speak to us because she is working most
19 directly with the group that is still focused
20 on this effort. But one of the things that
21 they are trying to address is by bringing the
22 patient involvement into the development

1 process in a more significant way, so that
2 they are getting this kind of feedback as they
3 are developing the measure.

4 Some other things that we are
5 working on are providing a way for them to
6 kind of check in with NQF about whether or not
7 their testing plans are appropriate. That
8 actually really was less of an issue for the
9 measures today. But we do often get measures
10 that meet the importance criteria and that are
11 considered reliable by our committees.

12 So, we are trying to work with
13 them upstream as they are developing the
14 measures, rather than having our process be at
15 the very end once all the development dollars
16 are spent.

17 MEMBER BREEN: I mean I would hate
18 to add anything more to this agenda because it
19 is a very ambitious agenda that we have just
20 got there. But it might be interesting to get
21 a little preview of things that are in the
22 works like that while you have this critical

1 mass of expertise in the room. And again, you
2 don't want to sway things too much but it
3 might be useful for people to be able to pitch
4 an idea or whatever that they are working on.

5 DR. PACE: And each of the
6 developers has their process and advisory
7 committees. But oftentimes, things are raised
8 when it comes to NQF that, for one reason or
9 another, weren't raised in their development
10 process. So, it is always interesting and we
11 have toyed with different ideas of how to have
12 earlier input but it has been challenging.

13 CO-CHAIR ROSENZWEIG: I mean as a
14 Steering Committee, I think it would be nice
15 if we had like time to reserve or be able to
16 reserve a certain amount of time to discuss
17 potential candidate measures that we would
18 like to see come our way in the future.

19 Now, you have this wonderful
20 newsletter that you sent out that I get all
21 the time. And at least in theory you can
22 include candidate, potential candidate

1 measures that NQF itself is interested in
2 considering.

3 Sue.

4 MEMBER KIRKMAN: I've almost
5 forgotten what I wanted to say. But I agree
6 with Anna that we do want new measures but I
7 am not sure that we just want more measures.

8 So again, I think we also need to
9 be thinking about how to sort of drop
10 measures. And I actually think for
11 accountability measures, if things are going
12 to get publicly reported, I think it does need
13 to have a high bar and be very rigorous. So
14 I actually don't think I would change too much
15 about -- I certainly wouldn't drop any of the
16 criteria. Because I think when you are
17 talking about something that is going to be
18 out there for everybody to see, you don't want
19 kind of a bad measure.

20 And similarly, we don't want to
21 come to this meeting and review 12 measures
22 and only approve two of them. So, I think you

1 need to keep the quality pretty high.

2 But the other thing I wanted to
3 say was just I would, and maybe you all have
4 already done this, but I would just love to
5 continue this discussion of how do you move
6 increasingly toward individualization of care
7 and yet be able to measure quality, which kind
8 of by definition you have to sort of bucket
9 large groups of people into the same bucket
10 and say that the same thing should happen to
11 them. And I just think that that tension is
12 just going to get greater and greater with
13 time.

14 MEMBER McCOLLISTER-SLIPP: And as
15 a patient, I mean I think that is really,
16 really critical. I mean, and I don't know
17 what the answer is. You guys are smarter than
18 me when it comes to this stuff but we have got
19 to come up with a way to incorporate into
20 policy and incentives outliers and the need
21 for individuality and care. Otherwise, it
22 creates all sorts of unintended consequences

1 that are pretty negative.

2 DR. PACE: So, one way that people
3 talk about that has maybe more merit is really
4 focusing on outcomes and including patient
5 reported outcomes. Because then you are not
6 so focused on process. You are focused on the
7 provider using their best process to get the
8 best results.

9 Now of course, we have risk
10 adjustment issues but that is one advantage of
11 outcomes because it frees you up from having
12 to precisely specify the process and expect
13 that everyone has to deliver the same process
14 the same way to every patient.

15 And again, I think we should have
16 more of those conversations in this group.
17 But I think that is certainly one advantage of
18 outcomes and patient-reported outcomes that we
19 have a lot of need for.

20 CO-CHAIR ROSENZWEIG: Yes, Jessie?

21 MEMBER SULLIVAN: I just wanted to
22 follow-up on that. I do think that that

1 underscores, the patient-centeredness
2 underscores the contradiction we were talking
3 about when we were looking at the statin
4 measure. And there is a certain bluntness to
5 our measure. And I think there is no question
6 but that it is directionally correct to look
7 for adherence in a Medicare population who
8 have been started on statins. That is the
9 bigger problem.

10 But when you get down to the
11 individual physician level, and okay, it is
12 not specified for the individual physician but
13 that doesn't mean it won't be applied that
14 way. And when you get down to that level, the
15 fact that someone has two patients who should
16 be excluded, they have done the right thing,
17 it is just extremely irksome and it makes it
18 very hard to --

19 So, I think it is a contradiction.
20 And one of the things that I think might be
21 helpful is if in publishing the measures as
22 they are, some of that could be teased out in

1 a comment. And it isn't. I mean, it is
2 buried in the specs but we know the specs
3 aren't always going to be followed exactly.

4 So, if in the specs it says this
5 was built for Medicare and the issues that
6 might apply if you use this in a non-Medicare
7 population are, statins aren't always
8 indicated in younger people. They are
9 contraindicated in pregnancy. Some people
10 with low incomes may be buying their
11 prescriptions.

12 So if just some of the things we
13 identified were in a signing statement, it
14 would alert people if they start using the
15 measures in different ways.

16 MEMBER McCOLLISTER-SLIPP: Or
17 perhaps even statements about inherent biases
18 within population groups. So, I mean again,
19 not to harm on erythropoietins but I want to
20 take a erythropoietin and have a hemoglobin
21 over 11 because I want to go to the gym five
22 times a week, not like struggle to get there

1 once. And the population that was measured
2 for that particular outcome was probably not
3 looking at getting to the gym five times a
4 week.

5 So, there needs to be some degree
6 of consideration for what is the population
7 that was studied to support this measure
8 versus what are the real life applications
9 that are going to happen based on the fact
10 that we have endorsed this measure?

11 You know, similar with hemoglobin
12 A1c in some respects.

13 MEMBER BREEN: I think what we are
14 all trying to say is rather than just that up-
15 down vote, we would like the outside people to
16 know the very robust conversations what we
17 have had with some summary statement.

18 I have always found that all these
19 expert groups put out opinion statements. But
20 what I find interesting is not the statement
21 but the back story, the discussion that went
22 on there when people either write an addending

1 article or something to say this is the
2 discussion. That is where the real
3 interesting stuff comes out. So, I think that
4 having a comment field or just some group
5 comment, yes we have passed this measure and
6 this is some of the concern that the committee
7 had would be an interesting -- but I don't
8 know if that happens right now at all.

9 So, I think that is what we are
10 looking for.

11 MS. JOHNSON: That does happen to
12 some extent. We usually have pretty detailed
13 notes of what happened in the committee
14 because that is our way of kind of showing
15 posterity what was discussed.

16 DR. PACE: But I think this is
17 consistent with other things that we have been
18 talking about and thinking about
19 implementation guidance, something that has
20 come up very similar to these suggestions in
21 our risk adjustment panel is really being
22 explicit about how the measure was -- the

1 endorsed specifications, what patient
2 population, what setting, what level of
3 analysis, risks of misuse.

4 So, I think you will see some of
5 those recommendations that maybe resonate,
6 even though that is specific to risk
7 adjustment. Some of their recommendations
8 really have applicability to some of the
9 things you are also mentioning.

10 MEMBER DUDL: I want to support
11 your idea of going with outcomes. If we went
12 for heart attacks and strokes in the diabetic
13 population, some groups will use titration.
14 Some will use initiation. Some will use
15 adherence to ACEIs or statins or whatever
16 works.

17 Far more powerful, far more
18 driving, and far more simplistic, yes, it
19 can't be used at the individual level, this is
20 the health plan level, but it could be the
21 single most powerful driver and it eliminates
22 all this issue of process. I think you are

1 right on and I would keep feeding that back to
2 the people who give you or ask you advice or
3 give you measures.

4 CO-CHAIR ROSENZWEIG: Okay. Any
5 other comments?

6 MEMBER DUVA: I just wanted to
7 give quick feedback, jumping back to the
8 evidence. We had a long conversation about
9 evidence. I thought the algorithms that you
10 gave us were very helpful to keep us all on
11 the same page, so I just wanted to say that.

12 The other thing I thought was
13 interesting and I am not a psychologist or
14 group process expert but I really think that
15 because we started with the measures that have
16 been in use, that our assessment of the
17 evidence was less critical for the measures
18 that have already been in use that we are kind
19 of used to now, hemoglobin A1c that has been
20 reported.

21 And then when we were identifying
22 the evidence and its exact applicability to

1 the new measures, we were a little bit harder
2 on those measures. And I am not saying that
3 is a good bad thing. I just say it mostly
4 because Sue keeps bringing up like when are
5 measures going to get dropped. When have we
6 kind of been there done that with a measure?
7 I think it is going -- if that is the group
8 thing, just that is a natural thing way to
9 think about it might be kind of hard. I don't
10 know.

11 DR. PACE: Along those lines, I am
12 just going to throw out a question to all of
13 you because we had a little bit of a surprise.

14 So, along these lines of retiring
15 some measures, moving on, we had that
16 situation yesterday with continuing to report
17 on whether hemoglobin A1c test was ordered
18 once a year or not just ordered but given once
19 a year, when we had that embedded in measures
20 that were actually about the results.

21 So, I guess we would just like to
22 hear more of your thinking about why you felt

1 that was necessary to continue that measure,
2 especially in light of some of the
3 conversation we have just had.

4 MEMBER DUVA: Just real quick I
5 want to say that my impression was that we
6 passed it here but it would come back up when
7 we talked about harmonization and which
8 measures were redundant. Is that not coming
9 back up again?

10 Because I feel like we didn't
11 necessarily finish the conversation.

12 MS. JOHNSON: I kind of wondered
13 if maybe --

14 MEMBER DUVA: That was my
15 impression.

16 MS. JOHNSON: Yes, so the only
17 thing that you would be looking at in a
18 harmonization throwing stuff out later on
19 would be a head to head competing measure.

20 So, am I not saying that right,
21 Karen?

22 DR. PACE: That is exactly right.

1 I was just going to say we hadn't really
2 thought of harmonization or competing measures
3 in that way. So, it is just something we need
4 to kind of maybe rethink about. But that is
5 a good observation.

6 We have thought of it more if
7 there was another measure specifically about
8 measuring hemoglobin Alc, not the issue of
9 that is actually embedded in another measure.
10 So, that is an excellent observation that we
11 need to think of in our process.

12 MEMBER BREEN: But I think those
13 measures were also different. I mean the
14 measuring of an Alc is a pure process measure.
15 Do you do just the basic stuff? The other two
16 things told you different things about the
17 care of your patient. So, I don't think that
18 those are necessarily redundant. I mean I
19 don't need to rehash yesterday's discussion
20 but I think in my mind, those were actually
21 similar but different issues.

22 MEMBER DUVA: True, but we didn't

1 really finish the conversation of putting them
2 altogether. You know, we did a little bit
3 more today where we said are we looking at
4 these together or separate? Because there are
5 some things that you might consider. And
6 maybe it is that they are different enough
7 that you keep the process measure when you
8 have got an outcome measure but I didn't feel
9 like we finished that conversation.

10 MEMBER BREEN: We did not finish
11 the conversation.

12 DR. PACE: No, that is helpful to
13 us. That is why we wanted to ask because we
14 obviously haven't framed it that way and we
15 need to think about it.

16 MEMBER BAILEY: I think some of
17 the other considerations also were the sample
18 size, the availability of the data. And I
19 think Jessie had provided the example
20 yesterday in terms of so you have a sample of
21 400 patients, for instance, that may or may
22 not involve a specific provider. So, they are

1 not able to give feedback first of all how
2 they are performing but more importantly,
3 develop actionable lists for people to act
4 upon. Where if you had a larger sample, like
5 administrative claims, then you can go back to
6 Dr. Bailey and say, okay, you have got these
7 15 people who haven't values within the last
8 year.

9 MEMBER SULLIVAN: If I could just
10 underscore that about how we use these
11 measures in our Medicaid health plan.

12 So, when we have -- we used to
13 have more leeway than we have now to create
14 our own measures as Aetna does. But now the
15 Medicaid Office of the Inspector General of
16 New York would get on us if we used non-NQF-
17 endorsed measures or measures that haven't
18 been endorsed. So, our hands are a little bit
19 more tied in inventing our own measures.

20 And the screening measure, we use
21 it as a composite. We look at nephro, eye
22 exam, and A1c and LDL. We look at them

1 together and we create a denominator of every
2 patient in the health plan who meets the
3 criteria for diabetes, regardless of time of
4 enrollment. And then we send those names to
5 every primary care doctor in the health plan.
6 So, we are putting in front of them a list of
7 all their patients with diabetes.

8 If we were just restricted to the
9 chart review measure, we wouldn't have a
10 measure that allowed us to do the outreach
11 around the broader population that has
12 diabetes. So, it would really harm our
13 quality improvement work if that measure -- I
14 mean the way we use it, it could be composite
15 of those four measures wouldn't hurt us. But
16 that denominator of the patients who just have
17 diabetes and have not been in for service is
18 really critical.

19 So, you would do harm to us, the
20 work we do if you took that measure away.

21 CO-CHAIR ROSENZWEIG: Sue?

22 MEMBER KIRKMAN: So, I understand

1 that about this measure, although I was one of
2 the people, maybe I was the only person that
3 voted to drop it. But I do think we -- and I
4 think it is really hard to drop things but I
5 think we are going to have to continue to
6 wrestle with this because there are so many
7 performance measures in diabetes and there are
8 so many -- and the primary care people in the
9 room can say this. I mean there are so many
10 performance measures about everything and we
11 don't want to just keep adding more and more
12 and more.

13 And I brought up the thing
14 yesterday about you know so if you are
15 collecting this data, then you are not
16 collecting something else. And I agree it is
17 an easy one to collect but I just think we do
18 have to be more open to dropping measures,
19 even though it is hard to do. Because we all
20 kind of think about well, there is some
21 benefit and that is going to be true of pretty
22 much any of them.

1 MEMBER McCOLLISTER-SLIPP: That
2 kind of gets to my point, though. And I
3 completely understand what you are saying and
4 the last thing we want to do is add additional
5 burdens for PCPs and endos because that is a
6 huge issue. But I mean if the intent is to do
7 public reporting for consumers to eventually
8 be able to judge, that is going to be one of
9 the things that they specifically look for,
10 that they will know to look for; whereas,
11 statin, ACEI versus ARB, or whatever, might be
12 a little bit more abstract.

13 I mean we now have gotten to a
14 point, which is very different than we were
15 five, seven years ago, where people kind of
16 get that as a measure that they need to go
17 for.

18 So if they are looking at a quick
19 cheat sheet of is this doctor any good and he
20 has a low score for testing for hemoglobin
21 Alc, then that is a pretty good thing that
22 somebody who is not nerdy enough --

1 MEMBER KIRKMAN: Yes, but it is
2 only going to screen out about seven percent
3 of the doctors because the adherence is
4 something like 93 percent or something.

5 And you could probably screen
6 people on other measures. I mean it is
7 probably concordant with other things.

8 DR. BURSTIN: I think part of what
9 we are also -- I think what we also see is
10 that committees tend to be hesitant to take
11 something away when there is not something
12 else better there. And that has come up a
13 fair amount.

14 So for example, I chair the
15 Quality Measures Workgroup for the Health IT
16 Policy Committee. And I was going back and
17 forth yesterday with my friends at ONC saying
18 so, what is up? Anything new on the EHR space
19 for diabetes? And they have looked at, for
20 example, doing delta measures of where you
21 start an A1c and where you wound up. There
22 are so many issues of figuring out where the

1 baseline is, which follow-up, et cetera.

2 So, they are exploring all these
3 new ideas, which is why I think it would be
4 wonderful to have this group give input. One
5 thing to start thinking about is could you do
6 something like time and therapeutic range in
7 a given year. So, you actually get a more
8 meaningful number which you can do with
9 electronic data that you can't do with this
10 sort of forced cut point.

11 So, I think the more time, now
12 that you are a standing committee, we can
13 actually work with you on sort of the future,
14 I think will make it easier to let go of the
15 past. Because I think it is kind of hard to
16 let go of what you have when there is nothing
17 else there, particularly to Anna's point,
18 where people are wanting some meaningful
19 information to use.

20 You know the health insurance
21 exchanges have been trying to put data into
22 measures for people with chronic illness.

1 There is just not a lot available, as people
2 are searching.

3 MEMBER TAYLOR: The idea of
4 getting out not only the final recommendation
5 that comes out of the standing committee but
6 something about the rationale for how we got
7 there would actually help a lot for issues
8 like getting rid of measures that we think are
9 outdated.

10 I think there was a discussion
11 yesterday sort of offline about the foot care
12 measure, where we talked about gee, if you
13 vote that down, people will misinterpret it
14 and think that foot care is not important, as
15 opposed to it is already being accomplished at
16 a high level and so on.

17 But if there were some place
18 prominently to say this is why we did what we
19 did so that anybody -- I'm sure most of the
20 people who use this are not going to be nerdy
21 enough to want to go find those details. But
22 if a discussion is happening somewhere about

1 how are we going to apply this or what did
2 they mean when they did that, if it was easily
3 accessible, it would make us feel less worried
4 about voting certain ways because there were
5 unintended messages that we didn't intend to
6 deliver and so on. We could say what the
7 message is.

8 You know we talked about excluding
9 pregnant women with statins but we didn't
10 worry so much because it was Medicare or
11 whatever it is. If we could say that
12 somewhere that people could get access to, it
13 might help us to try to actually adhere to the
14 evidence and say something that we could feel
15 proud of.

16 MS. JOHNSON: So, this may be
17 something that we will ask you to help us
18 with. We actually do include those kinds of
19 details in our current printed written reports
20 but they are, you have to get into the weeds
21 to see that kind of stuff. And we are trying.
22 And another thing that we are experimenting

1 with is changing our report format somewhat to
2 include all that detail but also include more
3 high-level things.

4 So usually, we provide those draft
5 reports to the committees and ask them to look
6 at them. And a lot of times, I mean you guys
7 are busy, but maybe the first one that we try
8 you might -- we might ask you to spend a
9 little bit more time than you might otherwise
10 do, since it will be our first one and see if
11 we are getting to where you think that would
12 be. And we haven't figured out what that is
13 going to look like yet.

14 DR. BURSTIN: Actually, building
15 on Karen's comment, it might be interesting to
16 actually send you one measure, the very
17 intensive display we usually put in and the
18 technical review reports. And then this idea
19 we have been having of how you try to get
20 exactly at what you just said. Almost an
21 executive summary of the measure, to Anna's
22 point earlier, why it is important. What does

1 this impact? What are the issues discussed?
2 Karen's laughing because she doesn't believe
3 you can do this in a couple of paragraphs.
4 But I think it would be really good for us to
5 be able to bounce that kind of thing off you,
6 even before we do all whatever it is, 20
7 measures and be glad you are not on
8 cardiovascular safety because they have about
9 60 measures. So, this isn't so bad.

10 CO-CHAIR ROSENZWEIG: Anyone else?
11 I think people still have their things up
12 without really wanting to comment any further.

13 Okay, well than you very much. I
14 think this was an extremely productive
15 meeting.

16 MS. TIGHE: Operator, if there
17 anyone on the line who would like to provide
18 any public comment.

19 OPERATOR: Okay, if you would like
20 to ask a question or make a comment, please
21 press * then the number 1 on your telephone
22 keypad.

1 And there are no comments at this
2 time.

3 DR. BURSTIN: Thank you to
4 everybody. We realize this is a huge
5 investment of your time. And especially
6 thanks to Jamie and to Bill for guiding us so
7 effectively.

8 So, thank you and safe travels
9 home.

10 CO-CHAIR ROSENZWEIG: Thank you.

11 MS. STREETER: And also just
12 quickly as for next steps, we will be sending
13 you the call information for the March 12th
14 meeting, where we will review 0416 and 0417,
15 the two APMA measures.

16 And I think that will be it. Oh,
17 and if you could, please complete the surveys
18 in either SurveyMonkey or we have paper copies
19 as well. That would be really helpful.

20 Thank you all.

21 (Whereupon, the above-entitled
22 matter 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: Endocrine Measure Endorsement

Before: NQF

Date: 02-27-14

Place: Washington, DC

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