

NATIONAL QUALITY FORUM

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IN-PERSON MEETING
PATIENT SAFETY STANDING COMMITTEE

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THURSDAY
JUNE 18, 2015

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The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:30 a.m., Ed Septimus and Iona Thraen, Co-Chairs, presiding.

PRESENT:

ED SEPTIMUS, MD, Co-Chair, Medical Director
Infection Prevention and Epidemiology
HCA and Professor of Internal Medicine
Texas A&M Health Science Center College of
Medicine, Hospital Corporation of America
IONA THRAEN, PhD, ACSW, Co-Chair, Patient Safety
Director, Utah Department of Health
JASON ADELMAN, MD, MS, Patient Safety Officer,
Montefiore Medical Center
CHARLOTTE ALEXANDER, MD, Orthopedic Hand Surgeon,
Memorial Hermann Health System
KIMBERLY APPLGATE, MD, MS, FACR,
Radiologist/Pediatric Radiologist & Director
of Practice Quality Improvement in
Radiology, Emory University *
LAURA ARDIZZONE, BSN, MS, DNP, CRNA, Chief Nurse
Anesthetist, Memorial Sloan Kettering Cancer
Center
RICHARD BRILLI, MD, FAAP, FCCM, Chief Medical
Officer, Administration, Nationwide
Children's Hospital

CHRISTOPHER COOK, PharmD, PhD, Director, Quality
and Performance Measurement Strategy,
GlaxoSmithKline

MELISSA DANFORTH, BA, Senior Director of Hospital
Ratings, The Leapfrog Group

THERESA EDELSTEIN, MPH, LNHA, Vice President of
Post-Acute Care Policy, New Jersey Hospital
Association

LILLEE GELINAS, MSN, RN, FAAN, System Vice
President & Chief Nursing Officer, CHRISTUS
Health

STEPHEN LAWLESS, MD, MBA, FAAP, FCCM, Vice
President, Quality and Safety, Nemours

LISA MCGIFFERT, Project Director, Safe Patient
Office, Consumers Union

SUSAN MOFFATT-BRUCE, MD, BSc, PhD, MBOE, FACS,
FRCP(c), Chief Quality and Patient Safety
Officer, The Ohio State University

ANN O'BRIEN, RN, MSN, CPHIMS, National Director
of Clinical Informatics, Kaiser Permanente

PATRICIA QUIGLEY, PhD, MPH, ARNP, CRRN, FAAN,
FAANP, Associate Director, VISN 8 Patient
Safety Center, Department of Veterans
Affairs

VICTORIA L. RICH, PhD, RN, FAAN, Hospital of the
University of Pennsylvania

JOSHUA RISING, MD, MPH, Director, Medical
Devices, The Pew Charitable Trusts

MICHELLE SCHREIBER, MD, SVP Clinical
Transformation and Associate Chief Quality
Officer, Henry Ford Health System

LESLIE SCHULTZ, PhD, RN, NEA-BC, CPHQ, Clinical
Consultant, Premier, Inc.

LYNDA SMIRZ, MD, MBA, Chief Medical Officer and
Vice President of Quality, Universal Health
Systems of Delaware

TRACY WANG, MPH, Public Health Program Director,
WellPoint, Inc.

KENDALL WEBB, MD, FACEP, Associate Chief Medical
Information Officer, University of Florida
Health Systems

YANLING YU, PhD, Physical Oceanographer and
Patient Safety Advocate, Washington Advocate
for Patient Safety

NQF STAFF:

HELEN BURSTIN, MD, MPH, Chief Scientific Officer
ELISA MUNTHALI, MPH, Vice President, Quality
Measurement

ANDREW ANDERSON, Project Manager
JASON GOLDWATER, MA, MPA, Senior Director
LAURA IBRAGIMOVA, Project Analyst
JESSE PINES, MD, Senior Director
SUZANNE THEBERGE, MPH, Senior Project Manager

ALSO PRESENT:

MARY BARTON, MD, MPP, National Committee for
Quality Assurance
SVEN BERG, MD, MPH, CPE, West Virginia Medical
Institute

NATHANIEL BREG, BA, RTI International
ALYSSA CRAWFORD, Mathematica Policy Research
THOMAS W. CROGHAN, MD, Mathematica Policy
Research

CYNTHIA CULLEN, MBA, Mathematica Policy Research
RICHARD DUTTON, MD, MBA, American Society for
Anesthesiologists *

ERIN GIOVANNETTI, PhD, National Committee for
Quality Assurance
DANIEL GREEN, MD, Centers for Medicare and
Medicaid Services *

NICOLE KEANE, MSN, RN, Abt Associates *
QINGHUA LI, PhD, RTI International
EUGENE NUCCIO, PhD, University of Colorado Denver
DANIEL POLLOCK, MD, Centers for Disease Control
and Prevention *

ANGELA RICHARD, PhD, RN, University of Colorado
Denver *

LAURA SMITH, PhD, RTI International
WILLIAM SOUTHERN, MD, MS, Albert Einstein College
of Medicine, Montefiore Medical Center *

* present by teleconference

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

2 8:26 a.m.

3 CO-CHAIR SEPTIMUS: Good morning,
4 everyone. Good morning. Good morning. Who's on
5 the phone first? Who's on the phone?

6 MS. O'BRIEN: Good morning, this is
7 Ann O'Brien from Kaiser Permanente.

8 CO-CHAIR SEPTIMUS: Okay, who else?
9 Is that it? Any Patient Safety Committee members
10 on the phone this morning? I guess not yet.
11 Okay, and we really appreciate those of you who
12 were in there almost all day yesterday on the
13 phone; thank you very much. It's extremely
14 difficult. So I hope everybody had a good
15 dinner; I had to apologize to the group, there
16 was no Septimus wine on the wine menu last night,
17 which I know disappointed many of you. We had
18 really a very productive day yesterday. Just to
19 sort of recap, we tabled two measures on the
20 failure to rescue; we'll take those up on our
21 call post-meeting. We put on reserve status
22 0038, and as you know for PSI 90, we only

1 achieved a 58 percent, so short of the 60 percent
2 consensus, so as you know that's in a gray zone.
3 We're going to wait for public comment and we may
4 come back and discuss this after public comments
5 are in.

6 So as you know because of yesterday,
7 we made some slight changes in the schedule.
8 That was emailed out, but just to go over, this
9 morning before the break--we hope we can get to a
10 break--we're taking up 2726, which is Prevention
11 of Central Venous Catheter-Related Bloodstream
12 Infections from the American Society of
13 Anesthesia, then 2720 is a new measure,
14 Antimicrobial Use Measure from the CDC, and then
15 2729, which is Timely Evaluation of High-Risk
16 Individuals in the ED, and then 0687, Residents
17 Who Were Physically Restrained in Long-Stay, and
18 then 0689, Residents Who Lose Too Much Weight,
19 also in Long Stay. Both of those, the developers
20 are CMS. And then we hope we can take a break,
21 and we'll tell you about the schedule after that.

22 Also, we're very excited, we're going

1 to take up our first eMeasures today, which is--I
2 think--is it a first for this committee? For
3 this committee, right, so it's a first for this
4 committee, so we're very excited about that. And
5 so to introduce us to the eMeasure evaluation--
6 where's Jason--he's behind us. Jason, get up to
7 the--we re-named you the measure developer Jason.
8 So Jason will take us through that, and then
9 we'll get right into the agenda, starting with
10 2726.

11 MR. GOLDWATER: Thank you very much,
12 and good morning, everyone. I am sure that when
13 you woke up this morning, you were bristling with
14 excitement over learning about eMeasures. I
15 can't blame you; I get excited about this every
16 time I talk. It's all over my face, I'm sure.
17 So my name is Jason Goldwater, I'm a Senior
18 Director here at NQF, I've been here since
19 January. I have a multitude of responsibilities,
20 as does everyone that works in this organization,
21 but my primary responsibilities are overseeing
22 our Health Information Technology Group and

1 portfolio of work, and also overseeing our
2 eMeasure development and approval process.

3 And eMeasures have somewhat really
4 come into the forefront over the last several
5 years. The passage of HITECH in 2009 initially
6 was designed to serve as a catalyst to increase
7 adoption of electronic health records throughout
8 the United States, particularly in hospitals and
9 what was defined as eligible providers, as well
10 as devising a baseline to evaluate how EHRs could
11 be used in the course of care, and that of course
12 was meaningful use. And so this is not a
13 discussion about the ins and outs and merits of
14 meaningful use, but rather the part of meaningful
15 use that dealt with what you will be discussing
16 later on, which is the development and use of
17 electronic clinical quality measures. eCQMs--is
18 the short form for this--have been around for
19 some time. It's not like it's a brand new
20 occurrence, but certainly they have taken on much
21 more life since 2009, and particularly over the
22 last three years as EHR adoption has increased

1 substantially.

2 The reason why eMeasures have taken on
3 so much more attention, have been given so much
4 more attention, is because the availability of
5 data, real clinical data to populate and test and
6 use a measure, is much more available than it was
7 in the past. Part of my career, which is long
8 and diverse and incredibly strange, which I will
9 spare you all of the details, but I did work at
10 CMS for 10 years, when it was called HCFA. You
11 all remember the good old days when it was--refer
12 to the name as it should continue to be referred
13 to as--well, that's my own opinion. So I worked
14 for what was then OCSQ, which apparently has
15 changed to CCSQ, during the Eighth Scope of Work
16 for QIOs in which paper-based, traditional claims
17 measures were still highly prevalent, but at that
18 point in time, which was 2003, CMS was really
19 trying to make a move into developing and
20 utilizing eMeasures, and the first project they
21 undertook, which some of you that are real
22 historians of HCFA might remember was the

1 Doctor's Office Quality Improvement Technology
2 Project, or DOQ-IT for short, in which they
3 wanted to take advantage of the increase in EHR
4 adoption to see if there was a way of
5 automatically generating electronic clinical
6 quality measures rather than through what was the
7 traditional paper-based claims abstraction
8 process, through the CDACs, at which time when I
9 joined OCSQ, there were four. There are now--I
10 think there's one, and I'm not even sure if that
11 one is still around.

12 DOQ-IT did not succeed as well as I
13 think everyone had hoped, for a couple of
14 reasons. One is there was not widespread EHR
15 adoption. There was only maybe a 21 percent
16 adoption rate at that point in time. So really,
17 culturally, the country wasn't ready for this.
18 And secondly, they found out that trying to
19 generate electronic clinical quality measures
20 from data other than claims was an incredibly
21 trying and very difficult process, something that
22 still is pervasive to this very day. So what I

1 wanted to talk about in, I guess the next 10
2 minutes, is sort of what you need to look for
3 when you're considering eMeasures, and what NQF
4 does when an eMeasure arrives, and what we do
5 when we're performing our evaluation, and how
6 that is going to differ from what you're going to
7 be asked to do. Under no circumstances would you
8 ever be asked, at least unless something is
9 going--somebody is going to pop a surprise in the
10 next two minutes, where you would be asked to
11 look at formats or codes or markups or value
12 sets. Those are things that we take care of when
13 we do the evaluation, but really when a committee
14 is evaluating an eMeasure, it's not that much
15 different from the way you look at a traditional
16 measure, there's just a few things that need to
17 be considered.

18 When an eMeasure arrives to NQF, we do
19 an assessment very similar to the way we would do
20 it with a normal, traditional-based measure. We
21 look at its evidence, we look at the scientific
22 acceptability of the measure as we would with

1 anyone, we look at its reliability, we look at
2 its feasibility, we look at its validity.
3 There's a feasibility scorecard that every
4 eMeasure developer must submit to let us know how
5 the eMeasure, when it was tested--now remember,
6 when an eMeasure is tested, it's not tested in
7 the same way a claims measure is; it does need to
8 be tested on an EHR system. In the past, it used
9 to be three or more EHR systems.

10 That is difficult, not just simply
11 because of trying to find three diverse EHR
12 systems to test, but also actually asking the
13 providers or the hospitals for a specific period
14 of time to generate the data necessary to
15 appropriately test the measure is a time-
16 consuming process.

17 Our policy has changed over that time
18 that we've gone from three to just more than one,
19 and allowing measure developers to use at least
20 more than one system to try to test their
21 measures so we can get the results to determine
22 whether it can feasibly be done within an EHR in

1 the normal course of business.

2 We also look at the formats, and what
3 I mean by formats, without getting into a lot of
4 detail, is when information is transmitted from
5 one system to another, in order for it to
6 maintain its integrity and meaning, it has to be
7 formatted in a very specific way. We use
8 something known as the Health Quality Measures
9 Format, which, if I really were to get into the
10 higher level of this, is just like a basic
11 webpage, in all honesty. It's marked up in very
12 much the same way, it's marked up in a mark-up
13 language that if--for those of you that can go
14 way back to the days of devising, creating web
15 pages; have any of you ever done that? None of
16 you have done that, all right. So fine.

17 Back in the glory days when the
18 internet was first becoming this ubiquitous term
19 that we all know and love, you actually had to
20 design web pages in what was known as hard-
21 coding, which is you actually had to type in the
22 codes of how the page was supposed to look. And

1 I often joke with people that when you had to
2 create moving graphics--which nowadays is
3 ridiculously easy--back then you actually had to
4 program how you wanted the graphic to go from
5 left to right or top to bottom, and you could
6 never get it right, and you would spend an hour
7 typing in things such as inches or centimeters
8 just to get it correct. That's very similar to
9 what you have to do with an eMeasure, but that's
10 not something you would ever have to look at;
11 that's what we look at to make sure that it is
12 coded and formatted appropriately, and that it
13 can move from one system to another with its
14 meaning and integrity still intact.

15 We also look at the way it would be
16 outputted, so CMS requires it to be reported on
17 what they call a Quality Document Reporting
18 Architecture, which allows reporting on
19 individual patients or population of patients.
20 We check the formats to make sure there will be a
21 seamless transition from one to the next. Again,
22 not something you have to worry about. We also

1 look to make sure that the right measure
2 artifacts are in place, that the right files are
3 there, that we have the electronic information
4 that we need, that it's complete because that
5 document is a complete and comprehensive
6 electronic measure. And then it gets to you. So
7 then what do you have to do?

8 There's really four things you really
9 have to think about when you're looking at an
10 eMeasure. In terms of evaluating the numerator
11 or denominator or an exemption or exclusion,
12 nothing changes from evaluating an eMeasure as it
13 would be over a traditional measure. In
14 examining its reliability, its feasibility, its
15 validity, again nothing truly changes, and we
16 will have written our comments and our concerns
17 about what we think about those topics when we
18 are evaluating the measure for your
19 consideration. Other things you really need to
20 consider are the following: the first is, is the
21 measure good enough? And I think that's kind of
22 a basic question, which is yes it's an eMeasure,

1 and yes it's contained within an EHR, but in your
2 opinion is this measure good enough? If you're
3 going to have to go through the work of actually
4 getting the data in a structured format and
5 exporting that data out of an EHR, is the measure
6 viable, is the measure necessary, will the
7 measure actually make improvements in quality in
8 your mind, and is robust and good enough that it
9 should continue?

10 The second is can the data that's
11 needed to populate this measure actually be
12 obtained within the system it's supposed to come
13 from? Do you think the data is there in the--now
14 all of you work in these clinical environments;
15 you're going to have a better assessment and
16 understanding of this than anyone--do you think
17 that that data is available and obtainable and
18 can be taken out of a system so that an eMeasure
19 could be generated and utilized and evaluated?
20 If you really think it's going to be highly
21 problematic, then that's a concern. But you have
22 to look at it not in terms of is it on a claim,

1 which is somewhat easier, but can it be found
2 within the very system it's supposed to come
3 from.

4 Thirdly, and I think this is
5 important, there's always this talk about EHRs
6 improving the efficiency of care, and that's
7 true. There's a lot of efficiencies that come
8 with it, particularly in the area of patient
9 safety. I mean, there are a lot of--there's
10 significant functionality within EHRs to improve
11 patient safety. How successful that is is an
12 entirely different discussion, but in order to
13 ensure that the data is there in the system that
14 can be used for the measure, it does have to be
15 inputted. It doesn't magically just somehow
16 generate itself within the system.

17 So in your mind, in the normal course
18 of providing care to patients, is that something
19 that would be entered in the normal course of a
20 workflow, or is it something that would be so
21 overly burdensome for some--a nurse or for a
22 physician to do that it would be almost

1 impractical to be considering this as a measure
2 because it would be impossible for the data to be
3 entered and even harder for the data to be
4 extracted? Those are the things you have to look
5 for, and I think workflow sometimes is
6 understated a bit, that it's not considered in
7 the evaluation of an eMeasure, and I think that's
8 important to consider because, again, in order to
9 get the data out, the data has to get in, and if
10 you really think that this is too complex for a
11 data to actually be put into a system by a
12 provider or by a nurse, then it would be
13 virtually impossible to be actually generating
14 any type of eMeasure.

15 And then the last one is do you think
16 this eMeasure would be sustainable over time,
17 which is in the course, you know the--I remember
18 when the AMI measure, aspirin on arrival, like
19 this is the oldest measure in time. Like I
20 remember when I was significantly younger--in NQF
21 years, I'm like ancient really, I mean I'm like
22 one of the oldest people in this company really.

1 Seriously. It's depressing, very depressing, but
2 I remember AMI, aspirin on arrival, being one of
3 the very first measures around, and that came out
4 because then, when it was released, the science
5 indicated that if you give aspirin on arrival,
6 somebody's having a cardiac event, it makes a
7 significant difference. And of course over time,
8 that has become so widely used and now it's
9 common practice. It's been a sustainable measure
10 over time, and even as they transition from
11 traditional claims-based measures into electronic
12 measures, that's still being used.

13 It's very easy to find the data within
14 the EHR that somebody has presented with a
15 cardiac event, indicating AMI, and they were
16 prescribed aspirin on arrival, and here's how
17 much aspirin they were prescribed. And for those
18 of us that are real nerds about this, we can tell
19 you the values and how it was coded and how to
20 evaluate it, but it's very common. That's
21 something to consider as well; do you believe if
22 this measure is used, and that if the data is

1 going to be available within the system, and the
2 data could be entered in the system in the normal
3 course of workflow, do you also believe over time
4 this measure would be sustainable, it would
5 continue to make improvements in quality over
6 time, or after a year, is this going to be so
7 unbelievably burdensome to everyone, even if it
8 has the best of intent, that it would no longer
9 be used, in which case it's something to be
10 considered for a possible endorsement, because
11 that's--if you're only going to have a measure
12 for a short period of time, do you really want to
13 continue to engage in moving that measure
14 forward?

15 So those are really the four things to
16 be considering in the context of evaluating an
17 eMeasure. Again, not overly technical; I don't
18 think we've ever asked our committees to be
19 specialties in the technical expertise of coding
20 or formatting, but really it's more policy-level
21 use questions, usability questions on how the
22 data is used and how the data can be extracted to

1 create an eMeasure. Yes? Sure.

2 CO-CHAIR THRAEN: Sorry, so in your
3 analysis, in your process, do you--since you're
4 only--you changed your rule from more than one,
5 okay, and there are like many three dominant
6 players in the market right now, and each of them
7 are using different standards-based, you know,
8 how do you account for the reliability of the
9 measure capturing what it is it's supposed to be
10 capturing? How do you analyze that?

11 MR. GOLDWATER: Right, so that's an
12 excellent question, and that was a big concern
13 when we switched the rule, because there are--so
14 there are 175 EHR vendors at the moment, but
15 there's only about five of them that have roughly
16 90 percent of the market; Epic, Allscripts, and
17 Cerner are the ones that have roughly 80 percent
18 of the market. So if we were going to go to more
19 than one, are we just going to have people
20 testing out of Epic? So there's two--I don't
21 want to say there's answers, but there's two sort
22 of things to consider. The first is that even

1 though Epic may have 100 implementations
2 nationwide, each implementation of Epic is
3 different; it is not the same. They do have a
4 common base system, which is what they sell, but
5 they will change the base system and they will
6 add options based upon what the hospital or the
7 ambulatory provider needs. So there are
8 different variations of the same system.

9 It is true that they do use some
10 different standards, but really the standards
11 that they use that are varying are the way the
12 information is transmitted, and that's a separate
13 discussion because Epic has its own proprietary
14 standards in which information is transmitted,
15 usually within a hospital or between Epic
16 systems. However, the way the information is
17 coded and the way those codes reflect a clinical
18 content are similar whether it is Epic or whether
19 it is Cerner or whether it is Allscripts. That's
20 correct, at the data element level, it's very
21 similar. So problems are SNOWMED codes,
22 diagnoses are ICD-9, soon to be ICD-10 much to

1 the chagrin of some people, and then eventually,
2 if you're ready for this, potentially ICD-11.
3 Outpatient ambulatory codes are still CPT or
4 HCPCS, laboratory codes are still LOINC,
5 medications are still RxNorm.

6 So regardless of the diversity of
7 systems, the coding at the data element level is
8 still the same, which makes it easier to populate
9 and understand the value sets within the EHR
10 system, even though it brings up some issues of,
11 you know, when we do the evaluation of the
12 testing, we're really going to have to look at
13 the--so if somebody does three tests, and they're
14 all Epic, then our analysis has to be, and what
15 we have to present to you is how the systems
16 differed. Yes?

17 MS. DANFORTH: I just have two
18 questions. When the eMeasures come to you, if
19 there's already been a measure that's not an
20 eMeasure, is there any kind of analysis or
21 comparison? I'm saying when there is, do you do--
22 -yes, so when there is. So for example, like in

1 the IPPS proposed changes, there's a handful of
2 measures that are going from paper measures to
3 eMeasures.

4 MR. GOLDWATER: Right.

5 MS. DANFORTH: Is there--and the way
6 that CMS worded it, it sort of implied that
7 there's actually a difference in the rates
8 produced from the eMeasures versus the paper
9 measures?

10 MR. GOLDWATER: That's correct.

11 MS. DANFORTH: So in evaluating the
12 measure, is that part of the discussion, like
13 what those changes are and what the significance
14 of those changes are?

15 MR. GOLDWATER: Yes, well not
16 completely, but in our process or our policy is,
17 if you're going to move from a traditional
18 claims-based measure to an eMeasure, the eMeasure
19 is considered new, and--because it is a new
20 measure. Now that has brought up some policy
21 questions we're still discussing, as Helen is
22 well aware, and probably those conversations will

1 continue on for a while. But we do evaluate it
2 as an eMeasure, and we have to look at the same
3 things we would look at for any eMeasure. Now
4 granted, there's a past precedent to base that
5 on, but it is considered an eMeasure and has to
6 be evaluated that way.

7 DR. BURSTIN: Just building on part of
8 your question though, I think the other piece of
9 this, and we'll see, is we don't actually know
10 whether in fact the rates will be comparable, and
11 it's actually I think an important piece of work
12 we'd like to engage in going forward because I
13 think it may truly change some baselines in ways
14 that change trend lines, et cetera, which is why
15 we feel like very strongly we need to really
16 understand what those differences are. It's a
17 great question.

18 CO-CHAIR SEPTIMUS: Excellent.

19 MS. DANFORTH: Can I ask one more
20 quick question? So yesterday we spent a lot of
21 time talking about sort of the inadequacy and
22 sort of known issues with claims-based measures.

1 Is anyone looking at potential issues with
2 standardized documentation that are going to
3 create issues in clinical documentation-based
4 measures, and is there just any--will that kind
5 of information be provided to us as well? I
6 mean, I think yesterday there was a lot of
7 conversations about well, you know, I think Jason
8 said when we find this problem, we look in the
9 claims and we saw that it was a coding problem,
10 right? So everyone's looking at coders and what
11 coders are doing, but the documentation that's
12 going into the EHRs is extremely important; if
13 it's not done in a standard, high-quality way,
14 then these measures aren't going to be any more
15 accurate than the claims-based ones. So is part
16 of the work that you're doing sort of looking at
17 that and developing sort of a list of known
18 issues, then letting the committee members know
19 about that?

20 MR. GOLDWATER: Do you want to explain
21 the measure developer?

22 DR. BURSTIN: So one of the things

1 you'll see from what Jason and the staff will
2 present to you on these eMeasures is an
3 assessment of the things we require for
4 eMeasures, one of which is called eMeasure
5 feasibility; it's a score where they actually
6 look to see the data elements you would need to
7 do this measure: are they something you can
8 actually find in an electronic record? It's
9 still pretty early, and I think one of the
10 reasons we shifted from saying three or more EHRs
11 to more than one is it's really hard right now to
12 find EHRs to test measures in, and we don't want
13 it to be a rate-limiting step, but we want to be
14 able to get them out there, but we recognize
15 there's got to be a lot of testing.

16 MR. GOLDWATER: And one of the other
17 problems that we also have to look at, and it's
18 actually interestingly a project we're taking on
19 independent of this, which is the way that it
20 measures--the way the values are developed with
21 an eMeasure. So value sets play a large part in
22 eMeasure development, and there are varying value

1 sets for all different types of measures, and at
2 times those value sets will overlap, will be
3 redundant, and will not have a lot of meaning to
4 the actual measure that they're--they will have
5 very little relevance to the intent of the
6 measure. So we're working now on a project to
7 sort of harmonize and remove that variance, but
8 that's something else that we consider as well in
9 the feasibility testing, which is what value sets
10 are you using and how are those measures coded,
11 and is it reflective of the intent of the
12 measure, as well.

13 CO-CHAIR SEPTIMUS: We only have time
14 for one more question, because we're running
15 right up to the next measure, so--

16 DR. LAWLESS: Yes, Steve Lawless. My
17 question for you is, are there lessons learned
18 from both the implementation of meaningful use
19 and the level 3 that way that you're using to
20 say, you know, lessons learned from trying to
21 extract even simple stuff from an EMR, turning it
22 into a measure that can be--that you're utilizing

1 or saying, aha, let's avoid these paths of this,
2 and the other thing about EMR is it's very
3 sensitive data and very specific, so how do you
4 code it, you can miss a lot because you've missed
5 a decimal place here versus somebody looking at
6 what your intent was. So my more important
7 question is the first one about lessons learned.

8 MR. GOLDWATER: So it's interesting
9 that the final question is of course the easiest
10 one to be answering. I can do it in 60 seconds--
11 it's an excellent, excellent question. And
12 there's a lot of lessons to learn from meaningful
13 use, and I think when it comes to eMeasures, the
14 two most dominant ones have been is the
15 information coded appropriately, so there are of
16 course domains of terminology that ONC has really
17 recommended to use, but are those being used
18 correctly? Are those being used to adequately
19 code diagnoses, procedures, medications, et
20 cetera? Are the appropriate value sets being
21 used that reflect the intent of the measure?

22 We have found that that has been

1 somewhat problematic, not as problematic as we
2 expected, but then again the measures are coming
3 in relatively slowly, so if we get 40 eMeasures,
4 which would be great, and we get those in in the
5 next couple of months, we may find those problems
6 to be far more pervasive. And then secondly, you
7 know, one of the problems has really been on the
8 vendor side, which is, are they able to develop
9 the system to be able to collect and report out
10 the data based on the specifications that have
11 been documented by CMS and that NQF has moved
12 forward with?

13 And that has been a problem since
14 meaningful use came out, and it's not just with
15 eCQMs, it's just with everything. There are
16 issues about whether the EHRs can function in the
17 way that CMS would like, particularly with
18 reporting quality measures, and will they get the
19 information that is needed. That was a problem
20 that existed when DOQ-IT was around; that problem
21 hasn't exactly gone away, particularly when you
22 start talking about measures that go outside the

1 traditional AMI, pneumonia, stroke, VTE, which
2 have been around for a while. When you get into
3 the behavioral health measures, the eye, ear,
4 nose and throat measures, things that are newer,
5 that becomes an issue because, do they have the
6 ability to code and reflect that data adequately?

7 So those are things we have to really
8 look at, which is why our eMeasure review process
9 takes a little bit of time, because we have to
10 really get into the nuances of those elements and
11 the value sets to make sure they're done
12 appropriately.

13 CO-CHAIR SEPTIMUS: I think we'll have
14 opportunities as the eMeasures come forward to
15 have some further discussion on this, and I hate
16 to cut off conversation; this is the first time
17 this committee has considered eMeasures. Before
18 we get started with the first measure, is
19 anybody--any other committee members joined the
20 call?

21 DR. APPLGATE: Yes, this is Kimberly
22 Applegate; I'm non the call. Thank you.

1 CO-CHAIR SEPTIMUS: Okay, so we have
2 two from yesterday, and did we lose anyone here?
3 So Tracy. So we're down to 23 for voting, that's
4 what I'm--22, that's what I'm counting. All
5 right, so we have 22 for voting--

6 DR. BURSTIN: Josh just said he'd be
7 in late; he has to drop his kids off--

8 CO-CHAIR SEPTIMUS: Okay so for now,
9 it's going to be 22 for voting. Okay, so the
10 first measure is 2726--thank you. 2726. So the
11 first one is a measure that we looked at last
12 year, Prevention of Central Venous Related
13 Bloodstream Infections from the American Society
14 of Anesthesiology; they'll present for the first
15 couple of minutes, and then Dr. Alexander will be
16 the discussant. Yes, I said 2726; didn't I say
17 that?

18 CO-CHAIR THRAEN: You may have.

19 CO-CHAIR SEPTIMUS: Okay.

20 DR. DUTTON: Good morning, can you
21 hear me?

22 CO-CHAIR SEPTIMUS: Yes, who--is that-

1 -

2 SPEAKER B: Yes, that's Dr. Dutton
3 who's--he will be speaking with us today.

4 CO-CHAIR SEPTIMUS: Okay. Dr. Dutton,
5 would you like to introduce yourself to the
6 committee members, please?

7 DR. DUTTON: Sure. This is Dr.
8 Richard Dutton, I am an anesthesiologist and the
9 Chief Quality Officer of the American Society of
10 Anesthesiologists; I also participate in some
11 other NQF activities. Thank you for having us
12 back to discuss this measure. As you've just
13 heard from Dr. Septimus, we did present this last
14 year. We had just taken over management of the
15 measure from the AMA, from PCPI, and I have to
16 admit the handoff wasn't good, so there were
17 questions we were unable to answer last year.
18 We've tweaked it a little bit this year, and
19 we've completed the validity reliability testing
20 with new data, which I think will help the
21 presentation this time.

22 So you have the measure in front of

1 you. You've had the opportunity to review it.
2 It's fairly simple. It calls for measurement of
3 the use of preventive measures for preventing
4 central line infection at the time the line is
5 placed. As many of you know, depending on your
6 hospital and your system, up to half of all the
7 central lines in the hospital will be placed by
8 anesthesiologists in the OR or ICU environment,
9 so this is an important measure for our
10 specialty. But very often we are putting lines
11 in, but then not around or not managing the
12 patient later when the complication occurs, and
13 this is why we feel that a process measure is
14 still appropriate for this activity, because the
15 process and the outcomes are separated in time,
16 and in our case, separated by professional
17 service.

18 Successful compliance with this
19 measure calls for using maximal sterile barrier
20 precautions when placing the line, use of a cap,
21 mask, sterile gown and gloves, full body drape on
22 the patient, and if ultrasound is used, which is

1 recommended, sterile gel and sterile ultrasound
2 probe cover. It applies to all patients
3 regardless of age who have a central line placed,
4 and it's a fairly broad definition of central
5 line placement. Of course, it's hard to tell
6 from the measure, which is full of CPT codes, but
7 that covers both tunneled and untunneled central
8 lines, so both temporary and longer term central
9 lines, and it includes peripherally-inserted
10 central lines, PICC lines. Current performance
11 on the measure, looking at the data in our
12 registry and now about four years of performance
13 on this, about 60 to 70 percent of
14 anesthesiologists report the measure when a
15 central line is placed; we can see that in both
16 Medicare data and our own registry data, so
17 there's a significant gap in utilization of the
18 measure and reporting it at all.

19 When it is reported as you might
20 imagine, it is mostly successful, in the low 90s
21 right now, but we also know that there are many
22 practices and many physicians who achieve 100

1 percent or close to 100 percent performance on
2 this measure. The connection with outcome has
3 been very strong; AHRQ has recently published
4 data on the rate of CLABSI central line
5 infections in the United States, which have
6 dropped precipitously since this measure has been
7 in place, and since the use of sterile techniques
8 when placing lines has been focused by
9 anesthesiology and other specialties. So I'll
10 stop there; I'm happy to take any questions or
11 react to any comments from the committee.

12 CO-CHAIR SEPTIMUS: Thank you very
13 much. Charlotte, do you want to take us through
14 the measure, please?

15 DR. ALEXANDER: Certainly. You had an
16 excellent introduction. You want me to go
17 directly into evidence?

18 CO-CHAIR SEPTIMUS: Let's go to the
19 evidence and go from there.

20 DR. ALEXANDER: As he stated, this is
21 a process measure. Hospital-acquired infections
22 are a common complication that leads to increased

1 cost and mortality; 51 percent occur in the ICU
2 and central venous catheter is probably the
3 largest risk factor. Catheter-related
4 bloodstream infections commonly occur when the
5 catheter becomes contaminated by microbes on the
6 skin during insertion. Maximal barrier technique
7 has been shown to be a cost-effective way to
8 reduce these infections. There is a guideline
9 which has 12 recommendations for sterile
10 technique for insertion of these lines. There are
11 also 14 studies that are high-grade, half of
12 which are root cause and random control studies
13 with large sample sizes. They're uniform in their
14 evidence that maximal sterile barrier technique
15 can decrease bloodstream infections from five to
16 35 percent consistently, and up to 65 percent in
17 some cases.

18 CO-CHAIR SEPTIMUS: Any questions on
19 the evidence? Just a great, great presentation.
20 There's actually two components to prevention of
21 central lines; one is on insertion, and early
22 central line infections, the predominant

1 pathogenesis is colonization around the insertion
2 site. Later in the course of central lines,
3 it's really related to maintenance and
4 contamination of the hubs, which would not be
5 related to insertion. Just wanted to balance
6 that in terms of the pathogenesis. But as is
7 stated, they're looking at the so-called CDC
8 guidelines and the level of evidence for
9 insertion of the central line, and they're well
10 outlined in your packet. So are there any other
11 questions before we vote on the evidence? Yes,
12 Steve.

13 DR. LAWLESS: I just--this is--but in
14 the definitions and maybe the evidence, the
15 evidence doesn't include the type of skin prep
16 used?

17 CO-CHAIR SEPTIMUS: What skin prep are
18 you talking about? It should be CHG alcohol.

19 DR. LAWLESS: That's what I'm saying.
20 I see from the front sheet, it talks about, you
21 know, the standard stuff, the cap, the mask and
22 everything else and skin prep, but it doesn't

1 mention type of skin prep, or -- that's not part
2 of the evidence?

3 DR. ALEXANDER: That's in the CDC
4 guidelines.

5 CO-CHAIR SEPTIMUS: But you're
6 correct, CHG alcohol is--

7 DR. LAWLESS: But it's included, that
8 is included as part of the numerator here in
9 terms of that --- that would be also being
10 followed or looked at?

11 DR. DUTTON: Yes, and one of the small
12 changes in our presentation this year is it--the
13 last time around, they called for just use of
14 chlorhexidine; it now includes alcohol, tinctured
15 iodine or chlorhexidine as acceptable prep
16 solution, based on the newest data.

17 CO-CHAIR SEPTIMUS: Yes, Lisa?

18 MS. MCGIFFERT: It looks--I want to--
19 is this just a measure for anesthesiologists, or
20 is this a measure for anyone? And it also looks
21 like --is it always going to be --it's not always
22 going to be in a hospital setting; I'm just

1 trying to figure out who are we measuring here?

2 DR. DUTTON: The denominator codes for
3 eligibility for this measure are CPT codes for
4 insertion of central lines. So any providers who
5 place central lines would be eligible to report
6 this measure. The cyberstudy includes
7 anesthesiologists, nurse anesthetists and others
8 working in the OR; it includes surgeons,
9 oncologists, intensive care physicians, or even
10 nurse practitioners closing PICC lines.

11 CO-CHAIR SEPTIMUS: Are there any
12 other--I don't see any, so let's go ahead and
13 vote on the evidence.

14 MS. IBRAGIMOVA: So importance to
15 measure and report 1A evidence structure process
16 intermediate outcome, the votes are 1 high only
17 eligible if QQC submitted, 2 moderate, 3 low, 4
18 insufficient evidence.

19 CO-CHAIR SEPTIMUS: Are we getting the
20 ones on the phone through the WebEx? Okay, good.
21 Two more.

22 DR. ALEXANDER: Susan stepped out of

1 the room.

2 CO-CHAIR SEPTIMUS: Okay so that's--
3 that's going to be--so that's going to be 21.
4 Okay, got it.

5 MS. IBRAGIMOVA: So the results are 67
6 percent high, 33 percent moderate, zero percent
7 low, zero percent insufficient evidence.

8 CO-CHAIR SEPTIMUS: Okay Charlotte, if
9 you'll take us through the gap.

10 DR. ALEXANDER: So for priority, only
11 28 percent of ICUs have a written policy, only 28
12 percent of physicians use maximal sterile barrier
13 technique. Catheter-related bloodstream
14 infections increase length of stay an average of
15 20 days with a cost of \$3,000 to \$60,000 per
16 case. This involves a large number of line
17 insertions with a significant morbidity and a
18 high resource use.

19 CO-CHAIR SEPTIMUS: Question?

20 MS. ARDIZZONE: I just--I had a
21 question when you said--you said 28 percent of
22 the ICUs, you know that was a survey from 2002,

1 and some of the data is a little dated that was
2 submitted. Do the developers have anything
3 newer? Because I would think maybe in 15 years or
4 so, practice has changed around maximal sterile
5 barriers.

6 DR. DUTTON: We're certain it has, and
7 in fact we're certain that's the reason why the
8 CLABSI rate has dropped dramatically in the last
9 few years, but there is no more recent published
10 data on this. More anecdotally looking at our
11 anesthesia practices that we went with and
12 participate in the registry, there's been a
13 substantial change in practice in this area in
14 the last five to 10 years.

15 CO-CHAIR SEPTIMUS: Missy?

16 MS. DANFORTH: Yes, in terms of the
17 performance gap, I'm just trying to understand,
18 because we have--and we're going to be talking
19 about it today--an outcome measure related to
20 this, how you really judge--what's the
21 significance I guess of the performance gap and
22 the process measure if all the focus nationally

1 has been on the outcome measure?

2 DR. DUTTON: The importance of having
3 both in this case is that the outcome measure is
4 obviously what's most meaningful to patients and
5 facilities and to the team as a whole, but in
6 addressing gaps in the outcome, and obviously
7 central line infections still happen, and they're
8 still dangerous and expensive. In addressing a
9 gap like that, as you heard Dr. Septimus say,
10 there are multiple causes for central line
11 infections, one of the more significant ones
12 being care with how the line is placed, and that
13 falls on a particular group of providers who are
14 putting the lines in but may not be the ones
15 managing them or using them for the long term.
16 So we think at least that this is a situation
17 where it's very appropriate to measure both the
18 outcome and this component of the process,
19 because it can give you real evidence for where
20 to make improvements.

21 MS. DANFORTH: Is the measure then
22 most appropriate for internal use for hospitals

1 and quality improvement, then?

2 DR. DUTTON: Well, this measure is
3 obviously presented as a measure for providers,
4 and we use it at multiple levels. Within the
5 registry, it's reported at the level of
6 anesthesia practices, at the level of facilities,
7 and at the level of individual providers.

8 DR. BURSTIN: Just a brief comment.
9 So--oh, I have so many microphones. So in
10 general, you know, most of the measures we talk
11 about, for example like the CLABSI rate, are at
12 the hospital level. This is a clinician-level
13 measure, so that's one of the disconnects. And
14 so you still need clinician-level measures and we
15 only--you know, a process measure in our parlance
16 would really only be appropriate if there's a
17 clear connection to outcomes. And this is one,
18 you just discussed it in terms of the evidence,
19 there's a clear process outcome link, and it's at
20 a different level of analysis. So that's at
21 least the logic of potentially maintaining some
22 process measures that show directionality of how

1 to improve, even if you have the outcome measure
2 at a different level.

3 CO-CHAIR SEPTIMUS: Okay, Rich?

4 DR. BRILLI: Rich Brilli. I don't
5 mean to belabor it, but the developer continues
6 to use the word CLABSI, and the measure talks
7 about catheter-related, and as I said yesterday,
8 they are not the same, and I think there needs to
9 be some clear change in the language. Is this
10 catheter-related? The vast majority of the adult
11 hospitals, I was talking to Susan, actually
12 report CLABSI, central line associated, which is
13 the surveillance definition, not catheter-
14 related, which is--I went through it yesterday so
15 I won't repeat it. And in here it says catheter-
16 related; he's saying CLABSI; I'm not sure which
17 it is, so that's the first point.

18 Second point is I don't see an age
19 issue here, and all of this applies to children,
20 except premature infants where CHG may have
21 significant skin problems, and they may use
22 iodine alone and not chlorhexidine. So I think

1 that if it doesn't indeed apply to children, and
2 I think most NICUs and ICUs, most children's
3 hospitals are doing this already and have been
4 doing it for a long time, with the exception of
5 neonatal intensive care premature infants where
6 CHG is not appropriate or may not be appropriate.
7 So those are two things that need to be addressed
8 somewhere in here.

9 DR. ALEXANDER: They did add the
10 iodine as an appropriate skin prep.

11 DR. BRILLI: He said iodine with
12 something else--

13 DR. ALEXANDER: Alcohol.

14 DR. BRILLI: Yes, so that still is not
15 appropriate for a 1200 gram or 500 gram baby who
16 has a PICC line put in; it needs to be just
17 iodine alone. Their skin is very fragile and
18 anything with alcohol or chlorhexidine may be
19 problematic. So that's--and I didn't see an age
20 limitation in here; it just said everybody. So I
21 support it except for these premature infants.

22 CO-CHAIR SEPTIMUS: Okay, so the

1 question that I'm a little bit confused about--
2 oh, do you have a question? But it's just the
3 fact is there's another bullet point here that
4 says the reported performance scores show limited
5 room for improvement, that the providers with
6 non-zero reporting rates, Medicare patients
7 aggregate by practice 2014 shows a mean
8 performance of 94 percent. So where is that data
9 from? And facility aggregate mean of 92 percent.

10 DR. DUTTON: Yes, so we have several
11 different sources of data that we've examined for
12 rates here. The Medicare five percent files are
13 one; the National Anesthesia Clinical Outcomes
14 Registry reporting rates are another. As I said,
15 they're not exactly the same but running, as you
16 point out, in the low 90s. We do have groups and
17 there are facilities where the rate is close to
18 100 percent; we have other groups that are lower
19 than that, but honestly from our perspective, the
20 biggest gap in this is the many practices that
21 still don't report it, and up to 40 percent of
22 the central line placements we see in

1 administrative code sets like the five percent
2 files, those measures are not reported.

3 CO-CHAIR SEPTIMUS: Okay, so we only
4 have five more minutes, so I don't want to
5 prolong, because I want Jason to give his
6 comment, but the question based on the more
7 recent data is, have we topped out in this, and
8 has this becomes hard wired as the standard
9 practice? I think that's the question that I
10 think we have to ask ourselves when we vote on
11 the gap. Jason?

12 DR. ADELMAN: Jason Adelman. I'm
13 going to make some statements that I'm not sure
14 are 100 true, so the developer can correct me,
15 but the way I see this measure is that it's a
16 great idea to--I support the idea of capturing
17 the process measure that we follow proper
18 technique; however, the way the developer
19 describes where we are right now is that they've
20 requested new CPT codes made that will capture
21 all sorts of elements. Did you wear a cap? Did
22 you wear a mask? Did you wear a sterile gown?

1 Did you wash your hands? This CPT code doesn't
2 exist, and they say it will be approved --- it's
3 supposed to be approved in August. And then so
4 if it's--so it's a measure looking at capturing a
5 CPT code that doesn't currently exist that we're
6 voting on now, and then --- so you can't really
7 test it, because it doesn't exist. And I would
8 think that even if it does happen, it's not going
9 to, in my opinion, do anything because you know,
10 coders can only code if the doctors write all
11 these things in the chart. And the only way a
12 doctor is going to write, "I wore a cap and a
13 mask and a sterile gown and sterile gloves and
14 washed my hands" is if it's pre-written on some
15 form, and when they sign that they've done it,
16 they're just going to sign off on it, otherwise
17 the coders--you know, it's not practically--and
18 so I may be right, I may be wrong, and we can't
19 even test it because the code doesn't even exist.
20 So we're voting on a measure for something that
21 may or may not work and I'm not sure if that's
22 right or not, but I think that's how I read

1 what's going on, so I'll ask the developers.

2 DR. DUTTON: Actually, all of the
3 codes--

4 CO-CHAIR SEPTIMUS: We'll ask the
5 developer, and then we're going to vote.

6 DR. DUTTON: All of the codes have
7 existed for four or five years; they -- we're
8 changing some of them in small ways as I
9 mentioned, to incorporate sterile ultrasound and
10 to allow for the use of different prep solutions,
11 include iodine, plain iodine. So the codes have
12 been around; most of this data is captured from
13 clinical documentation in the medical record, and
14 when I put a central line in, I do record the use
15 of maximal sterile barriers, appropriate prepping
16 and draping.

17 DR. ADELMAN: Do you--sorry, do you
18 write each element down or does your form sort of
19 have--I mean there's a lot of elements that
20 specify 2A1.

21 DR. DUTTON: Sure, and the question
22 you're asking is obviously a moving target. At

1 the University of Chicago, I'm documenting this
2 in Epic with a series of checkoff that might be
3 completed by either me or by the operating room
4 nurse who's observing the procedure.

5 CO-CHAIR SEPTIMUS: Okay we--

6 DR. DUTTON: But--

7 CO-CHAIR SEPTIMUS: --we need to vote
8 because the timekeeper tells me we're out of time
9 here already. So let's vote on--Lisa, go ahead.
10 Lisa, go ahead, just do it real quick.

11 MS. MCGIFFERT: Okay, I'm looking at
12 the skin prep directions here, and they seem to
13 be saying--it says to use the chlorhexidine prep
14 first, and if there's a contraindication to
15 chlorhexidine, you go to tincture or an iodophor
16 or 70 percent alcohol, and then it clearly says
17 there's no comparison has been made between using
18 chlorhexidine preps and the other preps, so it's
19 an unresolved issue, and that no recommendation
20 can be made for the safety or efficacy of
21 chlorhexidine in infants, to address Rich's
22 concern. So it's hard for me to know, to figure

1 out; it looks like still the first line is to use
2 chlorhexidine or I mean the very first bullet
3 says you can use any of these, and then the
4 second and third bullet--the second bullet said
5 you should use one first, and then if that's not
6 indicated, you should use something else. So I'm
7 just trying to get some clarity on the skin prep
8 issue, and I know this is under evidence, and I'm
9 sorry I didn't get that in earlier.

10 CO-CHAIR SEPTIMUS: Yes, we can talk
11 about evidence. It's clear that chlorhexidine
12 and alcohol is the preferred prep scientifically,
13 so--but we'll get to that, but let's vote on the
14 gap, okay? Do we think there's a gap in
15 performance that would merit moving to the other
16 discussions, okay? So, Laura?

17 MS. IBRAGIMOVA: Importance to measure
18 and report 1B performance gap, the votes are 1
19 high, 2 moderate, 3 low, 4 insufficient.

20 CO-CHAIR SEPTIMUS: We got it.

21 MS. IBRAGIMOVA: So the results are 29
22 percent high, 38 percent moderate, 33 percent

1 low, zero percent insufficient.

2 CO-CHAIR SEPTIMUS: Okay then, we move
3 forward. Charlotte?

4 DR. ALEXANDER: Specifications. The
5 numerator is the patient for whom the central
6 venous catheter was inserted with maximal sterile
7 barrier technique that is CPT code 6030F; 6030F-
8 1P as a documentation of medical reason for not
9 using the maximal sterile barrier technique,
10 including an increased risk of harm to the
11 patient; 6030F-8P is the all elements were not
12 followed. The denominator is all patients who
13 undergo central venous catheter; the exclusion is
14 6030F-1P, which is where there was a
15 contraindication. They have a proposed change to
16 6030F to add the ultrasound; it does not
17 currently add ultrasound to it. Do you want to
18 go into reliability yet?

19 CO-CHAIR SEPTIMUS: Yes.

20 DR. ALEXANDER: Reliability, this is
21 captured through administrative claims, the
22 Medicare Limited Data Set Carrier SAF five

1 percent and NACOR, which is the National
2 Anesthesia Clinical Outcomes Registry. The
3 performance level for NACOR, we had kappa of
4 0.97, for the SAF, the five percent Medicare was
5 0.95. I have a question, and I want to know how
6 they're capturing the CPT-2 codes on non-
7 Medicare, non-registry patients.

8 DR. DUTTON: We did capture--if
9 they're not participating in either Medicare or
10 the registry, we don't have any data from them,
11 but that would be true of any measure. NACOR
12 currently includes about 25 percent of all of the
13 anesthesia practices and cases in the United
14 States though, so it's a very large sample.

15 DR. ALEXANDER: So if there's a
16 surgeon who's putting a line in a non-Medicare
17 patient, how does he report it?

18 DR. DUTTON: The surgeon, sorry, the
19 measure is specified for use by any physician who
20 places a central line. It depends on the purpose
21 that the measurement is being put to how the
22 person would report it, whether at the local

1 level, the facility level, or to a national
2 project. But surgeons could use this measure for
3 PQRS, and this is a PQRS measure as well. If
4 they report the appropriate codes, they would
5 have to work out with their billing company or
6 hospital system how to do the reporting. Many
7 anesthesiologists do report this measure in PQRS
8 and that's why the data is in CMS; many also
9 report it to the registry; there's not a perfect
10 overlap between those sets.

11 CO-CHAIR SEPTIMUS: Okay. Let us vote
12 on reliability, please.

13 MS. IBRAGIMOVA: Scientific
14 acceptability of measure properties 2A
15 reliability, the votes are 1 high, 2 moderate, 3
16 low, 4 insufficient. The results are 14 percent
17 high, 62 percent moderate, 24 percent low, zero
18 percent insufficient.

19 CO-CHAIR SEPTIMUS: Okay, so let's go
20 on to validity.

21 DR. ALEXANDER: For validity, this was
22 done at the face value of a group of experts; the

1 score was 4.16 out of a 5 score.

2 CO-CHAIR SEPTIMUS: I'd say let's go
3 ahead and vote.

4 DR. ALEXANDER: A meaningful
5 difference--

6 CO-CHAIR SEPTIMUS: I'm sorry.

7 DR. ALEXANDER: --I'm sorry.
8 Meaningful difference. There was a high
9 performance rate among people reporting, but I
10 had 60 percent; he stated at least 40 percent
11 were not reporting, so of the people that report,
12 they do a pretty good job, but there are a lot of
13 people that are not reporting.

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

15 MS. IBRAGIMOVA: Scientific
16 acceptability of measure properties 2B validity,
17 the results are 1 high, 2 moderate, 3 low, 4
18 insufficient. The results are 14 percent high,
19 67 percent moderate, 19 percent low, zero percent
20 insufficient.

21 CO-CHAIR SEPTIMUS: Feasibility?

22 DR. ALEXANDER: This is captured

1 through administrative claims and electronic data
2 through a clinical registry and uses CPT codes to
3 capture the data.

4 CO-CHAIR SEPTIMUS: Seeing no hands,
5 let's vote.

6 MS. IBRAGIMOVA: Feasibility, the
7 votes are 1 high, 2 moderate, 3 low, 4
8 insufficient. The results are 33 percent high,
9 38 percent moderate, 29 percent low, zero percent
10 insufficient.

11 CO-CHAIR SEPTIMUS: Okay, then we go
12 to usability.

13 DR. ALEXANDER: This is currently
14 being used for PQRS, for the anesthesia registry,
15 and there's some discussion about Joint
16 Commission using it also in evaluation of
17 hospitals.

18 CO-CHAIR SEPTIMUS: Discussion? Yes.

19 MS. ARDIZZONE: Just one comment. I
20 agree this is really important because it
21 identifies something--because there's two
22 components of the line: the insertion, and the

1 maintenance, and this really gets at the
2 insertion. The only thing I'm concerned about is
3 in many places, this is just self-reported, that
4 I've done maximal sterile barrier precautions.
5 It might be better if, you know, someone was
6 actually observing that someone was doing maximal
7 sterile barrier precautions. I don't know how
8 feasible that is to have somebody observing, an
9 independent observer watching everybody. So I'm
10 concerned that it's just self-reported, but--

11 DR. DUTTON: Yes, this is Dr. Dutton
12 again. Us too. We get that. First, in many
13 institutions, and depending on the documentation
14 system, it actually is an observer documenting
15 this. I mentioned the OR nurse, it can also be
16 the ICU nurse documenting this for the procedure.
17 You can argue about how independent they are;
18 it's still a checkbox exercise. And this is why
19 we're working with this measure, as with all of
20 our measures, on e-specifications, and hope to
21 come forward next year with an eMeasure on the
22 same topic. As you heard earlier, it won't

1 exactly match this one, but we believe it will be
2 able to get the same data or similar data in a
3 much more objective way.

4 CO-CHAIR SEPTIMUS: Okay. Usability.
5 Let's vote.

6 MS. IBRAGIMOVA: Usability and use.
7 The votes are one high, two moderate, three low,
8 four insufficient information.

9 CO-CHAIR SEPTIMUS: One more.

10 MS. THEBERGE: Ann, I need your vote.

11 CO-CHAIR SEPTIMUS: All right, we've
12 got 21.

13 DR. APPLGATE: Ed, this is Kimberly,
14 could I make a comment about that last comment?
15 A concern about the observation?

16 CO-CHAIR SEPTIMUS: Of course,
17 Kimberly. Wait one minute, because we're trying
18 to get the one last vote and then, you can
19 comment.

20 DR. APPLGATE: Well, I'd like to make
21 it before the vote.

22 CO-CHAIR SEPTIMUS: Well, the vote --

1 DR. APPLGATE: I raised my hand.

2 CO-CHAIR SEPTIMUS: The vote's been
3 cast, Kimberly, I'm sorry.

4 DR. APPLGATE: That's all right.

5 CO-CHAIR SEPTIMUS: And I know it's
6 difficult for you on the phone, so if you would
7 text Suzanne, and we'll make sure that you -- oh,
8 so you missed it? Okay. Well, I'll tell you
9 what. Since we have to vote again, why don't you
10 go ahead then and tell us your comment.

11 DR. APPLGATE: I just wanted to
12 second the author's comment that when the
13 healthcare -- it's an awful lot of line
14 placements and oversight and review of infections
15 CLABSI by interventional radiology, he puts in an
16 enormous number of these central lines and PICCs
17 honestly, when the nursing teams can't put them
18 in. And so, I review a lot of these cases and
19 try to ascertain if it's secondary to placement
20 or dwell. And so, the healthcare system tries
21 very hard to say everyone does it the same, and
22 it's just, at least at Emory, a bundle.

1 So, you know, yes, we'd love to have
2 observations, and we do do a little bit of
3 observation. But basically, it is a check right
4 now, and we try to audit some of the checks,
5 internally, and in our department, a very large
6 department, but I would say that just by having
7 the bundle and having it across all systems with
8 everybody doing it the same and everyone given
9 the bundle, I think that that's the way to
10 address this concern that was raised by someone.
11 I don't know who it was.

12 CO-CHAIR SEPTIMUS: Thank you,
13 Kimberly. All right, now, let's vote again on
14 usability. That was fast.

15 MS. IBRAGIMOVA: So, the results are
16 23 percent high, 59 percent moderate, 18 percent
17 low, zero percent insufficient information.

18 CO-CHAIR SEPTIMUS: Okay. We're going
19 to go to the last one. I'm going to just make a
20 comment, not as co-chair but as someone who knows
21 a little bit about this area. We've focused a
22 lot of our attention on insertion, but I want to

1 tell you that most of the more recent studies in
2 terms of prevention emphasize maintenance. This
3 has nothing to do with maintenance and again I'll
4 just come back to my original comment: I think
5 we're seeing a higher level of compliance. I
6 think compliance should be, by the way, should
7 occur. I think maximum barrier in putting this
8 in carefully is very, very important, but I just
9 want to put this in relative --- as to what the
10 most salient points are in 2015 to prevent
11 CLABSIs, just to put that in perspective.

12 Okay. Let's vote on whether or not
13 it's suitable for endorsement.

14 MS. IBRAGIMOVA: Overall suitability
15 for endorsement: does the measure meet NQF
16 criteria for endorsement? One yes, two no.

17 CO-CHAIR SEPTIMUS: Sorry, did I miss
18 you again, Richard?

19 DR. BRILLI: Well, I don't think I had
20 my card up in time. I think there's something
21 important on page ten, there's a competing
22 measure which talks about CLABSI as opposed to --

1 so I'm not sure -- page ten of the document
2 that's submitted, it talks about competing
3 measures. And there's a whole other measure that
4 this group has already approved, which talks
5 about CLABSI, C-L-A-B-S-I. And this is -- I
6 don't know if it's the exact same measure, this
7 is just C-R-B-S-I. So again, it's the same --
8 I'm not quite sure what we're doing here that
9 sounds like it's completely --

10 CO-CHAIR SEPTIMUS: Well. Well, I
11 think it actually was explained by Helen very
12 well that this is a process measure, other one's
13 an outcome measure.

14 DR. BRILLI: Is there no process
15 measure in the CLABSI measure?

16 CO-CHAIR SEPTIMUS: No, there's no
17 process measure, and this is at the clinician
18 level and not at the hospital level. So they're
19 different measures.

20 You want to vote again? I think we
21 need to vote again. Sorry, let's vote again.

22 MS. IBRAGIMOVA: Yes, we need four

1 more votes. Just one more.

2 CO-CHAIR SEPTIMUS: Can we tell,
3 Laura, who hasn't voted? Did Missy vote? Okay.

4 MS. IBRAGIMOVA: So results are 86
5 percent yes, 14 percent no.

6 CO-CHAIR SEPTIMUS: Well, thank you
7 for the developers and thank you for an excellent
8 discussion, Charlotte. And now we're going to
9 move to a new measure. Are the CDC developers on
10 the phone?

11 MS. ARDIZZONE: Are we going to talk
12 about retirement, or?

13 CO-CHAIR SEPTIMUS: Retirement?
14 Reserve status?

15 MS. ARDIZZONE: Yes, that. Sorry.

16 DR. POLLOCK: Yes, Ed, this is Dan
17 Pollock, I'm on the phone.

18 CO-CHAIR SEPTIMUS: Yes, one second,
19 Dan. So --- since it passed gap, it doesn't go
20 into reserve. Okay. All right, so the next
21 measure -- we may have to cut our break short
22 here, but that's okay -- is a new measure from

1 NHSN on antimicrobial use measure from the CDC.
2 And I think Dan Pollock is going to be discussing
3 it as a developer; is that correct, Dan?

4 DR. POLLOCK: That's correct.

5 CO-CHAIR SEPTIMUS: Okay. The floor
6 is yours.

7 DR. POLLOCK: Okay. Thank you so
8 much. I'm Dan Pollock. I'm a medical
9 epidemiologist at CDC working with colleagues on
10 the National Healthcare Safety Network, N-H-S-N.
11 We have a proposed measure of antimicrobial use.
12 Antibiotic overuse or inappropriate use in U.S.
13 hospitals is a widely recognized clinical and
14 public health problem that places individual
15 patients at risk for adverse outcomes, increases
16 the incidence and prevalence of antimicrobial
17 resistance, and jeopardizes the effectiveness of
18 a vitally-important healthcare resource for the
19 general population.

20 CDC estimates that at least two
21 million people become infected with bacteria that
22 are resistant to antibiotics, leading to 23,000

1 deaths, and recommends strongly improvement of
2 antibiotic prescribing as a core action to
3 prevent resistance.

4 Numerous individual studies and
5 systematic reviews provide strong evidence that
6 measurement of antimicrobial use and data-driven
7 interventions by antimicrobial stewardship
8 programs, or ASPs, lead to more judicious use of
9 antibiotics, reduced antimicrobial resistance,
10 and other favorable healthcare outcomes.

11 So the NHSN AU measure proposal is one
12 that really seeks to provide data, benchmarks of
13 antimicrobial use at the national level for
14 stewardship programs to use in their systematic
15 efforts to guide prescribing practices. The AU
16 measure provides summary results that hospital
17 and health system ASPs can use as quantitative
18 aids. The core metric is the standardized
19 antimicrobial administration ratio, or SAAR, and
20 we focus in that measure on the ratio of observed
21 to predicted antimicrobial use.

22 The SAAR is focused on high-value

1 targets for stewardship programs and high-level
2 indicators of antibiotic use for ASPs. The SAARs
3 can be used by ASPs to benchmark antimicrobial
4 use in multiple patient care locations, identify
5 opportunities for improvement, and gauge impact
6 of stewardship efforts.

7 At the outset, the SAARs provide a set
8 of signals that often warrant further analysis,
9 such as an evaluation of the extent to which a
10 specific antibiotic or group of antibiotics
11 accounts for a high SAAR value and the extent to
12 which an antibiotic or group of antibiotics were
13 used appropriately. The SAAR, in and of itself,
14 is not a definitive measure of appropriateness.
15 That requires additional information.

16 Some of the analytic follow-up can be
17 completed with hospital and patient care
18 location-specific data reported to CDC's National
19 Healthcare Safety Network using analytic features
20 built into the application. However, additional
21 analyses to determine the appropriateness of
22 antibiotic use in individual instances are likely

1 to require access to detailed patient-level data
2 that is beyond the scope of data collection and
3 analysis using the NHSN antimicrobial use and
4 resistance module, such as clinical indications
5 for specific antibiotics and dose duration
6 decisions. Those are not part of our
7 surveillance.

8 The measure relies completely on
9 electronic data using for the numerator,
10 medication administration data that are
11 ascertained via electronic medication
12 administration record systems or barcode
13 medication administration record systems with the
14 denominator data coming from ADP systems. We've
15 worked closely with five vendors and a homegrown
16 system, as well as stewardship programs and three
17 leading healthcare systems nationwide to
18 implement, develop, and preliminarily use data
19 from the system.

20 We're proposing a measure for public
21 health surveillance for quality measurement and
22 improvement. We are decidedly not proposing this

1 measure for public reporting or payment purposes
2 until we gain greater experience with the measure
3 and provide additional information around the
4 predictive modeling, grow that predictive model
5 in ways that would allow appropriate use for
6 public reporting and payment purposes.

7 With that, I'll stop.

8 CO-CHAIR SEPTIMUS: Thank you very
9 much, Dan. Charlotte, are you on to discuss this
10 one again? Boy, Charlotte, so --- Charlotte's
11 going to walk us through the data elements, Dan,
12 and then we'll take questions from all. And
13 please stay on the line because I'm sure we'll
14 have some questions for you. Charlotte?

15 DR. POLLOCK: Sure.

16 DR. ALEXANDER: So, I think he gave a
17 pretty good description of data elements. I'm
18 going to go to the evidence. Clinical practice -
19 -- this uses a clinical practice guideline, which
20 recommends prospective audit and feedback,
21 formulate a restriction, computer-based
22 surveillance to target antimicrobial

1 interventions, resistance patterns in nosocomial
2 infections, and adverse drug events. Up to 50
3 percent of antibiotic use is inappropriate,
4 leading to the development of increased drug
5 resistance, such as carbapenem-resistant
6 Enterobacteriaceae and C. diff.

7 Several systematic reviews
8 demonstrated that stewardship programs can lower
9 the risk of C. diff and other outcomes. They did
10 not specifically test this measure, but the
11 quality, quantity, and consistency is high.

12 CO-CHAIR SEPTIMUS: Lisa?

13 MS. MCGIFFERT: Yes. Hi, Dan, it's
14 Lisa McGiffert. I had some questions about the
15 measure, not about evidence, so much, but the
16 measure.

17 CO-CHAIR SEPTIMUS: I'm sorry.

18 MS. MCGIFFERT: Is this the time to
19 talk about it?

20 CO-CHAIR SEPTIMUS: No, we're only
21 talking about evidence.

22 MS. MCGIFFERT: Well, when will we

1 talk about the measure?

2 CO-CHAIR SEPTIMUS: As we go along.

3 MS. MCGIFFERT: Okay. What I would
4 like to know is what the SAAR, can you talk to me
5 about the SAAR a little bit more? I see that
6 it's a one is the score that people would be
7 going for, and I'm trying to figure out is one an
8 average? How did you determine that is the
9 optimal score? Can you tell us a little bit more
10 about that?

11 CO-CHAIR SEPTIMUS: Lisa, that is
12 going to be -- that's a reliability question.
13 So, if you can hold that thought, let's go
14 through the evidence and then, we'll get to the
15 relia-- that's an excellent question, but it's
16 like a SAAR, but it's for antibiotics. But let's
17 wait until we get to the reliability. Let's go
18 through the evidence first. I'm sorry to hold
19 off on that question.

20 Anything else? Yes, Pat?

21 DR. QUIGLEY: Thank you, Dr. Septimus.
22 This is Pat Quigley presenting, Dr. Pollock, and

1 I hope it would be acceptable in relationship to
2 the evidence to share that I have recently had
3 recent conversations with Dr. Ann Hendrich, nurse
4 extraordinaire of Ascension Health, and she had
5 shared that there was a recent meeting at the
6 White House with the three major healthcare
7 systems in launching this leadership stewardship
8 with CDC. And while there may be evidence
9 related to the work that they're doing already,
10 and these three healthcare systems are not in the
11 public domain in terms of the literature.

12 So, maybe this is part of public
13 reporting, that maybe you could do a little
14 summary of that White House Conference Aging to
15 help inform this body? Or the White House
16 Conference on -- I was at the White House
17 Conference on Aging, I'm sorry. But the White
18 House conference on this measure.

19 CO-CHAIR SEPTIMUS: You mean the White
20 House Summit on Antimicrobial Resistance that was
21 just held?

22 DR. QUIGLEY: Yes. Yes. Just held

1 like two weeks ago I think.

2 CO-CHAIR SEPTIMUS: I was at the
3 conference!

4 DR. QUIGLEY: You were there, huh?

5 CO-CHAIR SEPTIMUS: But I'm just ---
6 you said about the measure specifically?

7 DR. QUIGLEY: It was a White House
8 meeting. It was a meeting at the White House.

9 CO-CHAIR SEPTIMUS: About this
10 specific measure?

11 DR. QUIGLEY: Yes. Yes.

12 CO-CHAIR SEPTIMUS: I'll let Dan
13 answer that.

14 DR. POLLOCK: Well, actually, Ed, I'm
15 going to toss it back to you, because I was not
16 at the Antimicrobial Stewardship Forum that was
17 at the White House. But I understand that it was
18 a very successful meeting with many national
19 organizations stepping up, articulating their
20 commitments to stewardship efforts to reporting
21 into the Antimicrobial Use and Resistance Module.
22 And we're expecting a lot of positive energy to

1 come out of that process.

2 DR. QUIGLEY: Thank you.

3 CO-CHAIR SEPTIMUS: They didn't have
4 a detailed discussion about this specific
5 measure. But certainly, in the White House
6 report that was published in March, certainly
7 getting facilities to report into the AU Module,
8 was it by 2017, Dan?

9 DR. POLLOCK: Correct.

10 CO-CHAIR SEPTIMUS: It's certainly a
11 high priority to increase the number of
12 facilities that are already doing --- just like
13 they are for HAIs. But in terms of specific
14 measures, it's assumed that measures will come
15 forth through NQF. But actually, this particular
16 measure was not discussed at the White House
17 summit.

18 DR QUIGLEY: Okay, I apologize.

19 CO-CHAIR SEPTIMUS: That's fine.

20 DR. BURSTIN: Although, I will say
21 that we've been actually outreaching to CDC and
22 others. And given this huge interest in

1 antimicrobial stewardship, and how important it
2 is, we actually have -- we were delighted CDC was
3 willing to bring forward some of their newer
4 measures in this area, where we, frankly, have
5 none.

6 MS. MCGIFFERT: This is actually
7 included in the Administration's National Action
8 Plan.

9 CO-CHAIR SEPTIMUS: Well, measures
10 like this. Yes, that's correct.

11 DR. YU: Yanling Yu. I have a
12 question about denominator and nominator. Is
13 this include -- should it include -- under
14 reliability thing?

15 CO-CHAIR SEPTIMUS: It's reliability,
16 also.

17 DR. YU: Thank you.

18 CO-CHAIR SEPTIMUS: Steve?

19 DR. LAWLESS: Yes, it is just a
20 question of reliability, or not. In the
21 numerator piece, is this antibiotic days captured
22 with a positive culture or, just --

1 CO-CHAIR SEPTIMUS: Hold that
2 question, okay? All right, so, Yanling, did you
3 have another question? No. Okay. So let's
4 vote.

5 MS. IBRAGIMOVA: Importance to measure
6 and report 1(a) evidence, structure, process,
7 intermediate outcome. The votes are one high,
8 only eligible if QQC submitted; two moderate;
9 three low; four insufficient evidence.

10 And the results are 68 percent high,
11 23 percent moderate, 5 percent low, 5 percent
12 insufficient evidence.

13 CO-CHAIR SEPTIMUS: Gap. Charlotte?

14 DR. ALEXANDER: I'm going to make one
15 little statement to help clarify Lisa's question
16 and just as I go into gap. This measure is
17 antibiotic use reported to the CDC for adult and
18 pediatric patients compared to predicted on the
19 basis of nationally-aggregated data. SAARs
20 summarizes the observed to predicted
21 antimicrobial use for one of 16 antibacterial
22 patient-care location combinations.

1 If the measurement equals the SAARs,
2 it's a one. If it does better than SAARs, it's
3 negative. If it does more than SAARs, it's
4 positive.

5 DR. POLLOCK: This is Dan. I just
6 need to correct that. There are no negatives
7 here. The value of one would mean that the
8 observed to predicted is equivalent. A value
9 higher than one would mean that the observed to
10 predicted is higher, the observed antimicrobial
11 use is higher than would be predicted. And,
12 similarly, if the observed is below one, it would
13 be indicative of antimicrobial use that was less
14 than predicted.

15 CO-CHAIR SEPTIMUS: So does everybody
16 know what a SAAR is before we -- just to make
17 sure everybody -- okay. And just to let you
18 know, in HAIs, it's a standard infection ratio.
19 Again, it's observed over expected based on
20 certain risk adjustments. But, Lisa, you had a
21 question about SAAR?

22 MS. MCGIFFERT: Okay. Dan, me again.

1 Lisa. So the SIR, the predicted, we know where
2 the predicted came from. Can you tell us where
3 the predicted comes from in the SAAR, please?

4 DR. POLLOCK: Sure. So the predicted
5 is the days of therapy that would be predicted
6 from the data that are available to CDC, that are
7 aggregated by CDC, that are used in conjunction
8 with a predictive model to produce a summary of
9 what would be predicted for patient location or
10 facility-wide. So we have a statistical process
11 that's applied to the actual data that are
12 reported in.

13 To construct the SAARs, we use data
14 from over a hundred healthcare facilities that
15 were reporting from 25 states. And this is an
16 initial group of early adopters whose data were
17 used to develop the predictive models that
18 comprise the denominators for each of the 16 SAAR
19 metrics, which, as I said earlier, are a
20 combination of antimicrobial categories with
21 patient-care locations.

22 So an example of a particular SAAR

1 would be anti-MRSA agents used in adult ICU
2 locations: medical, medical/surgical, and
3 surgical. That would be a single one of the 16
4 SAARs.

5 MS. MCGIFFERT: And that would be
6 based on what you would ideally want to see in
7 the hospitals. So you took the 100 hospitals and
8 you looked at appropriate use.

9 DR. POLLOCK: Let me clarify, Lisa.
10 This is not a statement of ideal. This is not a
11 statement of appropriateness. This is a
12 statement of what would be predicted, what's
13 going on nationally for the particular patient
14 care location.

15 MS. MCGIFFERT: So let me ask you
16 this: what is going on nationally, is that a
17 good thing or a bad thing?

18 DR. POLLOCK: We need more, we need
19 more data with which to address that. And,
20 certainly, that's part of what CDC and partner
21 organizations are pursuing is to, you know,
22 ultimately drive down the overuse of

1 antimicrobial agents, which leads to
2 antimicrobial resistance and other bad outcomes.
3 So this is an integral part of that effort, but
4 it is not the singular solution to driving down
5 overuse and improving the prescribing practices.
6 However, it does provide a mechanism for the
7 first time to enable national benchmarks to be
8 available to literally thousands of hospitals
9 throughout the country that enroll and
10 participate in the module.

11 MS. MCGIFFERT: Okay. Well, I'll just
12 say one more thing because, you know, we've been
13 around this road before, about using the terms
14 "benchmarks" because when people see benchmarks
15 they see targets. That's what they want to
16 strive to achieve. And I guess a benchmark is a
17 little bit better than using the word "target."
18 But, you know, just to be clear, it's just going
19 to be an observed where everyone is, rather than
20 a goal.

21 And I know you're not suggesting this
22 for public reporting, but I sure am going to

1 suggest you use it for public reporting. And I
2 think it's, you know, we're just going to have to
3 be real clear about what, you know, what the
4 measure shows us. So thanks.

5 DR. POLLOCK: Again, I agree with you,
6 Lisa. But I think we're, we have to be clear
7 about it. And I think, eventually, you know,
8 we'll be very supportive of a next iteration of
9 this measure for public reporting and payment
10 purposes. But it's a new measure. It reflects
11 what we had worked very closely with stewardship
12 programs on over a period of years, and we're
13 confident that this is a very important first
14 step to take. But it is just a first step.

15 CO-CHAIR SEPTIMUS: Richard?

16 DR. BRILLI: Hi, Rich Brillli. Just a
17 question for the developer. Since this applies
18 to kids, is there sufficient data, predictive
19 data for children that this should apply there,
20 not that this is going to be used as a benchmark?
21 We certainly don't use it at our place, and I've
22 got a number of other pediatric people I've

1 communicated with that don't use it. So do you
2 have sufficient pediatric predictive data to use
3 this here?

4 DR. POLLOCK: We believe that we do.
5 And I think one of the reasons why it's not used,
6 yes, it's because it is a new metric, it is a new
7 measure. But we've worked closely with
8 stewardship programs, including pediatric
9 stewardship programs, to develop the measure.
10 We've got a separate set of SAARs entirely for
11 pediatric patient care locations. We are
12 confident that what we are developing will be
13 relevant for both the adult and the pediatric
14 patient populations.

15 Neonates are another story. That one
16 is on the horizon, but we have a strategy for
17 bringing the neonatal population in, as well.

18 DR. BRILLI: Okay, thanks.

19 CO-CHAIR SEPTIMUS: Okay. I think
20 it's time to vote. Laura?

21 MS. IBRAGIMOVA: So importance to
22 measure and report 1B, performance gap, the votes

1 are one high, two moderate, three low, four
2 insufficient. Just two more votes.

3 DR. RISING: Please don't count me in
4 for now. Since I just arrived, I'm going to sit
5 this vote out. Thank you.

6 CO-CHAIR SEPTIMUS: We would never
7 discount you, Josh.

8 MS. IBRAGIMOVA: So the results are 59
9 percent high, 32 percent moderate, zero percent
10 low, 9 percent insufficient.

11 CO-CHAIR SEPTIMUS: Okay. Now we get
12 to the some of the questions that some of you
13 were raising with reliability. So Charlotte?

14 DR. ALEXANDER: Under scientific
15 acceptability, the numerator is the days of
16 antimicrobial therapy for antimicrobial agents
17 administered to adult and pediatric patients in
18 medical, med/surg, and surgical wards and
19 medical, med/surg, and surgical ICUs.

20 Specific measurements are, one, broad
21 spectrum antibiotics for hospital onset multi-
22 drug-resistant infections; two, broad spectrum

1 antibiotics for community-acquired infections;
2 three, anti-MRSA agents; and, four, surgical site
3 prophylaxis agents; and, five, all antibiotics.

4 The denominator is days present for
5 each patient care location defined as any portion
6 of a day in a calendar month. All days are
7 summed for each location and month, and the
8 aggregate sums comprise the denominator.

9 Exclusions are locations other than
10 those stated above. The data is stratified by
11 hospital and patient location-specific variables,
12 teaching status, hospital bed size, ICU status,
13 ICU bed size, patient care location and bed size.
14 It is risk adjusted using a negative binomial
15 regression model to find factors associated with
16 differences in use rates and to predict days of
17 therapy that can be compared to observed days.
18 SAAR is the ratio of observed to predicted
19 antimicrobial use less than, equal, or greater
20 than one. I have a concern that patient days may
21 be double-counted if you have transfers since
22 they're being counted any time a patient is in a

1 location.

2 Reliability testing. This is tested
3 at the level of the facility. There were 24
4 hospitals used for the aggregate and 13 for the
5 data. These were hospitals who were reporting to
6 CDC NHSN Antimicrobial Use and Resistance Module
7 over the years 2011 to 2014.

8 On the data elements, there was a 60
9 to 80-percent reliability and greater than 99
10 percent on the process. And my only comment is
11 it is a small sample for data.

12 CO-CHAIR SEPTIMUS: Do you want to,
13 you raised a question about double counting.

14 DR. ALEXANDER: Yes. I think --

15 CO-CHAIR SEPTIMUS: Dan, do you want
16 to, how you count days? Is there a --

17 DR. POLLOCK: Right. So, yes, a
18 portion of a day in a patient care location where
19 an antimicrobial agent is administered counts as
20 an antimicrobial day for that patient care
21 location. So if a patient is transferred from a
22 ward location to an ICU location, for example, or

1 vice versa, if they're maintaining that
2 antimicrobial agent throughout, that
3 antimicrobial agent administered for a portion of
4 the day in each of those locations would be
5 counted as an antimicrobial day in each of those
6 locations.

7 CO-CHAIR SEPTIMUS: Okay. Questions?
8 Steve?

9 DR. LAWLESS: Yes, this is Steve
10 Lawless. A couple of questions. One is I've
11 looked at the references that you provided, so
12 thank you for that. But there's nothing in the
13 references that would actually show anything
14 about the data. All the references are mostly
15 about association with C. diff, and I get that.
16 But in terms of the general distribution of
17 SAARs, where they are, the details and the
18 numbers and the risk adjustments. We're used to
19 seeing a lot more of that data out there,
20 percentile rankings. Where is that?

21 And the other piece is --

22 DR. POLLOCK: Well --

1 DR. LAWLESS: Okay, go ahead.

2 DR. POLLOCK: Well, good question. I
3 mean, again, this is a new measure. We've
4 provided in table three that accompanies the
5 measure proposal the SAAR distribution and
6 statistical comparisons for each of the 16 SAAR
7 metrics. And, admittedly, this is the first time
8 that the SAAR is being reported.

9 But, again, it's grounded on concepts
10 that have existed in the stewardship domain for
11 many years, albeit with specifications that we've
12 had to tailor to fit with NHSN and what NHSN can
13 produce so that, yes, it is novel. But you have
14 to start somewhere.

15 DR. LAWLESS: Right. And the next
16 question would be is just consider the idea of
17 positive cultures versus non-positive cultures as
18 a comparative so that overuse of antibiotics a
19 lot of times is, you know, we have this classic
20 7, 14, 21 days of antibiotic courses grounded in
21 no particular fact. But if something as positive
22 as a culture may be appropriate versus no

1 cultures for just overuse, are we considering
2 that as you're developing that?

3 And the third piece is what about the
4 outpatient? A lot of patients do come into the
5 hospital already started on an antibiotic, and so
6 people tend to continue the antibiotic because
7 you just don't know what to do or not, whether
8 it's working. Is that a consideration or not?

9 DR. POLLOCK: So very good
10 observations and comments. I would say that the
11 presence or absence of a positive culture
12 certainly would be part of a consideration that a
13 stewardship program would ultimately incorporate
14 in evaluating a SAAR value at the patient level.
15 But we're not ascertaining the presence or
16 absence of a positive culture as part of the
17 routine surveillance effort.

18 We do have a companion piece to the
19 antimicrobial use reporting, which is the
20 antimicrobial resistance part of our AUR module,
21 and that will provide at least some indication of
22 the amount of bacterial culturing that's going on

1 and the results that are being ascertained. But,
2 again, that will be not at the patient level,
3 that will be at the location and the facility
4 level.

5 Your other question is a very good
6 one. This is a starting place. The patient care
7 locations that we have selected can be expanded
8 out to include emergency department and other
9 locations, but we wanted to begin with some
10 targets that we think are important. Not to say
11 that there aren't other targets, but we want to
12 learn from these initial set of targets and then
13 propose expansion of the coverage, both in terms
14 of patient care locations and other facility
15 types. These are hospital participants, and the
16 measure is really focusing on hospital
17 antimicrobial use.

18 CO-CHAIR SEPTIMUS: Okay. One last
19 comment, and then we're going to vote. Yanling?

20 DR. YU: Yes, I have a couple of
21 questions. One is there's a reliability test,
22 the paper records were used to analyze the model

1 and the numerator. But in the measure, it says
2 only electronic records would be used. I'm just
3 wondering if you have any source of explanation
4 why the paper records would not be considered
5 eventually?

6 DR. POLLOCK: Well, that's a good
7 question. I think that we, like others, want to
8 move forward to electronic quality measurement
9 and using electronic supply chains of
10 information. We have in the past attempted to
11 capture a true NHSN antimicrobial use with manual
12 processes and manual data entry. It's simply
13 proved to be untenable operationally. The good
14 fortune that we have is that there is rapidly-
15 increased use of the electronic bedside
16 medication administration record-keeping systems.
17 So really our operational design pivots off of
18 use of those systems, extracting, transforming,
19 and loading data that have been ascertained
20 through those systems into a message that could
21 be sent to CDC. Again, that's electronic supply
22 chain of information.

1 The reliability testing that we are
2 doing is reliability testing before the messaging
3 begins, and it looks at the data that are put
4 into the message compared with the data that are
5 in native systems, be they the medication
6 administration systems in the case of the
7 numerator or the admission discharge transfer
8 systems in the case of the denominator.

9 DR. YU: Okay. Thank you for your
10 explanation. My second question is, in your
11 regression model, you called standard population.
12 I just wondered if you have any examples about
13 this standard population? Are those theoretical
14 ones, or do you just gather real data and then
15 start to, you know, to characterize those
16 different population?

17 DR. POLLOCK: It's the latter. I
18 mean, we're using real data. We're using the
19 nationally-aggregated data, and the initial
20 adoption and use of our AU reporting that we use
21 to develop a measure includes data from over 100
22 healthcare facilities nationwide from 28 states:

1 critical access hospitals, children's hospitals,
2 an oncology hospital, in addition to the
3 predominant general acute care hospitals that
4 participated. We've used multiple vendor systems
5 and a homegrown system.

6 So we have, I think, quite
7 heterogenous participation in the AU reporting
8 already. That's going to grow. It's growing
9 considerably, even since we introduced a bit of a
10 measure proposal in April. And as we further the
11 participation in the module, we can use these
12 additional data in the modeling process.

13 DR. YU: Okay. So help me understand.
14 So SAARS really is a model --

15 CO-CHAIR SEPTIMUS: It's SAAR. It's
16 SAAR, not SAARS, please.

17 DR. YU: Yes, SAAR. It's really a
18 theoretical number; is that right?

19 DR. POLLOCK: Well, I'm not sure what
20 you mean by --

21 DR. YU: It's optimal days compared
22 with what's observed, the ratio.

1 DR. POLLOCK: Well, it doesn't have to
2 do with optimal. It doesn't have to do with
3 ideal. It has to do with what's going on
4 nationally. It doesn't assume what's going on
5 nationally is appropriate. That's why it
6 requires additional analysis at the institution
7 level to really get at questions of optimization
8 of the antimicrobial prescribing.

9 Now, over time, when we had the
10 opportunity to add to our model, perhaps using
11 data from the antimicrobial resistance reporting,
12 we'll be in a better position to get closer to an
13 understanding of where, on the basis of the SAAR
14 alone, antimicrobials are being overused.

15 DR. YU: Okay. All right, thank you.

16 CO-CHAIR SEPTIMUS: Okay. We're going
17 to vote on this. We have to move fairly quickly
18 here, but I want to allow enough time because
19 this is a new measure. So let's vote on
20 reliability.

21 MS. IBRAGIMOVA: Scientific
22 acceptability of measure properties, 2A,

1 reliability. The votes are one high, two
2 moderate, three low, four insufficient.

3 CO-CHAIR SEPTIMUS: Josh, you're not
4 voting, right? Okay.

5 MS. IBRAGIMOVA: The results are 26
6 percent high, 61 percent moderate, 4 percent low,
7 and 9 percent insufficient.

8 CO-CHAIR SEPTIMUS: Validity. Any
9 major comments on validity, Charlotte?

10 DR. ALEXANDER: I think it's important
11 to point out that the evidence refers to the
12 value of a stewardship program and audit
13 feedback, not directly to reporting. Face
14 validity was done with an expert panel, and this
15 is risk adjusted with a statistical risk model.

16 CO-CHAIR SEPTIMUS: Yanling, is that
17 still up, or are you finished with it? Okay.

18 DR. YU: I apologize.

19 CO-CHAIR SEPTIMUS: No, don't
20 apologize. Okay. Let's vote.

21 MS. IBRAGIMOVA: Scientific
22 acceptability of measure properties, 2B,

1 validity. The votes are one high, two moderate,
2 three low, four insufficient. Just need one more
3 vote.

4 The results are 30 percent high, 57
5 percent moderate, 4 percent low, 9 percent
6 insufficient.

7 CO-CHAIR SEPTIMUS: Okay. We'll move
8 to feasibility.

9 DR. ALEXANDER: This measure is
10 captured through electronic data during the
11 provision of care.

12 CO-CHAIR SEPTIMUS: Yes, Leslie?

13 DR. SCHULTZ: Leslie Schultz. Dan, I
14 have a question. There are probably more
15 hospitals that are not fully e-enabled than there
16 are hospitals that are. Is there a proxy for
17 those who cannot easily get to the administration
18 data?

19 DR. POLLOCK: At this point, we think
20 that there is overwhelming movement to electronic
21 medication administration systems or barcode
22 systems. And we've got survey data that's

1 indicative of that. We have critical access
2 hospitals that are using this type of technology.

3 So it's really ubiquitous. And rather
4 than introducing a manual process which we've had
5 experience in the past it leads to frustration
6 and inability to report, we've placed a stake in
7 the ground here in saying we want to go
8 electronic. And we think this is a good place to
9 begin. This is, indeed, while not meeting the
10 criteria of what is defined as an eMeasure, it's
11 still an electronic measure, and it's time for us
12 to move forward and move from here.

13 CO-CHAIR SEPTIMUS: Lisa?

14 MS. MCGIFFERT: Dan, this is Lisa
15 McGiffert. Did you say that you had a homegrown
16 version of electronic reporting?

17 DR. POLLOCK: Right.

18 MS. MCGIFFERT: And so does that --
19 and just to follow up, does that mean that CDC,
20 that's something CDC could make available to
21 smaller hospitals that might not be able to
22 afford a private contract?

1 DR. POLLOCK: Well, the homegrown
2 system is a system that was developed and used to
3 extract the data from an electronic system that
4 is commercial. So it's, in essence, analogous to
5 a third-party software system, which is what the
6 vendors are providing. And, yes, we hear, you
7 know, it's possible to have a vendor system
8 deployed for purposes of extract, transform, and
9 load into a message to send to CDC. But when you
10 look at the dollar amounts that are being
11 discussed, \$25,000 to \$50,000 for these types of
12 implementations, and you compare that dollar
13 amount with what IT budgets are in hospitals or
14 what's been expended societally on the meaningful
15 use program and what the return on investment,
16 the \$25,000 to \$50,000 a year for stewardship
17 efforts, we think that this is, again, a place to
18 put a stake in the ground and say this should be
19 part of the cost of doing business in American
20 healthcare.

21 CO-CHAIR SEPTIMUS: Okay. Let's vote
22 on this then, please. Feasibility.

1 MS. IBRAGIMOVA: Feasibility. The
2 votes are one high, two moderate, three low, four
3 insufficient. The results are 22 percent high,
4 65 percent moderate, 4 percent low, 9 percent
5 insufficient.

6 CO-CHAIR SEPTIMUS: Okay. Now we get
7 to usability. Charlotte?

8 DR. ALEXANDER: This is not currently
9 a reported measure. It's a new measure, but it
10 is intended to be reported in the National
11 Healthcare Safety Network and used for internal
12 and external quality improvement and
13 benchmarking.

14 CO-CHAIR SEPTIMUS: Missy? Haven't
15 heard from you in a while.

16 MS. DANFORTH: Hi, Dan. This is Missy
17 Danforth from the Leapfrog Group. I just have a
18 quick question. I know that data is going to be
19 reported through the electronic reporting system.
20 I'm wondering, because you've acknowledged this
21 as a new measure, not an ideal measure, you're
22 still learning a lot. Is there an opportunity to

1 incorporate the CDC's checklist that was
2 developed for antimicrobial stewardship into the
3 reporting on this measure so we can get a better
4 sense of what are the elements on that checklist
5 that are most tied to lower, more appropriate
6 use, since the checklist is really expansive?
7 It's something that the CDC has developed and
8 recommending that all hospitals use. Is there a
9 way to incorporate that into the reporting, as
10 well, so that we can get as much information as
11 possible and possibly improve on the measure
12 faster?

13 DR. POLLOCK: That's a good question.
14 I think that the way -- and we certainly have
15 that in our sights, as well, but not so much to
16 incorporate it into the measure but to use the
17 measure results for antimicrobial use reporting,
18 as well as the survey results of what elements of
19 the stewardship program are present and reported
20 by a facility through a NHSN annual survey. We
21 can use those in conjunction with each other in
22 analyzing the relationship, and that certainly is

1 part of our strategy going forward.

2 DR. BURSTIN: And just to add this on,
3 we've also had conversations with Arjun at CDC
4 about that. And I think there may be an
5 opportunity as they get back the survey data this
6 year from 4,000 hospitals or something like that
7 to think about how to build that into a measure
8 to follow.

9 DR. POLLOCK: That's right, Helen.
10 That's exactly right.

11 CO-CHAIR SEPTIMUS: There's been some
12 discussion about a process measure built around
13 that. Also, the TATFAR report, Transatlantic
14 Taskforce on Antimicrobial Resistance, will
15 release its structure and process measures any
16 moment, right, Dan?

17 DR. POLLOCK: Let's hope so.

18 CO-CHAIR SEPTIMUS: It's been
19 approved, but that will also be out there. But
20 we have discussed looking at process measures as
21 another potential measure for stewardship.
22 Leslie?

1 DR. SCHULTZ: Leslie Schultz. A
2 comment here. It is a new measure. I think it's
3 going to be a wonderfully-helpful measure. We
4 need something standardized that's endorsed so we
5 can grow that hundred to forty-five hundred and
6 really understand what is going on. What are we
7 using? We can't talk about overutilization until
8 we see what that distribution is. And having
9 done work with CDC on potentially inappropriate
10 overutilization of intravenous antibiotics, I
11 think this is very important. We as a nation
12 need to measure so we can manage.

13 CO-CHAIR SEPTIMUS: Steve? One last
14 question?

15 DR. LAWLESS: Yes, just a question of
16 NQF processing protocol. I think everybody is
17 realizing the importance of this, the value long-
18 term. It's something that really has a lot of
19 development to be done. I mean, the value is
20 there. As we endorse this, it's lots of measures
21 that need to be done, future success of
22 everything is going to be independent. Our

1 endorsement will do what for this measure, versus
2 they would develop it and come back later with a
3 more mature, guys, we have something we proudly
4 endorse versus we don't know where it's going.

5 DR. BURSTIN: I think that's a great
6 question. This is Helen for Dan on the phone. I
7 think our feeling is that we want to get
8 something out in a space. It's really important,
9 it's a national priority, and, frankly, we don't
10 feel like there's enough there. I think putting
11 it out in a space makes it clear this is
12 important in the measurement enterprise.
13 Hopefully, people begin using it. And, again, as
14 you've seen, it's not as if when we endorse
15 something it stops the development train. I
16 think there's a lot of momentum here to keep
17 making new measures, make them better. It also
18 potentially makes it something that could be
19 picked up as part of some of the federal
20 infrastructure around payment or public
21 reporting, not immediately but at least puts it
22 on their radar screen perhaps, I think, in a way

1 that it may not be if it doesn't kind of go
2 through this national process.

3 CO-CHAIR SEPTIMUS: That's a very good
4 question, Steve. Okay. One more question and
5 then we've got to -- go ahead, Lisa.

6 MS. MCGIFFERT: Okay. I just would
7 say that the history with NHSN and CDC has
8 certainly been that when these measures have
9 first been put out, even when they first started
10 collecting infection information, it has
11 significantly changed over time through input
12 from the users and looking at the data. And I
13 expect we'll see a lot of that in the future,
14 too.

15 CO-CHAIR SEPTIMUS: Okay. Let's vote
16 on usability, please.

17 MS. IBRAGIMOVA: Usability and use.
18 The votes are one high, two moderate, three low,
19 four insufficient information. Just two more
20 votes. The results are 39 percent high, 48
21 percent moderate, 4 percent low, 9 percent
22 insufficient information.

1 CO-CHAIR SEPTIMUS: Okay. So the last
2 vote then is suitability for endorsement. So
3 it's either yes or no.

4 MS. IBRAGIMOVA: So overall
5 suitability for endorsement, does the measure
6 meet NQF criteria for endorsement? One yes, two
7 no.

8 CO-CHAIR SEPTIMUS: One more.

9 MS. IBRAGIMOVA: So the results are 91
10 percent yes, 9 percent no.

11 CO-CHAIR SEPTIMUS: Thank you, Dan,
12 for being on the phone. This is a historic first
13 step, I think, to addressing antimicrobial
14 resistance, and we certainly expect over time
15 that we'll see other measures and refinement as
16 more institutions report in to the AU Module. So
17 thank you for all the effort it took in bringing
18 this forward and thank the Committee for
19 considering this. So thank you very much, Dan.

20 DR. POLLOCK: Thank you and thanks to
21 the Committee.

22 DR. BURSTIN: Thanks, Dan.

1 CO-CHAIR SEPTIMUS: When I get the
2 TATFAR report, I'm more than willing to share. I
3 have it on my computer, but it has not been
4 publicly released. I'm sorry. I can't do it.

5 Okay. The next on our agenda is 2729,
6 timely evaluation of high-risk individuals in the
7 emergency department. CMS and Mathematica -- I
8 am going to recuse myself from voting on this
9 one, so if you see 23 votes, Laura, it means I
10 shouldn't have voted. But I'm not going to vote
11 on this because I was one of the consultants of
12 the development of the measure. Tom, are you
13 going to do this? Cindy, okay. So if you'll
14 introduce yourself to the Committee, and the
15 discussant on this is, oh, Kendall. Thank you.
16 Go for it.

17 MS. CULLEN: Great, thanks. Good
18 morning. My name is Cindy Cullen. I'm the
19 project director for the CMS Hospital Inpatient
20 and Outpatient Process and Structural Measure
21 Development and Maintenance Project at
22 Mathematica Policy Research. With me today is

1 our project clinical lead and principal
2 investigator, Dr. Tom Croghan.

3 Our project is tasked with developing
4 and maintaining clinical quality measures
5 supporting five of CMS's hospital quality
6 reporting programs. As indicated in our project
7 title, our focus is limited to development and
8 maintenance of process and structural measures
9 that define quality care for inpatient,
10 outpatient, ambulatory surgical center, and
11 cancer hospital patients. We also develop and
12 maintain the electronic clinical quality
13 measures, or eQMs, for the hospital side of the
14 meaningful use program.

15 The two measures we present and will
16 be discussed today were developed by another CMS
17 contractor, FMQAI. FMQAI's contract term ended
18 prior to the initiation of this consensus
19 development project. They had completed all
20 measure development and testing and developed the
21 initial drafts of the submission documents you
22 reviewed.

1 We are here today representing CMS's
2 interests in the development and, hopefully,
3 endorsement of these measures. We want to
4 acknowledge and thank FMQAI for their work and
5 their generosity in helping us to understand this
6 work and prepare for this presentation.

7 We do understand that the Committee
8 may have questions about the measures that we are
9 not able to answer as a result of our not being
10 the original developer. We will note these
11 questions, and we'll work with CMS and FMQAI to
12 obtain answers for you to help inform your
13 decision-making.

14 The measure under consideration now,
15 timely evaluation of high-risk individuals in the
16 emergency department, looks at the median time
17 from ED arrival to qualified provider evaluation
18 for patients triaged at the two highest severity
19 levels on a five-level triage scale and addresses
20 an important patient safety issue. This is an
21 electronic measure data-sourced from the EHR.

22 Recent reports indicate that mean ED

1 wait times are rising. This is seen most
2 critically for patients triaged at the two
3 highest triage levels. Although waiting longer,
4 patients triaged at the three lowest levels are,
5 on average, obtaining care within the time frames
6 recommended by the National Center for Health
7 Statistics. Those at the highest two levels,
8 though, are not.

9 In 2009, estimated mean wait times for
10 those triaged at the highest or immediate level
11 were 29 minutes, while recommended wait time is
12 less than one minute. At the next highest level,
13 emergent, the estimated mean wait times were 51
14 minutes while recommended wait times were between
15 1 and 14 minutes. Delay puts patients,
16 especially those in most need of immediate
17 attention and care, at risk.

18 FMQAI undertook extensive field
19 testing at seven geographically and
20 characteristically diverse hospitals.
21 Reliability tests indicated ability to
22 distinguish that the performance of at least one

1 hospital was statistically different from that of
2 other hospitals. Construct validity tests
3 identified cases where outcomes could have
4 improved if care had not been delayed.

5 Feasibility testing demonstrated that
6 all data elements were found to be available in
7 the EHR systems and used by the hospitals, which
8 included Epic, Cerner, and McKesson products.

9 Criterion validity tests showed strong agreement
10 between electronic and manual abstraction for two
11 of the three data elements, ED arrival time and
12 triage score, but less so for first provider
13 contact time. These findings were reviewed by
14 FMQAI's TEP and hospitals who acknowledged the
15 challenge to accurately record this in the EHR
16 but also noted an interest in increasing accuracy
17 for their own quality improvement purposes.

18 This measure is not yet in a CMS
19 program but has been reviewed and approved for
20 continued development by the MAP for hospital
21 inpatient quality reporting and the meaningful
22 use programs. CMS has six other median time

1 measures in the hospital inpatient and hospital
2 outpatient quality reporting programs. OP-20 is
3 the closest similar measure, door-to-diagnostic
4 evaluation by qualified medical personnel, but it
5 reports median time to provider contact is chart
6 abstracted and does not look at the severity
7 level of the patient.

8 We thank you for your consideration
9 and look forward to your review.

10 CO-CHAIR THRAEN: Kendall?

11 DR. WEBB: Okay. So I'm not going to
12 repeat the introduction of the measure. I think
13 it was adequately introduced. I'll go straight
14 into evidence, if everybody is okay with that.

15 This is a process measure. There was
16 a systematic review and QQC presented. I believe
17 when I used the algorithm, actually, I came up
18 with a high value for this.

19 To go over it just a little bit, being
20 an ED doc and also an IT, this is probably
21 perfect, actually, for me. Certainly, if you go
22 over the data, you definitely want to triage your

1 highest-priority patients first. ESI is a triage
2 system used in a lot of places but not
3 everywhere, used mostly in larger places. And,
4 actually, one of the things I'm going to want to
5 talk about later is that it can actually be an
6 onerous construct on some of the smaller EDs.

7 The ESI level-1 is basically the
8 patient comes in dying or dead and you need to
9 take care of them right away, and ESI 2 is
10 they're not quite to that point but they'll get
11 there if you don't take care of them right away,
12 and that's why the 1-minute and 14-minute wait
13 times are named here.

14 This does affect a large number of
15 patients. It says here 130 million in 2010 was
16 the number. And there are, you know, multiple
17 studies to talk about, you know, getting to the
18 patient faster is going to improve outcomes.

19 So this is in alignment with national
20 priorities. This is electronically kept and can
21 be gotten from there.

22 So just from an evidence perspective,

1 personally, when I looked through the algorithm,
2 I thought the evidence was actually pretty high.

3 CO-CHAIR THRAEN: I have one
4 clarification question. I thought I heard you
5 say this was an eMeasure but in the documentation
6 it says it is not. Could you clarify?

7 MS. CULLEN: It is an eMeasure --

8 CO-CHAIR THRAEN: It is an eMeasure.

9 MS. CULLEN: -- and electronic measure
10 specifications were submitted.

11 CO-CHAIR THRAEN: Okay. So the
12 documentation is a bit long. Jason, did you want
13 to make any comments about, as an eMeasure,
14 related to the evidence, is there anything?

15 MR. GOLDWATER: No, there's nothing on
16 evidence. Their form was complete, and it's
17 succinct.

18 CO-CHAIR THRAEN: Okay. Go ahead.
19 Richard?

20 DR. BRILLI: I guess I just have one
21 concern about the use of mean wait times for
22 something like this. So mean wait times, even

1 median wait times but in particular mean wait
2 times are highly subject to outliers. So you
3 could have 99 patients who wait one minute and
4 you have one patient who waits four and a half
5 hours, and the meantime is totally skewed. So,
6 to me, the measure ought to be percent of
7 patients who achieve the goal. So if the goal is
8 one minute or the goal is 14 minutes or whatever
9 it ought to be, you want 99 percent or 90 percent
10 of the patients or even 100 percent of the
11 patients to achieve that goal.

12 I think mean wait times are very, it's
13 a very bad measure to really figure out
14 performance. It's what a lot of people do, but
15 you really want the percent of patients who
16 achieve the goal so that you take the outlier
17 issue out of it in terms of time.

18 CO-CHAIR THRAEN: Any response?

19 MS. CULLEN: This measure is a median
20 wait time, not a mean wait time.

21 DR. BRILLI: You have the same, you
22 have the same issue, though. If you don't talk

1 about the number of patients who achieve the
2 goal, you're still going to be affected by those,
3 you know, the patients who have an excessive wait
4 time.

5 DR. WEBB: So I have to tell you, as
6 an ED doc, you're going to start out with this
7 measure with a zero percent and you're not going
8 to have any way to do any comparisons at a lot of
9 hospitals because we're not meeting this measure
10 right now. The vast majority of us are not
11 meeting this measure right now.

12 DR. BRILLI: I get it. All I'm saying
13 is that it's just going to be highly susceptible.

14 DR. WEBB: I understand. Yes, I
15 understand.

16 CO-CHAIR SEPTIMUS: The percentage of
17 patients who met that goal was about 25 percent,
18 so it's not actually zero. And there is a
19 correlation with the median wait time.

20 DR. ALEXANDER: For ED docs, 25
21 percent feels like zero.

22 DR. WEBB: And the number of hospitals

1 that were done where it looked at were seven
2 hospitals, and none of them had a volume greater
3 than 19,000.

4 DR. BRILLI: And just because it's not
5 being done now or it's not -- it doesn't mean we
6 should continue to perpetuate a measure that I
7 think could be better if we used percentage to
8 achieve as opposed to either median or mean wait
9 times. This is an opportunity to change it.

10 CO-CHAIR THRAEN: So I think we need
11 to go to Lisa and then Jason and then Josh.

12 MS. MCGIFFERT: Just a quick question
13 on if it's an eMeasure, is the data collected
14 automatically when somebody checks in and then
15 when they get assessed, or how does that work?

16 MS. CULLEN: That depends upon the
17 electronic record system. What was done in the
18 testing was to compare what was recorded in the
19 electronic record with someone going in and doing
20 a manual abstraction to see if there were other
21 keys that would identify that there might be
22 potential other locations for that. And there

1 seemed to be, in some cases, good agreement, in
2 some cases not good agreement.

3 CO-CHAIR THRAEN: Jason?

4 DR. ADELMAN: I recently had the
5 opportunity to review a project that was
6 proposing to have an improved system for
7 classifying these different stages of emergency
8 room triage, and the premise was that the current
9 system was just often inaccurate with lots of
10 variability. And so I'm not an expert in it.
11 I'm just reflecting what I read.

12 But if that were true, then this
13 measure, you know, will reflect the accuracy of
14 triage, as opposed to the time, or it's capturing
15 time of something that's very inaccurate. So I
16 wonder if the developers and those who know more
17 about this can comment on that.

18 CO-CHAIR THRAEN: Okay. That's a
19 reliability question. Let's hold on that one.
20 Is there any other questions related to the
21 evidence? Go ahead, Josh and then Lillee.

22 DR. RISING: Hi. Josh Rising. I just

1 want to respond, you know, to the percent versus
2 trying to use the mean versus median. I mean, I
3 think the goal is to see all these patients as
4 quickly as possible, not just necessarily, you
5 know, within a 14-minute kind of window. So I do
6 think kind of having the specific time, there is
7 some value in that.

8 I guess one question that I did have,
9 though, is that, you know, the data shows that,
10 you know, there's a lot of large hospitals and
11 presumably even more smaller hospitals that
12 aren't using the ESI kind of scoring system at
13 all. So I was curious how could the developers
14 and others talk about, you know, the value of
15 this measure if it's not even going to be able to
16 be applied at a large number of facilities in the
17 country?

18 DR. CROGHAN: The important concept
19 with ESI is that it has five categories, and
20 that's the valid reliable way and appropriate way
21 of triage patients. The comparison is a three-
22 level measure, and some of the ER docs in the

1 room may know this better. But those are not as
2 reliable, and so there is room in this measure to
3 use an alternative other than the ESI.

4 DR. RISING: Is the alternative system
5 used at all the hospitals that aren't using the
6 five-tier system?

7 DR. CROGHAN: I think most of the --
8 say again.

9 DR. RISING: So you said that, I said
10 that it looks like there's a lot of hospitals
11 that aren't using the five scoring system, and
12 you said, well, an alternative is there's this
13 other three-level system. But I wanted to know
14 if the other hospitals then are using this
15 alternative system.

16 DR. CROGHAN: I believe most of them
17 are. I'm going to look at Dr. Pines here.

18 DR. PINES: Sure. So if you look
19 across all hospitals, ESI is the most commonly
20 used system. There are -- ESI is a resource-
21 based system based on how many, how many
22 resources a patient is going to need to be cared

1 for in the emergency department, and on the
2 higher end it's about severity of illness. So
3 ESI has shown to be more reliable than when you
4 look at two nurses looking at the same patient
5 comparing ESI versus some sort of time-based
6 triage, you know, does this person need to be
7 seen in 15 minutes, 30 minutes, ESI tends to be
8 much better than that in terms of reliability.
9 So it is the most reliable and most used measure
10 but not used everywhere.

11 DR. CROGHAN: I think the correlation
12 between the three- and the five-category systems,
13 the five-category system is much more predictive
14 of eventual hospitalization and mortality
15 relative to the three-category system, as well.
16 So it is, you know, implicitly, you're sort of
17 driving people to use a five-categoric system.

18 DR. PINES: Yes, I recognize it sounds
19 like it's the right system to you. It's just a
20 challenge if there's a ton of facilities that
21 aren't using it currently.

22 CO-CHAIR THRAEN: And I think that

1 speaks to usability. Again, we're at the
2 evidence state. So if the cards that are up, do
3 you have questions regarding the state of the
4 evidence?

5 MS. ARDIZZONE: This is -- I just
6 wanted to support the evidence. I'm saying that
7 the evidence is extremely clear that this is
8 beneficial, helpful. And, remember, they're just
9 looking at ES-1s and 2s, so we're looking at the
10 most critical patients, making sure that we're
11 meeting the target for them.

12 CO-CHAIR THRAEN: Steve?

13 DR. LAWLESS: Yes, and the evidence,
14 just a clarification of the evidence. In the
15 justification of where the outcomes improve, the
16 numbers that were used were cited, you know.
17 Going from 77 minutes to 66 minutes were
18 dramatic. The data that shows where we currently
19 are with, you know, the 95th percentile is in the
20 12- to 14- to 16-minute range. So is the
21 evidence matching to what you actually surveyed
22 in the hospitals to what the literature says

1 where the improvement can be?

2 DR. CROGHAN: I'm not sure that, I
3 mean, the seven hospitals were chosen
4 conveniently because they had good data. And my
5 guess is that it's not a representative sample
6 and probably wouldn't reflect the national
7 surveys done by CDC.

8 DR. LAWLESS: Right. So I'm asking --
9 I got that. I mean, they didn't have the 77
10 minutes waiting for the ES-1. But would you see,
11 does the evidence support that, at the level
12 where these hospitals are, at a lower level where
13 these seven were randomly selected would have the
14 same improvement and outcome?

15 DR. CROGHAN: I'm just going to make
16 a point of order. Is that a validity question?

17 CO-CHAIR THRAEN: Steve, re-state it.

18 DR. LAWLESS: Is the evidence you're
19 showing for justification that this is, does the
20 evidence show that, at the level where you
21 surveyed your hospitals, you would have the same
22 outcome impact versus --

1 DR. CROGHAN: So if you're at 20
2 minutes or 14 minutes or whatever, you know, by
3 implementing this, would you improve care?

4 DR. LAWLESS: Right.

5 CO-CHAIR THRAEN: Yes, that's a
6 generalization question, so, yes, I think that
7 falls into validity. Sorry. You'll have to
8 answer it anyway.

9 DR. CROGHAN: I have to answer it.

10 CO-CHAIR THRAEN: Yes, but we'll give
11 you a minute to think about it. Let's vote on
12 the evidence.

13 MS. GELINAS: I just want quick
14 yes/no. In the evidence, were there studies
15 about the competency of the nurse being able to
16 perform triage?

17 DR. CROGHAN: Yes.

18 MS. GELINAS: Because we found the
19 same thing.

20 CO-CHAIR THRAEN: He answered yes.

21 MS. GELINAS: And it is a huge
22 problem. We just standardized from a number of

1 ESI levels to a five-level system across multiple
2 hospitals, multiple states. It's not easy. We
3 have Cerner and Epic. It is not easy. Did the
4 risk or adverse event landscape in your work in
5 the past indicate through the evidence that, by
6 applying the consistent levels and consistently
7 measuring the adverse event and sentinel event,
8 processes were improved?

9 DR. CROGHAN: We may have to get back
10 to you on that one.

11 MS. GELINAS: Because I can help
12 provide some of that, but I wanted to know if
13 it's in the evidence base.

14 DR. CROGHAN: I'm not 100-percent sure
15 I understand your question but --

16 CO-CHAIR THRAEN: Can we vote on the
17 evidence?

18 MS. IBRAGIMOVA: Importance to measure
19 and report, 1A, evidence structure, process,
20 intermediate outcome. The votes are one high,
21 only eligible if QQC submitted; two moderate;
22 three low; four insufficient evidence.

1 CO-CHAIR THRAEN: Okay. We're missing
2 a couple. We only have 19. We need one more.
3 Victoria stepped out, okay. We're good.

4 MS. IBRAGIMOVA: So the results are 40
5 percent high, 55 percent moderate, 5 percent low,
6 zero percent insufficient evidence.

7 CO-CHAIR THRAEN: Okay. Kendall,
8 performance gap?

9 DR. WEBB: All right. So opportunity
10 for improvement. I think we all see that there
11 is opportunity for improvement here. As far as
12 there were definitely, in these seven hospitals
13 that they looked at there was definitely a wide
14 variety of average minutes to get to the ES-1 and
15 ES-2 levels. Again, I would note that the sample
16 size was a convenient sample. And 19,000 visits
17 per year is a small hospital for most. So
18 whether it's generalizable to all hospitals
19 nationwide is unknown, although I would actually
20 think you would even, personally, I would think
21 you would get a bigger gap if you looked at the
22 large hospitals.

1 There was also some age and race
2 disparity noted in some of the evidence. So as
3 far as opportunity for improvement, I would say
4 absolutely there's opportunity for improvement
5 here.

6 CO-CHAIR THRAEN: Charlotte?

7 DR. ALEXANDER: I would like to make
8 a plea to add language to your race disparity
9 data.

10 CO-CHAIR THRAEN: Any other discussion
11 or questions? Let's vote.

12 MS. IBRAGIMOVA: Importance to measure
13 and report, 1B, performance gap, the votes are
14 one high, two moderate, three low, four
15 insufficient.

16 MS. THEBERGE: Ann, we need your vote.

17 MS. IBRAGIMOVA: The results are 64
18 percent high, 36 percent moderate, zero percent
19 low, zero percent insufficient.

20 CO-CHAIR THRAEN: Reliability?

21 DR. WEBB: Reliability -- all right,
22 so for reliability, this is where we get into a

1 little bit of issue, or a lot of issue as far as
2 I'm concerned.

3 It's noted by me and it was noted by
4 the pre-committee members that there was poor
5 agreement for the time to provider evaluated by
6 the patient and what was documented in the chart.
7 So - right, so what is that time point? And I
8 think we're struggling with that nationwide
9 actually.

10 Anecdotally, I can tell you that when
11 they looked at their seven hospitals, they had
12 one hospital that basically met these criteria
13 and six that did not, and most likely that one
14 that did had a practitioner out in the triage
15 area would be the most likely cause for that, and
16 the six that didn't did not have that
17 practitioner out there.

18 That's not going to be a feasible
19 model for a lot of hospitals for a lot of reasons
20 to have a practitioner out in triage. But as far
21 as meeting it, meeting a one-minute mark for ESI-
22 1, otherwise it's going to be very difficult,

1 especially in the age of the electronic medical
2 record.

3 So unless the doctor happens to be
4 standing where the patient comes in the door,
5 you're not going to meet that measure, or the PA
6 or whatever, but you're not going to have a PA
7 standing there to meet a patient who is coding.

8 Anecdotally, this has been a big issue
9 in my hospital as well. We have instituted a
10 thing called an MEI which is where we document
11 what time we saw the patient, but it's really an
12 attestation, right?

13 And a lot of -- I work in three
14 hospitals, and all three hospitals have this
15 where you go back and you say, I saw this patient
16 at this time, right? It's an extra step you have
17 to take. It's an extra page you have to fill
18 out, but the medical record creates this
19 artificial time line, right?

20 So if a patient comes in coding, I'm
21 not going to click a button that says, okay, I'm
22 seeing this patient now. I'm going to go see the

1 patient and then I'm going to go back and say, I
2 saw this patient at this time.

3 And frankly, my MEIs, because of the
4 way our process works and because I do go stand
5 out in triage, I see the patient before the
6 triage nurse gets done, and so my MEI actually
7 occurs before arrival time.

8 So I see the patient before the
9 patient even arrives in the ED, sometimes by up
10 to 10 minutes. So I have a lot of concern about
11 the data point, frankly --- anecdotally and as
12 it's described in this documentation.

13 CO-CHAIR THRAEN: Questions?

14 DR. ADELMAN: I had asked about just
15 the reliability of the triage system itself, not
16 the time so much. And as I was waiting, I was
17 doing a literature search and found that, you
18 know, some articles that question it, because I
19 read it in a proposal, but I don't have the
20 references readily available.

21 But I thought maybe some of the
22 experts would know because if the accuracy of the

1 measurement might not be as much about the time
2 and the time intervals, but if too many, you
3 know, threes are classified as fours and fours
4 are classified as threes, that would undermine
5 the reliability of the measure, so maybe you can
6 respond to that.

7 CO-CHAIR THRAEN: But I think Laura's
8 point that she made earlier, that it's really
9 focused on the ones and the twos. Is that
10 correct? Did I understand that correctly?

11 DR. ADELMAN: So then if twos are
12 confused as threes, and threes are confused as
13 twos.

14 CO-CHAIR THRAEN: Okay, Kendall?

15 DR. WEBB: And frequently twos change
16 to threes or threes change to twos or ones --

17 CO-CHAIR THRAEN: Sure.

18 DR. WEBB: -- as part of the process.

19 CO-CHAIR THRAEN: Sure, any other
20 questions before we vote? Let's vote.

21 MS. IBRAGIMOVA: Scientific
22 acceptability of measure properties 2a

1 reliability, the votes are one high, two
2 moderate, three low, four insufficient.

3 CO-CHAIR THRAEN: Does not pass.

4 MS. IBRAGIMOVA: So the results are
5 zero percent high, 23 percent moderate, 59
6 percent low, 18 percent insufficient.

7 CO-CHAIR THRAEN: Is that it? Okay,
8 sorry. So this does not pass the reliability
9 test.

10 CO-CHAIR SEPTIMUS: Thank you very
11 much. Thank you. The next measure is 0687,
12 percent of residents. And I'm sorry we're going
13 to go through the break. If there are those of
14 you who need to take a break, just please do, but
15 we're almost back on schedule here.

16 0687, percent of residents who are
17 physically restrained, long stay, CMS. So we
18 have the developers who I know are here. They
19 were just dying to come back today. We have a
20 new person though. So, do you want to -- or do
21 you want to introduce yourself?

22 DR. SMITH: Good morning, I'm Laura

1 Smith from RTI. I am the nursing home lead on
2 the CMS symptom management contract, and Nate
3 Breg is with me today, and he will be doing the
4 introduction for this measure.

5 MR. BREG: Thank you. The physical
6 restraint of nursing facility residents is a
7 safety concern discouraged by clinical experts
8 and its prevention is a CMS priority.

9 For years, this MDS-based quality
10 measure has reported to residents and families
11 the rates of residents physically restrained,
12 promoting patient safety.

13 The assessment items that determine
14 this measure are valid and reliable, and the
15 measure itself differentiates between facilities,
16 and is stable and valid.

17 The measure shows low prevalence of
18 restraint used, but it is important to maintain
19 this measure to continue to discourage the
20 practice, and to close racial and ethnic
21 disparities.

22 The measure reports the percentage of

1 all long stay residents who are physically
2 restrained daily during the seven days prior to
3 the target MDS 3.0 assessment during their
4 episode of nursing home care ending in the target
5 quarter.

6 This measure addresses a CMS quality
7 strategy priority. Use of physical restraints is
8 associated with adverse physical and mental
9 health outcomes.

10 The prevalence of physical restraint
11 use is low and falling. The mean facility levels
12 for this measure were 1.2 percent in quarter two
13 2014 and the median was zero. Two-thirds of
14 facilities have perfect scores of zero.

15 The mean scores had decreased since
16 quarter one 2011, which indicates continued
17 quality improvement. Overall, studies show the
18 measure and its items are reliable. Prior
19 studies show that the restraints' items have good
20 inter-rater reliability.

21 The quality measure itself is stable
22 and has a noise-to-signal ratio of about 84

1 percent. Sixty-six percent of facilities have
2 scores that differ from the mean, so high and low
3 quality facilities can be distinguished using
4 this measure.

5 There is good reason to believe this
6 measure is valid. Less than 0.1 percent of all
7 long stay episodes had missing data on restraint
8 or related items. The quality measure shows no
9 seasonality. This measure has strong face
10 validity as it captures use of devices, clinical
11 guidelines, and experts recognize as dangerous to
12 nursing home residents.

13 This measure has been providing
14 patients and their families with valuable
15 information about the safety of nursing
16 facilities through the CMS Nursing Home Compare
17 website and the CMS five star rating system.

18 With quality measures on chemical
19 restraints publicly reported by CMS, both
20 physical and chemical restraints are discouraged.
21 One-third of nursing facilities have some rate of
22 daily restraint use, and there is evidence of

1 differences in restraint use across races and
2 ethnicities of residents.

3 Furthermore, with the rates of falls
4 among residents being publicly reported, it is
5 important to report restraint use in order to
6 discourage this as an anti-fall strategy. This
7 quality measure remains important to keeping
8 nursing facility residents safe.

9 CO-CHAIR SEPTIMUS: Okay, Kim, are you
10 on the line? You're still on the line I hope,
11 Kim.

12 DR. APPLGATE: Yes, I am.

13 CO-CHAIR SEPTIMUS: Okay, Kim is the
14 discussant and we'll go through the evidence,
15 Kim.

16 DR. APPLGATE: Okay, so this is 67
17 percent of residents who are physically
18 restrained in long stay. Please note that the
19 measure is complementary, so it's related but not
20 competing with a couple of other measures,
21 including an acute stay measure and also a
22 related measure that captures a subset of

1 restraint measures, which I think is
2 complementary but not competing.

3 So this measure reports the percentage
4 of all long stay residents, defined as 101 day or
5 longer stays, who were physically restrained
6 daily during the seven days prior to the target
7 of the Minimum Data Set 3.0 assessment.

8 So this is required data captured, and
9 these are quarterly measures over a three-month
10 period and at nursing facilities around the U.S.

11 I agree with the developers and thank
12 them for the work they have done to look at trend
13 data, and I think this is a process measure and
14 so it has both the important positives but also
15 some of the limitations of a process measure.

16 But I think that the evidence is
17 strong in what they've shown of the value of
18 continuing this measure. They've done an
19 excellent summary of literature.

20 What I would ask is if the developers
21 would consider a table of the many factors that
22 they have summarized in the document of the

1 factors associated with increased and decreased
2 restraint use rather than having summaries of the
3 literature.

4 Because I found it fascinating, but it
5 was very difficult to capture all of the factors,
6 not consult but associations between increased
7 and decreased restraint use that becomes somewhat
8 circular in understanding whether they were truly
9 associated or confounding.

10 You know, for example, some of the
11 factors may be indirectly related to the
12 increased or decreased restraint use and may be
13 simply socioeconomic factors. So basically, I
14 would summarize saying that this is a very, very
15 important process measure to continue using it.

16 Should I stop there or continue?

17 CO-CHAIR SEPTIMUS: No, we're just
18 going to talk about the evidence, Kim, thank you.
19 Yanling?

20 DR. YU: Thank you, Yanling Yu. I
21 just have a question to the developer. Have you
22 compared the evidence of chemical restraint

1 versus physical restraint in any of those long
2 term care facilities, because my understanding is
3 the chemical restraint is pretty prevalent.

4 MR. BREG: The use of chemical
5 restraints is more prevalent, but as part of the
6 review of this measure, we didn't compare
7 literature finding relationships between
8 antipsychotics and health outcomes and comparing
9 those relationships to those between physical
10 restraints and health outcomes. We didn't
11 compare the relative health outcomes of those two
12 different types of restraints.

13 DR. YU: So do you have a plan in the
14 future that would consider that, to monitor those
15 types of restraints, because those can have a
16 very serious side effect, you know, on the
17 elderly?

18 DR. SMITH: So there is a paper that
19 came out within the last year or two by Tamara
20 Konetzka which looks at trends over time for
21 physical restraints and over the same time period
22 for chemical restraints, and you do see with the

1 advent of physical restraints being publicly
2 reported that the rates of antipsychotics have
3 been going up.

4 I can't remember, has there been a
5 follow-up? So CMS is now publicly reporting two
6 different chemical restraints, antipsychotic
7 measures. I'm not sure that someone has done a
8 look at kind of whether now we're seeing the
9 trend lines do something different, but it is
10 certainly something that we're aware of.

11 And when Tara McMullen was here
12 yesterday from CMS, we have been talking a little
13 bit about looking at some things like that and
14 the interrelationships between those measures.

15 CO-CHAIR SEPTIMUS: Theresa?

16 MS. EDELSTEIN: Thanks, I just want to
17 comment also on the same question. CMS has had a
18 national initiative going on for the last couple
19 of years to reduce the use of antipsychotic
20 medications in nursing home residents,
21 particularly those who have dementia, and the
22 trends are going down.

1 The goal was achieved over the first
2 few years to achieve an overall national 15
3 percent reduction in the use of antipsychotic
4 medications in nursing home residents, and a new
5 goal was set for an additional 25 percent
6 reduction over, I think it's the next two or
7 three years.

8 So there's good recognition that
9 lowering physical restraint use had increased
10 antipsychotic medication use and is now being
11 addressed nationally, so there is progress being
12 made.

13 CO-CHAIR SEPTIMUS: That's an
14 excellent point. Kim, was that you on the phone?
15 You were going to comment?

16 DR. APPLGATE: Yes, I sort of raised
17 my hand on the chat. Yes, I wanted to say that
18 the developers were aware of that and they did
19 talk about the CMS initiative and also the
20 association with chemical restraints, and the
21 increased use of the antipsychotic medication in
22 the elderly associated with decreased use of

1 restraints, and the potential unintended
2 consequences of, you know, the public reporting
3 of the use of restraints.

4 So there is some data on that, and
5 some of the references were included in this
6 report. And I think that it's very important to
7 also understand that there is a black box warning
8 by the FDA for all antipsychotic medications
9 because of the risk of arrhythmic deaths in the
10 geriatric population, so there is an
11 understanding that there is a downside to the
12 chemical restraints.

13 CO-CHAIR SEPTIMUS: Pat?

14 DR. APPLGATE: And I also -- if
15 that's not something that the developers did
16 discuss about the -- they have no detail about
17 the serious adverse effects of the antipsychotic
18 medications.

19 CO-CHAIR SEPTIMUS: Pat?

20 DR. QUIGLEY: Thank you, Pat Quigley.
21 And I'd like to speak in support of keeping this
22 a very clear indicator specific to physical

1 restraints. There is also an NQF measure for
2 physical restraint reduction in acute care.

3 And the physical restraint issue is
4 really a balancing measure in relationship to
5 falls, because when we know there's been a long
6 history or documented evidence that there is a
7 negative correlation, when you saw the fall rates
8 going down the restraint rates were going up, and
9 it was physical restraints and restraint
10 mobility.

11 The issue with chemical restraints is
12 an issue of validity, being able to describe are
13 we providing some of these medications to be able
14 to indeed manage very difficult behavior versus
15 limit mobility? And this is really focused on
16 limiting mobility, this issue of restraints.

17 So I'd like to thank the presenter and
18 the developer too for that excellent overview of
19 the evidence surrounding this.

20 CO-CHAIR SEPTIMUS: Okay, I think
21 we're ready to vote on the evidence.

22 DR. APPLGATE: Ed, this is Kimberly.

1 I have one other point to make that the
2 developers stated. The key point there really
3 comes out with the evidence, and I'm sorry I
4 didn't state this up front, is that restraints do
5 not prevent major adverse events.

6 Although falls will increase when
7 restraints and their abuse decreases, serious
8 falls do not increase. So I think that's a
9 really key point that is brought out with the
10 report and the evidence.

11 DR. QUIGLEY: Excuse me, Dr. Septimus,
12 if I may clarify, the issue with restraints and
13 with falls is that if a patient falls with a
14 restraint on, the severity of injury is greater,
15 and that's evidence that's been published for
16 years. So it's not the fall, it's the severity
17 of injury. Thank you.

18 CO-CHAIR SEPTIMUS: Thanks for the
19 clarification, okay.

20 DR. APPLGATE: Could you ask the
21 developers to clarify what their evidence is that
22 they bring out because they say the opposite,

1 that serious falls do not increase with the
2 decreased use of restraints?

3 CO-CHAIR SEPTIMUS: Pat, you'll have
4 to put your mic on.

5 DR. QUIGLEY: Excuse me, I had
6 mentioned with restraints. If a patient falls
7 with a restraint on, for example from a bed, the
8 severity of injury is greater.

9 DR. APPLGATE: Okay, good. Okay, I
10 was just making sure that we were agreeing.
11 Thank you.

12 CO-CHAIR SEPTIMUS: Okay, now we can
13 vote on the evidence.

14 MS. IBRAGIMOVA: Importance to measure
15 and report 1a evidence structure of process
16 intermediate outcomes. The votes are one high,
17 only eligible if QQC submitted, two moderate,
18 three low, four insufficient evidence.

19 And the results are 59 percent high,
20 41 percent moderate, zero percent low, zero
21 percent insufficient evidence.

22 CO-CHAIR SEPTIMUS: Okay, now we go to

1 gap. Kimberly?

2 DR. APPLGATE: I'm sorry about that.

3 Let me just pull this up. They talk about the
4 preponderance gaps, that there was a permanent
5 and prevalence of difficult restraint use from
6 the initial time, and they showed trends in the
7 appendix.

8 The development listed only 66.9
9 percent utility of that perfect score, so I think
10 there is appropriate evidence for potential
11 improvement.

12 And then in terms of disparities, I
13 think also they adequately discussed the gaps
14 with -- basically the significant difference
15 between black, Hispanic, and Medicaid patients in
16 the appendix.

17 CO-CHAIR SEPTIMUS: Kimberly, are you
18 finished, Kimberly? I just want to make sure I
19 don't cut you off.

20 DR. APPLGATE: Yes.

21 CO-CHAIR SEPTIMUS: Okay, Chris?

22 DR. COOK: Yes, I was looking in

1 further past the 66 --

2 CO-CHAIR SEPTIMUS: Chris, is your mic
3 on?

4 DR. COOK: Yes, this is Chris Cook.
5 Looking at the perfect scores of 66.9 percent
6 then caused me to look further down into the, you
7 know, the percentile ranks. And all the way
8 through the 60th percentile with zero percent,
9 70th percentile is 0.9 percent, 80th percent 1.9
10 percent, 90th percentile 3.6, and that's all
11 presented on page 36 and 37.

12 So the question to the developers is
13 within that, can you statistically tell a
14 difference between facilities with such a small
15 difference? And I guess the question is, is the
16 gap still there that allows for this measure to
17 continue forward or has this been topped out?

18 MR. BREG: Sure, thank you for your
19 question. The statistics that we present in the
20 reliability section show that you are able to
21 distinguish between facilities using this
22 measure.

1 The signal-to-noise ratio is 0.84,
2 which is acceptable for a facility level quality
3 measure. And we also present stratified means
4 that show that 66.4 percent of facilities had
5 scores that were statistically significant from
6 the mean at the 95 percent confidence interval.

7 Furthermore, a measure, as I
8 understand the NQF guidance documentation,
9 wouldn't be considered topped out if there is
10 evidence of disparities. And as we show, there
11 is evidence of racial and ethnic disparities.

12 And in the evidence documentation we
13 submitted, there is one study that used logistic
14 regression to show that there are different odds
15 ratios for white and black residents for being
16 restrained.

17 CO-CHAIR SEPTIMUS: Missy?

18 MS. DANFORTH: Yes, can you talk about
19 why the mean reported on the Nursing Home Compare
20 is so much higher than the mean in your
21 measurement documents? You're showing a mean of
22 1.2 percent. They're showing a mean of something

1 like 20 percent, a national mean for the purposes
2 of comparison.

3 So according to the data, the national
4 mean is like much lower than what's being shown
5 on Nursing Home Compare. Can you say why that
6 is?

7 DR. SMITH: And what was the number?

8 MS. DANFORTH: Nursing Home Compare is
9 showing a mean of -- hold on, I just had it in
10 front of me. I'm sorry, give me one second.

11 DR. SMITH: I'm only asking just
12 because that sounded very high.

13 MS. DANFORTH: Yes, so -- oh, I'm
14 sorry. Okay, so if the mean is -- back to the
15 question. They're showing a mean of 1.1, and
16 then you're showing a mean of 1.2. So because
17 the performance gap seems to be within the
18 disparities piece, can you just sort of talk
19 about how you're addressing that?

20 So if the performance gap seems to be
21 with the disparities, which seems clear, but that
22 seems to be washed away when you look at the

1 performance within the individual nursing homes.
2 Can you just talk a little bit about how you're
3 addressing that particular gap?

4 DR. SMITH: So I think one of the
5 other issues to consider is what the rate should
6 be for this measure. And since we're talking
7 about daily restraints and -- one would argue
8 that if you're having restraints every day, that
9 means that's sort of the underlying cause of why
10 the individual might be being restrained is not
11 being addressed.

12 I think that the -- it seems like the
13 ideal should actually be heading toward zero, and
14 so I think we would still argue that the fact
15 that we do have some facilities that have daily
16 restraint use going on that there's still room
17 for improvements.

18 You're correct that the way that the
19 data is being reported, it's not obvious, but
20 there is that racial disparity, but that there's
21 still value in tracking this measure.

22 It's not only a publicly reported

1 measure but a measure that's used through the --
2 via the CASPER reporting system that the nursing
3 homes use for their own internal purposes as
4 well, and so it may be more of making the nursing
5 homes aware of this being a particular issue than
6 they may have a disparity, sort of a formal
7 populations issue.

8 CO-CHAIR SEPTIMUS: Okay, let's vote
9 on gap.

10 CO-CHAIR THRAEN: I just want to
11 clarify. The only way that this goes into
12 reserve status if you believe it's been topped
13 out is if it does not pass the performance gap.
14 Is that correct?

15 (No audible response)

16 CO-CHAIR THRAEN: All right.

17 MS. IBRAGIMOVA: Importance to measure
18 and report 1b performance gap. The votes are one
19 high, two moderate, three low, four insufficient.
20 All right, so the results are 27 percent high, 50
21 percent moderate, 23 percent low, and zero
22 percent insufficient.

1 CO-CHAIR SEPTIMUS: Reliability, Kim?

2 DR. APPLGATE: Okay, reliability, the
3 -- so just to briefly talk about how the
4 residents are counted, they are defined as
5 residents, as I said, who have a stay of 101 days
6 or more. There's a separate measure for acute
7 care.

8 Data and reliability testing was
9 pulled from the Nursing Home Minimum Data Set
10 3.0, two serious reviews, the development and
11 validation of MDS 3.0 and the RTI. The testing
12 was done at the facility and agency level.

13 They ran reliability analyses to test
14 reliability of the data element levels. The
15 restraint items included in this measure have
16 kappa statistics for gold standard nursing,
17 sorry, nurse to facility nurse agreement ranging
18 from 0.746 to 0.844, so it was very high. Limit
19 restraint to in bed, and limit restraint in chair
20 or out of bed both had perfect agreement.

21 The gold standard nurse to gold
22 standard in nursing ratings have perfect

1 agreement for all items included in the measure
2 except for chair prevents to rising data, which
3 had a kappa of 0.887, also high.

4 And then I wanted to talk about what
5 the numerator and denominator exclusions were so
6 people understood that. The numerator is the
7 number of long-stay residents with a selected
8 targeted minimum data sets, and they have a
9 number of different definitions of different
10 restraints there in the MDS, and it has to be
11 daily for seven days within that quarter.

12 And then the denominator exclusions
13 were resident excluded if the denominator had
14 missing data in any of the responses relevant to
15 the question, so any of the different restraint
16 questions, and if the facility sample had fewer
17 than 30 residents in the facility, so if this was
18 a small nursing home.

19 And then as the developer mentioned,
20 they have a high --- signal-to-noise quality
21 measure. So I think that from the reliability
22 standpoint, it had a high rating.

1 CO-CHAIR SEPTIMUS: Okay, thank you.
2 Let's vote on reliability.

3 MS. IBRAGIMOVA: Scientific
4 acceptability of measure properties 2a
5 reliability the votes are one high, two moderate,
6 three low, and four insufficient. The results
7 are 67 percent high, 33 percent moderate, zero
8 percent low, zero percent insufficient.

9 CO-CHAIR SEPTIMUS: Okay, are you
10 ready for validity? Kimberly, any major points
11 on validity?

12 DR. APPLGATE: Yes, so the validity
13 testing was both at the data element level and at
14 the measure score level, and the RAND validation
15 of the MDS 3.0 tested the criterion validity by
16 comparing how different nurses assess the same
17 residents.

18 Using the MDS 3.0, they compared gold
19 standard research nurses to gold standard nurses,
20 and they compared gold standard nurses to staff
21 nurses trained by the gold standard nurses, and
22 they used kappa statistics.

1 The restraint items included in this
2 measure had kappa statistics for the gold
3 standard nurse to facility nurse agreement
4 ranging from 0.746 to 0.844, so high. The limb
5 restraint in bed and limb restraint in chair or
6 out of bed both had perfect agreement.

7 The other thing we were asked to
8 discuss is the threats to validity, and I think
9 they did two important analyses on the data which
10 addressed this, and I don't see any threats to
11 validity.

12 One was the correlation between this
13 measure and the indirect measure 0674, and they
14 looked at the percent of residents experiencing
15 one or more falls with major injury in quarter
16 three of 2013 and found that there was weak or
17 not significant correlation. They had an R of --
18 0.0145.

19 The other thing they did is they found
20 a lack of evidence for a relationship between
21 restraints and falls. It's possibly because the
22 prevalence of physical restraint use and

1 incidence of falls with major injury are both
2 very low, and they put in percent in parentheses,
3 1.2 percent and 1.6 percent respectively.

4 So they do raise that possibility that
5 they might have a lack of evidence and raise that
6 as a problem, a potential problem with validity
7 which was talked about by the developers.

8 CO-CHAIR SEPTIMUS: Comments? Okay,
9 let's vote.

10 MS. IBRAGIMOVA: Scientific
11 acceptability of measure properties 2b validity,
12 the votes are one high, two moderate, three low,
13 four insufficient. And the results are 41
14 percent high, 55 percent moderate, five percent
15 low, zero percent insufficient.

16 CO-CHAIR SEPTIMUS: Okay, feasibility?

17 DR. APPLGATE: Oh, there was no
18 concern with feasibility I don't think because
19 even though it's not considered an eMeasure, all
20 data elements are defined fields in electronic
21 clinical data with the MDS. Any comments?

22 CO-CHAIR SEPTIMUS: No, let's vote.

1 DR. APPLGATE: Okay.

2 MS. IBRAGIMOVA: So the feasibility
3 the votes are one high, two moderate, three low,
4 four insufficient. The results are 90 percent
5 high, 10 percent moderate, zero percent low, zero
6 percent insufficient.

7 CO-CHAIR SEPTIMUS: Next is usability.

8 DR. APPLGATE: Ed, can you remind me
9 what --- if there are -- I mean, I did not see
10 any particular concern about usability.

11 I just wanted to ask the developers a
12 question about whether they had looked into one
13 issue that I didn't see which was literature on
14 the association between use of restraints and
15 turnover rate of staff in terms of violent
16 patients and violence against the staff.

17 There was no discussion of that, and
18 I know that this has been an issue that, you
19 know, comes up, you know, with why restraints are
20 used and maybe under reporting of restraints, so
21 I just wanted to hear a comment from the
22 developers.

1 MR. BREG: We didn't come across any
2 literature on violence against staff members.
3 But I'd just like to repeat that this quality
4 measure is -- reflects daily restraint use.

5 And as Dr. Smith pointed out earlier,
6 it's the responsibility of the clinicians to
7 identify what underlying factors lead to the
8 behavior that leads to restraint use.

9 So if a facility is not -- is
10 restraining a resident every day for seven days,
11 there's a high probability that they're not
12 performing the function of identifying what the
13 underlying cause is.

14 And one clinical consultant to this
15 project suggested that such a resident would
16 probably be removed from the post-acute care
17 facility if there was such a disturbing behavior.
18 Does that answer your question?

19 DR. APPLEGATE: Sort of, but these are
20 long-term stay patients.

21 MR. BREG: Yes.

22 DR. APPLEGATE: Well, I'm just asking

1 the question. Anyway, I think it's a highly
2 useful measure, easily used and easily compared
3 to others across facilities.

4 CO-CHAIR SEPTIMUS: And it's currently
5 being reported, so --

6 DR. APPLGATE: Right.

7 CO-CHAIR SEPTIMUS: Theresa?

8 MS. EDELSTEIN: Theresa Edelstein,
9 just a quick comment to Kimberly's point. One of
10 the things we see in nursing home populations,
11 long-stay nursing home populations, is a growing
12 number of folks who have had lifelong psychiatric
13 diagnoses, and now they're living longer and
14 making their way to the nursing home and have the
15 physical needs as well as their psychiatric needs
16 to be addressed.

17 So I just wonder whether we will
18 continue to see improvement in this measure
19 because of the changing nature of the population
20 over time, and I think it's something that
21 warrants some deeper exploration, whether that
22 change is real, first of all, and what the impact

1 is on restraint use.

2 CO-CHAIR SEPTIMUS: Pat?

3 DR. QUIGLEY: Thank you, Pat Quigley.

4 And I also wanted to respond to the question that
5 Kim had presented, and thank you, Kim, for that.

6 And I would suggest that in the patients you are
7 describing that this would be the qualitative
8 component of physical restraint use.

9 That patient or resident may need to
10 have a restraint, but in policies and in long-
11 term care, they would use the least restrictive
12 restraint to still be able to reduce harm. Thank
13 you.

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

15 MS. IBRAGIMOVA: Usability and use the
16 votes are one high, two moderate, three low, four
17 insufficient. The results are 64 percent high,
18 36 percent moderate, zero percent low, zero
19 percent insufficient information.

20 CO-CHAIR SEPTIMUS: Okay, and last one
21 is it suitable for endorsement? So this is a yes
22 or no.

1 MS. IBRAGIMOVA: Overall suitability
2 for endorsement, does the measure meet and have
3 criteria for endorsement? One yes, two no. The
4 results are 100 percent yes, zero percent no.

5 DR. APPLGATE: Excellent.

6 CO-CHAIR SEPTIMUS: Number five,
7 fantastic. Okay, we'll tell you about some
8 modifications in the schedule after the next one,
9 but we are, as you can imagine, probably going to
10 have to have a working lunch.

11 So the next one, we'll go in order, is
12 0689 Percent of Residents Who Lose Too Much
13 Weight long-stay also from CMS. So, Laura, if
14 you stay, do you have somebody else to work with
15 you on this matter? Who is the discussant on
16 this? Oh, it's Laura. There she is. Okay,
17 Laura, remember efficiencies --- time, no
18 pressure. Okay, developers? Introduce yourself.

19 DR. SMITH: Yes, so I'm joined by Dr.
20 Qinghua Li also from RTI International. This is
21 for the same contractor, CMS.

22 DR. LI: Okay, briefly, okay, this

1 measure requires the percentages of -- nursing
2 from a resident to the target MDS assessment that
3 indicates a weight loss of five percent among the
4 last 30 days or 10 percent among the last six
5 months, which is not a result of a physician
6 prescribed weight loss regimen.

7 The data used for this measure is MDS
8 3, which is mandatory for all Medicare or
9 Medicaid certified nursing homes. On this
10 measure are strategies of serious strategy goal
11 in alignment with one priority of the National
12 Quality Strategy senior care.

13 It is important to maintain residents'
14 nutritional status in nursing homes, and we have
15 demonstrated that weight loss is the most
16 objective and reproducible marker of nutritional
17 status for nursing home residents.

18 Publicly reporting this measure will
19 provide nursing homes incentive to monitor and
20 maintain residents' weight and nutritional
21 status. Since the last endorsement in 2011, two
22 additional denominator exclusion criteria have

1 been applied.

2 First, prognosis of life expectancy of
3 less than six months, second, receiving hospice
4 care on the target assessment. Empirical
5 evidence has shown that weight loss is a part of
6 the trajectory for elderly with end stage
7 diseases.

8 Weight maintenance or weight gain is
9 not consistent with the goals of end of life care
10 or patients' typical preferences at the end of
11 life. To test whether these two additional
12 exclusions are appropriate, RTI conducted
13 analysis at the residents' facility and at
14 measure levels.

15 The findings support excluding
16 residents who are receiving hospice care or are
17 having a less than six-month life expectancy. We
18 also received public comments and a subject
19 matter expert's input supporting these addition
20 exclusions.

21 To reevaluate this measure, we used
22 data on all eligible long-stay residents from our

1 Medicare and Medicaid certified nursing homes
2 from 2011 to 2014.

3 Nationally, this measure is pretty
4 stable with a small variation from 5.7 percent in
5 quarter three 2014 to 6.8 percent in quarter one
6 2013. The MDS 3 data elements used to calculate
7 the weight loss measure were demonstrated to be
8 reliable.

9 The analysis on quarter measure
10 reliability showed that while the facility scores
11 on this measure were stable between two reporting
12 periods, the facility ranks on this measure
13 changed more frequently. Both the weight loss
14 annually on the MDS 3.0 and the weight loss
15 quarterly measure were demonstrated to have
16 moderate to high validity.

17 We also examined the proportions of
18 facility scores for this measure that are
19 significantly different from the national
20 facility level mean.

21 The findings indicated that this
22 measure can successfully distinguish facilities

1 in which there are quality concerns related to
2 weight loss from high quality nursing homes where
3 residents' nutritional status is managed very
4 well.

5 One possible unintended consequence is
6 that the increase in use of a feeding tube or
7 other aggressive feeding programs amongst some
8 residents. However, there is no evidence
9 indicating such increase in the feeding tube use
10 or other aggressive feeding programs.

11 A recent review of quarterly data from
12 quarter two 2012 to quarter four 2014 showed a
13 slow, but a very steady decrease in the feeding
14 tube use in nursing homes.

15 So in conclusion, this measure is very
16 important, valid, and a reliable quantum measure
17 for nursing homes. Thank you.

18 CO-CHAIR SEPTIMUS: So, Laura, this is
19 an outcome measure.

20 MS. ARDIZZONE: Yes.

21 CO-CHAIR SEPTIMUS: And so anyway, go,
22 Laura.

1 MS. ARDIZZONE: So this is re-
2 endorsement 689, percentage of long-term stay
3 nursing home residents with MDS assessment that
4 indicates weight loss of five percent or more of
5 the baseline weight in the last 30 days, or 10
6 percent or more of the baseline weight in the
7 last six months, and this is not a result of a
8 physician prescribed weight loss regimen.

9 I think the evidence is very strong.
10 I think this is an outcome measure, something we
11 keep asking for in this committee. So on
12 evidence, I think the evidence is supportive of
13 the measure focus, so I think the evidence is
14 strong.

15 CO-CHAIR SEPTIMUS: Comments? Yes,
16 Steve?

17 DR. LAWLESS: I know it's a
18 technicality. It shouldn't be increased
19 mortality. It should be decreased survival
20 because everybody dies.

21 DR. SMITH: I'm sorry, are you talking
22 --

1 DR. LAWLESS: Yes, just in terms of
2 the developer. It really is not an increased
3 mortality factor, it's a decreased survival.

4 And so from a technical standpoint,
5 it's actually -- it's -- it shows a little bit --
6 it's a little bit of a different slant to it, but
7 it also ---- when you publicly -- when you
8 report it, it's not likely to die. It's how long
9 less of a survival do you have by that, so for
10 the developers maybe just to consider that.

11 CO-CHAIR SEPTIMUS: Okay, let's vote.

12 MS. IBRAGIMOVA: For importance to
13 measure and report 1a, evidence health outcome or
14 PRO, the votes are one yes, two no.

15 MR. ANDERSON: Kimberly, we don't have
16 your vote.

17 MS. IBRAGIMOVA: The results are 90
18 percent yes, 10 percent no.

19 CO-CHAIR SEPTIMUS: Okay, next would
20 be gap.

21 MS. ARDIZZONE: My only comment on
22 gap, and I struggled with this a little bit, is

1 there's nothing to indicate any disparity data,
2 either race or socioeconomic status differences,
3 and there really has been no observed
4 improvements since the original measure in 2011.

5 So while I think it's important, I
6 think it's a marker of something, I think it's an
7 outcome, there just hasn't been showing any ----
8 that there's an improvement, or ---- no change,
9 so that would be my only comment.

10 CO-CHAIR SEPTIMUS: Developers want to
11 comment on that? I think there is something
12 about disparities in here, unless I misread it,
13 but what about the other comment about
14 improvement?

15 DR. LI: Thank you for your comments.
16 We recognize this kind of no improvement
17 indication in this measure, and we didn't find
18 the racial or socioeconomic disparity in this
19 measure either.

20 As we have mentioned, while
21 maintaining residents' nutritional status is very
22 important in nursing homes, weight loss has been

1 found to be the most objective and reproducible
2 marker of nursing home residents' nutritional
3 status.

4 And also, actually the lack of a
5 change in this quality measure may reflect that
6 nursing homes are not improving quality, meaning
7 taking care of patients' nutritional status. We
8 think this might further kind of highlight the
9 importance of keeping published -- publicly
10 reporting this measure.

11 So with this measure being kind of
12 retired, if we stop publicly reporting this
13 measure, nursing homes may lose this incentive to
14 keep monitoring and maintaining residents'
15 nutritional status.

16 CO-CHAIR SEPTIMUS: Theresa?

17 MS. EDELSTEIN: Theresa Edelstein.
18 Respectfully, I would like to ask you to not jump
19 to conclusions or make assumptions about whether
20 or not nursing homes are focused enough on
21 improving nutritional status.

22 It's very well documented that the age

1 and acuity of nursing home residents is
2 increasing over time, especially as we work very
3 hard to keep people at home and in their
4 communities receiving long-term care for much
5 longer periods of time.

6 So the frailty and acuity of the
7 nursing home population is increasing
8 significantly, and with that comes difficulty in
9 maintaining nutritional status.

10 CO-CHAIR SEPTIMUS: Okay, let's vote
11 on gap.

12 MS. IBRAGIMOVA: Importance to measure
13 and report 1b, performance gap. The votes are
14 one high, two moderate, three low, four
15 insufficient.

16 The results are 29 percent high, 57
17 percent moderate, 10 percent low, five percent
18 insufficient.

19 CO-CHAIR SEPTIMUS: Reliability,
20 Laura?

21 MS. ARDIZZONE: Okay, so they
22 presented two separate tests for reliability. So

1 they ran -- did some testing on the MDS and they
2 found really high kappa scores on data element.

3 There was a lot of discussion on the
4 RTI analysis on performance that the stability
5 analysis, the signal-to-noise was low, that maybe
6 this measure isn't particularly reliable in
7 separating facility characteristics from the
8 noise of the population.

9 But I think you did a pretty good
10 assessment at saying that the analysis on quality
11 measures was high, but the facility scores were
12 stable between two consecutive reporting periods,
13 but the facility ranks may change frequently, and
14 that might be associated with a relatively narrow
15 range of the measure.

16 So I think you explained it. I don't
17 think -- I think it's high on the data elements.
18 I think at the facility level it may not be as
19 high, if you wanted to comment on that.

20 CO-CHAIR SEPTIMUS: Jason?

21 DR. ADELMAN: I struggled with the
22 reliability on this one because inherent to me

1 that both the numerator and the denominator has
2 things that are -- would be very hard to measure
3 reliably.

4 Like in the numerator, a weight change
5 of five percent, which if you weigh 150 pounds,
6 would be seven, seven-and-a-half pounds. Like in
7 the hospital we see weights, you know, go up and
8 down all the time like that.

9 And in the denominator, it has, I
10 guess, a prediction of the life expectancy at six
11 months. That seems very hard to reliably
12 predict.

13 And so with both of these like -- so
14 I understand that the kappa score was such,
15 although the methods by which the reliability
16 testing was done is not clear to me.

17 And inherently since it intuitively
18 doesn't make sense that it would be super
19 reliable, I was wondering if the developers could
20 explain more about really how the reliability
21 testing was done and how they addressed these
22 variables.

1 DR. SMITH: So with regard to the item
2 level reliability, that work was done using pairs
3 of raters that have both been -- received
4 training on how to complete the MDS data set.
5 There was an agreed upon protocol for how that
6 evaluation would be done for whatever set of
7 items that there were.

8 I think they evaluate quite a few for
9 that MDS data set, and basically were evaluating
10 the person at the same time. So that rating is
11 more about sort of the repeatability between the
12 raters. You are referring more to this issue of
13 the changeability of weight loss over time.

14 I guess I would argue that while we
15 might not be capturing all of the instances where
16 weight loss would have occurred of that degree,
17 that we are sort of cross-sectionally going to be
18 capturing weight loss and that there's not going
19 to be one -- shouldn't be one particular bias
20 being introduced into the measure because of
21 that.

22 And certainly someone who might be

1 having that much of a change from moment to
2 moment, this is a -- the assessments are done
3 quarterly, but there should be, as a part of
4 care, some monitoring -- a part of regular care,
5 monitoring for weight loss.

6 And so the item is really asking about
7 have they had this happen? So if they are having
8 that much of a weight loss over this period of
9 time, it should be reporting because that's an
10 indicator of there being an issue. Okay, so that
11 was the item level reliability.

12 You had asked about measure level
13 reliability ---- oh, prognosis, sorry. And then
14 the prognosis -- so that is -- again, we'll
15 acknowledge that being a potential concern.

16 I guess, one of the things that we've
17 talked about is sort of the importance of,
18 regardless if it was not -- the reliability is
19 not as high, it's still a very important group of
20 individuals to be identifying in order to make
21 sure that we're not putting them at risk for
22 interventions that would be potentially -- really

1 against other objectives in terms of meeting
2 preferences at the end of life.

3 Qinghua, do you want to add to that?

4 DR. LI: Actually for the prognosis
5 item, which this is based on physicians'
6 prognosis. This is from residents' medical
7 record, which are kept by their physicians.

8 Also, the RAND report found that the
9 kappa statistics for this specific item between
10 the gold standard nurses was 0.87, and between
11 the gold standard nurse and the facility nurse
12 was 0.96, which means the reliability is very
13 high.

14 CO-CHAIR SEPTIMUS: Pat?

15 DR. QUIGLEY: Thank you, Pat Quigley.
16 My question in relationship to reliability, very
17 similar to Dr. Adelman's, in that the numerator
18 is those who have weight loss over a 30-day
19 period of time versus a six-month period of time,
20 and the RAI is completed quarterly.

21 So would it not be better to just go
22 ahead and have the period of time of any weight

1 loss -- and I was interested in weight gain,
2 because weight gain in older people in
3 wheelchairs is very difficult and impairs
4 mobility -- but is to have the measure just be
5 related to the 90-day period in which the RAI is
6 done, rather than the 30 days and then the six-
7 month period which actually covers two RAI
8 periods?

9 The RAI, for everyone, is a resident
10 assessment interview that's done. It's the
11 quarterly completion of the team review of the
12 patient, because you have an "or" component.
13 It's 30 days or six months.

14 DR. SMITH: Right, and I think the
15 idea in having that potential shorter time period
16 is to try to capture a precipitous loss or that
17 variability that we were talking about a moment
18 ago.

19 That perhaps if you compare a person's
20 weight now to three months ago, there might not
21 be that much change, but if you look at that 30-
22 day period back, they may have had a weight

1 increase and then a weight loss in that time
2 period, and what you're capturing with looking at
3 that 30-day window is this variability in the
4 weight that might be a concern.

5 DR. QUIGLEY: Yes, thank you, but the
6 question is really that six-month period that's
7 added to it because that covers two quarters and
8 two RAIs.

9 DR. SMITH: So you're concerned about
10 having the longer time period?

11 DR. QUIGLEY: Yes, yes.

12 DR. SMITH: Well, again, I think the
13 idea is sort of you're getting a slightly
14 different trajectory there that you may not have
15 a major weight loss within a 30-day period.

16 But looking over the -- sorry, the
17 larger ---- two time periods -- excuse me, for
18 the weight loss may be revealing some sort of
19 slower process of decline related to weight loss
20 that you might not see on that shorter time
21 period.

22 CO-CHAIR SEPTIMUS: Okay, let's vote

1 on reliability.

2 MS. IBRAGIMOVA: Scientific
3 acceptability of measure properties 2a,
4 reliability. The votes are one high, two
5 moderate, three low, four insufficient.

6 And the results are four percent high,
7 70 percent moderate, 22 percent low, four percent
8 insufficient.

9 CO-CHAIR SEPTIMUS: Validity, Laura?

10 MS. ARDIZZONE: For validity they did
11 data element and performance score level testing.
12 Both indicate acceptable validity testing.

13 They also did exclusion testing.
14 There is no risk adjustment and the exclusions
15 seem appropriate. So they exclude data if they
16 don't have the right assessment type, if they
17 have a six-month prognosis, or they're hospice
18 patients, or if they are residents less than 30
19 days. CO-CHAIR SEPTIMUS: I have a question
20 not related to the measure for my own education.
21 Okay?

22 Why is weight loss most common in the

1 first quarter of the year?

2 DR. LI: This is an observation?

3 CO-CHAIR SEPTIMUS: Weight loss is
4 most common in the first quarter of the year.

5 I'm just curious, Theresa. I mean, I don't want
6 to put you on the -- I'm asking for -- I actually
7 read this stuff.

8 MS. EDELSTEIN: Well, it is right
9 after the holiday season. It's also a time
10 period when influenza is significant -- can be
11 significant and other -- and respiratory
12 illnesses and people don't eat when they don't
13 feel well.

14 CO-CHAIR SEPTIMUS: I'm just curious.

15 Okay. Ready to vote on validity.

16 Let's vote.

17 MS. IBRAGIMOVA: Scientific
18 acceptability of measure properties, 2(b),
19 validity. The votes are one, high; two,
20 moderate; three, low; four insufficient.

21 (Voting.)

22 MS. IBRAGIMOVA: This might take a

1 second.

2 (Comments off record.)

3 CO-CHAIR SEPTIMUS: All right. Do you
4 want to vote by hand for this one while she --
5 why don't we do that.

6 Okay. So, all those who say high,
7 raise your hand. And vote by via phone for --
8 high. All right. So, zero for high.

9 Okay. Moderate. Who wants to count?

10 (Pause.)

11 CO-CHAIR SEPTIMUS: And on the phone?
12 Okay. So, one high and the rest are moderate.
13 No one for low or insufficient.

14 Okay. So, now we go to feasibility.

15 MS. ARDIZZONE: I have no concerns
16 about feasibility. I think it's important to
17 continue using this measure.

18 CO-CHAIR SEPTIMUS: Okay. We'll vote
19 by hand again. Is that okay with everybody?

20 Okay. So, feasibility. High.

21 MS. SPEAKER: Somebody needs to count.

22 CO-CHAIR SEPTIMUS: 14. Moderate.

1 (Pause.)

2 CO-CHAIR SEPTIMUS: Low. One low.

3 Did the people on the phone vote? So, what did

4 they vote? So, we have a medium and a high.

5 Okay.

6 So, what was the final vote then?

7 MS. THEBERGE: What was the number for

8 moderate?

9 MR. SPEAKER: Six.

10 MS. THEBERGE: Six, plus two on the

11 phone?

12 CO-CHAIR SEPTIMUS: Six plus one is

13 seven, and one additional one for high. Okay.

14 Usability. Laura.

15 MS. ARDIZZONE: This is already

16 publicly reported. I think continued use of this

17 measure can encourage adoption of improved

18 processes, improved quality of care.

19 As we have more and more of an aging

20 population, I think it's really important that we

21 find quantitative markers of quality care for

22 elders.

1 CO-CHAIR SEPTIMUS: Okay. I see no
2 comments. We can once again vote by hand. High.

3 (Voting.)

4 CO-CHAIR SEPTIMUS: Drew, what are you
5 doing?

6 (Comments off record.)

7 MS. IBRAGIMOVA: 20.

8 CO-CHAIR SEPTIMUS: All right.
9 Moderate. And that's to 22. So, no low and no -
10 - okay. Great.

11 Okay. Now, the measure is acceptable
12 for public reporting. It's a yes or no. I'm
13 getting to learn this thing. For endorsement.
14 So, all those in favor of endorsement.

15 (Voting.)

16 CO-CHAIR SEPTIMUS: How about the two
17 on the line?

18 MR. ANDERSON: Ann, could you -- oh,
19 yes. Okay.

20 CO-CHAIR SEPTIMUS: You could put your
21 hands down. We've got 22. So, another
22 unanimous.

1 Okay. Fantastic. Thank you so much.
2 So, this is what we're going to -- I'm going to
3 turn this over to Iona who's going to take us
4 hopefully most of the rest of the way.

5 And the next one we're going to go to
6 falls, 0101. Thank you.

7 CO-CHAIR THRAEN: So, 0101, it's from
8 yesterday's list. So, it's at the beginning of
9 your agenda. And it's the Falls: Screening,
10 Risk-Assessment and Plan of Care to Prevent
11 Future Falls developed by the National Committee
12 for Quality Assurance.

13 Could you please join us at the table?
14 (Pause.)

15 CO-CHAIR SEPTIMUS: And just in case
16 you're wondering, lunch will be at 12:30. And we
17 may have to make it a working lunch.

18 CO-CHAIR THRAEN: All right. Who's
19 the speaker on this one? Pat.

20 MS. GIOVANNETTI: Yes.

21 CO-CHAIR THRAEN: Better be. So,
22 developers, would you like to open your

1 statement?

2 MS. GIOVANNETTI: Yes.

3 CO-CHAIR THRAEN: Introduce yourselves
4 as well.

5 DR. GIOVANNETTI: My name is Erin
6 Giovannetti. I'm a research scientist with the
7 National Committee for Quality Assurance. And
8 I'm joined by Dr. Mary Barton who is our vice
9 president for performance measurement.

10 So, thank you for allowing us to come
11 today to present this measure, which I know is a
12 little bit out of sequence.

13 This measure is a maintenance
14 endorsement of a measure that previously came
15 before a similar panel in very late 2012. It
16 looks at falls risk prevention in the older adult
17 population.

18 It is three indicators that are really
19 all meant to be reported together as a group,
20 because they look at a continuum of care for
21 falls.

22 It starts by a measure that looks

1 first at whether or not you screened for whether
2 or not you have a population at risk of falls.
3 And this is really just asking -- assessing
4 whether or not older adults have had a fall in
5 the past year, two or more falls or a fall with
6 injury, which then defines the denominator for
7 the next two measures, which get into how do you
8 prevent future falls in this at-risk population.

9 So, looking at that population, the
10 people who have two or more falls, or a fall with
11 injury, did you do a multifactorial risk
12 assessment?

13 And we define what -- there are many
14 different factors you could look at. We define a
15 minimum set.

16 And then, did you do a plan of care
17 including consideration of Vitamin D therapy and
18 exercise or physical therapy.

19 This is based off of evidence from the
20 US Preventive Services Task Force and the
21 American Geriatric Society.

22 The USPSTF has guidelines that put in

1 place that all older adults who have a history of
2 falls should have consideration of Vitamin D
3 therapy and exercise or physical therapy.

4 It's also based off of recommendations
5 from both the AGS and USPSTF that all older
6 adults should be asked about whether or not they
7 have fallen.

8 And then the one area where the
9 evidence gets a little bit more difficult to
10 interpret is around risk assessment for falls.

11 This is an area where the USPSTF has
12 given a C recommendation that they basically said
13 that the evidence -- it's really difficult to
14 identify what's the population where a
15 multifactorial risk assessment has a significant
16 benefit. They note that it has a small net
17 benefit for -- across all the studies.

18 The American geriatric society
19 interpreted the evidence slightly differently and
20 they found that there was a significant net
21 benefit for adults who have a history of falls.
22 So, those adults which they define as two or more

1 falls, or a fall with injury.

2 So, that's the definition that we are
3 using as the at-risk population who would benefit
4 from a falls risk assessment.

5 This measure is specified for medical
6 record review collection. So, unfortunately
7 these are not things that are normally found in
8 billing codes. So, this is required to look at
9 medical records to determine whether or not
10 people have been asked about falls, whether or
11 not those people who are at risk of future falls
12 have had a risk assessment and a plan of care has
13 been put in place.

14 It is operationalized in the PQRS
15 program in two different ways. One is in their
16 claims and registry reporting option, which is an
17 optional reporting program for providers. And
18 then also in their GPRO program, which is the
19 reporting for Medicare shared savings plans and
20 group practices.

21 The testing that we did on this was
22 done back in 2009 looking at medical record

1 reviews. So, that's the way that this measure is
2 specified and being presented for endorsement.

3 CO-CHAIR THRAEN: Okay. Pat, do you
4 want to start with the evidence?

5 DR. QUIGLEY: Pat Quigley, and I'd
6 like to thank Erin for that excellent overview.
7 And to also say that she did an excellent
8 overview in terms of the evidence.

9 The evidence in supporting this from
10 the American Geriatric Society is also endorsed
11 by the British Geriatric Society and the American
12 Organization of Orthopedic Surgeons.

13 So, the evidence that is presented to
14 support each aspect of the three elements of this
15 measure have been graded by the United States
16 Preventive Services Task Force.

17 And you have that discussion on Page
18 10 of this report, but I would like to say that
19 there's been extensive effort in trying to get
20 this measure, the AGS guidelines into primary
21 care.

22 And that actually started in 2010 --

1 excuse me -- 2001. Reemphasized in 2010 with an
2 update of the evidence.

3 And I'd also like to add to your
4 presentation of this measure in that this measure
5 was originally presented and endorsed in 2007.

6 So, I think you did a great job in terms of the
7 evidence and I think we can go forward, but I did
8 want to make sure that everyone does appreciate
9 that this is specific to those people who have
10 fallen more than once or had an injurious fall.

11 And that's the more vulnerable side of
12 the algorithm. And that's why the United States
13 Preventive Services Task Force decided not to
14 just go with anyone who had a fall in the last
15 year, but the people who are more vulnerable in
16 the algorithm who have had more than one fall or
17 an injurious fall that they need to be worked up.

18 CO-CHAIR THRAEN: All right. Lisa,
19 then Ed.

20 MS. MCGIFFERT: Two questions. Who is
21 the population of patients? What is the
22 population of patients covered by this?

1 Inpatient? Outpatient? Nursing Home? Assisted
2 living?

3 DR. QUIGLEY: It's ambulatory care.
4 Ambulatory care.

5 MS. MCGIFFERT: So, somebody put in a
6 comment to recommend removing nursing home and
7 assisted living patients. Is that valid? Is
8 that a valid comment?

9 DR. GIOVANNETTI: Sorry. So, this
10 measure actually -- it is a measure of providers.
11 And so, included in this are eligible providers
12 who may make visits and provide care in nursing
13 homes.

14 So, some of the codes that are used to
15 determine the denominator, which is a visit with
16 an eligible provider, include claims codes for
17 visits to rest homes, nursing homes, non-acute
18 inpatient settings.

19 And so, it is possible that, you know,
20 providers choosing to report on this measure
21 through the PQRS program that have those types of
22 visits would be included.

1 It is not a measure that is used to
2 evaluate an institution. So, it's not used to
3 evaluate a nursing home. It's used for
4 providers.

5 DR. QUIGLEY: Provider.

6 MS. MCGIFFERT: Okay. Thank you.

7 And this seems really similar to the
8 one we heard yesterday, but -- they're very
9 close, but this is assessing whether the provider
10 does it rather than whether it happens in the
11 facility.

12 DR. QUIGLEY: Yes, and this is
13 structure or process. So, that's why we -- there
14 is a component to ask about fall risk, and then
15 complete a fall risk and get a plan of care.

16 So, it's not linked to an outcome and
17 reduce in fall, the reduction in terms of
18 reducing risk, it's the structure and the
19 process.

20 MS. MCGIFFERT: That was the one --
21 what was it? Just trying to remember. It was
22 the one I did. Can't remember the number.

1 Well, anyway, they had three parts.
2 Same thing. Assessment, plan, all of that.

3 DR. QUIGLEY: Pressure ulcers. Wasn't
4 it pressure ulcers?

5 MS. MCGIFFERT: It was pressure
6 ulcers. Thank you.

7 DR. QUIGLEY: Oh, you're welcome.

8 CO-CHAIR SEPTIMUS: All right. Just
9 a quick question. It says here on Page 1 of our
10 worksheet that identify patients at risk and that
11 family physicians have a pivotal role in
12 screening older patients.

13 Is there a particular reason you
14 mentioned family physicians? Shouldn't that be
15 any? It could be internal medicine. It could be
16 any primary care physician caring for these
17 patients. So, why do you mention family
18 physicians only here?

19 DR. GIOVANNETTI: It could -- you are
20 absolutely correct. It could be any type of
21 physician. And, in fact, the eligible providers
22 that can report on this include the whole range

1 of providers.

2 I think the family physician
3 specifically references -- the reference that
4 that came from was specific to family providers,
5 but you are correct.

6 CO-CHAIR THRAEN: Any other -- oh,
7 Lisa, are you done? Any other questions about
8 evidence? Let's vote.

9 MS. IBRAGIMOVA: It should be
10 working. Importance to measure and report, 1(a),
11 evidence structure process intermediate outcomes.
12 Votes are one, high only eligible if QQC
13 submitted; two, moderate; three, low; four,
14 insufficient evidence.

15 (Voting.)

16 (Discussion off the record.)

17 MS. IBRAGIMOVA: The results are 59
18 percent high. 36 percent moderate. Five percent
19 low. Zero percent insufficient information.

20 CO-CHAIR THRAEN: Performance gap,
21 Pat.

22 DR. QUIGLEY: Thank you.

1 In relationship to the performance
2 gap, there's a clear opportunity for improvement
3 and to get this into the hands of -- the practice
4 of providers.

5 This measure is reported on PQRS, the
6 Physician Quality Reporting System. For the
7 first measure which is Rate A, screening for
8 future risk, the performance measure was 41.5
9 percent. So, there's more opportunity, as you
10 can tell.

11 The rates range from 9.8, the tenth
12 percentile, to 79.8 percent, the 90th percentile,
13 of those that were eligible.

14 For the second component of this for
15 risk assessment of falls for fall rate, this was
16 5.2 percent that chose to actually report this.

17 So, I think that this was an issue in
18 relationship to choosing to report this in the
19 PQRS.

20 For Rate 5, the plan of care is also
21 used in PQRS which was 78.9 percent, which was of
22 those who chose to report it. So, this was much

1 higher and actually having a plan of care in
2 place.

3 And as was mentioned by the developer,
4 this is to address balance, as well as Vitamin D
5 and C.

6 So, with that there is opportunity.
7 There's also discussion in our report on
8 disparities. And the disparities in relationship
9 to this are trying to look at those that are
10 associated with repeat falls that are falling
11 higher that have -- more than twice and what we
12 need to do in terms of their care planning.

13 And also people over the age of 75 who
14 are four to five times more likely to be falling
15 even greater and having a serious injury.

16 There was disparities in older whites
17 that were 2.7 times more likely to die as a
18 result of a fall than African Americans. So,
19 there is a race disparity here. So, there is
20 great opportunity for improvement.

21 CO-CHAIR THRAEN: Victoria.

22 DR. RICH: (Speaking off mic)

1 particularly when it deals with disparities.

2 When you say that there's limited stratified, is
3 that something in the future to be looking at?

4 I think with the diversity of our
5 populations it seems to be such a keen, important
6 measure to consider.

7 DR. GIOVANNETTI: I wholeheartedly
8 agree. And I think that CMS is definitely moving
9 in the direction of trying to collect more
10 information stratified by race and ethnicity, as
11 well as things like language barriers, which I
12 think would be very important.

13 DR. RICH: Yes. Thank you.

14 CO-CHAIR THRAEN: Well, you cut
15 Charlotte off.

16 (Comments off record.)

17 CO-CHAIR THRAEN: All right. Any
18 other questions for performance gap?

19 (No questions.)

20 CO-CHAIR THRAEN: We'll vote.

21 MS. IBRAGIMOVA: Importance to measure
22 and report, 1(b), performance. The votes are

1 one, high; two, moderate; three, low; four,
2 insufficient.

3 (Voting.)

4 MS. IBRAGIMOVA: The results are 65
5 percent high, 26 percent moderate, nine percent
6 low, zero percent insufficient.

7 CO-CHAIR THRAEN: Okay. Reliability.

8 DR. QUIGLEY: Thank you. There's no
9 issues with reliability. They're very clear that
10 -- but I did want to mention that there is an
11 exclusion in terms of the denominator; those who
12 are non-ambulatory, those who are in wheelchairs.

13 CO-CHAIR THRAEN: Any questions?

14 (No questions.)

15 CO-CHAIR THRAEN: Vote.

16 MS. IBRAGIMOVA: Scientific
17 acceptability of measure properties, 2(a),
18 reliability. Votes are one, high; two, moderate;
19 three, low; four, insufficient.

20 (Voting.)

21 CO-CHAIR THRAEN: Could you revote
22 again?

1 (Revoting.)

2 MS. IBRAGIMOVA: The results are 48
3 percent high. 48 percent moderate. Four percent
4 low. Zero percent insufficient.

5 CO-CHAIR THRAEN: All right.
6 Validity.

7 DR. QUIGLEY: For validity, there was
8 face validity that was utilized for this measure,
9 this component of the measure.

10 The American Medical Association
11 convened a physician consortium of physicians
12 from multiple specialty areas.

13 They had a 23-member physician
14 consortium and they rated the validity of each of
15 the components of this measure on a five-point
16 rating scale where one was strongly disagree, to
17 five, strongly agreed. And all three of the
18 components rated over 4.3. So, there was a high
19 level of face validity.

20 CO-CHAIR THRAEN: Any questions?

21 (No questions.)

22 CO-CHAIR THRAEN: All right. Let's

1 vote.

2 MS. IBRAGIMOVA: Scientific
3 acceptability of measure properties, 2(b),
4 validity. The votes are one, high; two,
5 moderate; three, low; four, insufficient.

6 (Voting.)

7 MS. IBRAGIMOVA: The results are 48
8 percent high. 52 percent moderate. Zero percent
9 low. Zero percent insufficient.

10 CO-CHAIR THRAEN: All right.
11 Feasibility is next, I think.

12 DR. QUIGLEY: Yes. With feasibility,
13 this data is collected through the administrative
14 claims data, electronic claims data and then also
15 paper medical record.

16 So, that's an opportunity to deal with
17 the issues surrounding feasibility and then also
18 whether or not the providers are actually
19 reporting it.

20 It's not an eMeasure, but the data
21 collection provided by the developer indicates
22 few concerns related to feasibility.

1 CO-CHAIR THRAEN: Questions.

2 (No questions.)

3 CO-CHAIR THRAEN: Vote.

4 MS. IBRAGIMOVA: Feasibility. The
5 votes are one, high; two, moderate; three, low;
6 four, insufficient.

7 (Voting.)

8 MS. IBRAGIMOVA: The results are 35
9 percent high. 61 percent moderate. Four percent
10 low. Zero percent insufficient.

11 CO-CHAIR THRAEN: Usability. Pat.

12 DR. QUIGLEY: Thank you.

13 In terms of usability this clearly
14 identifies the opportunity for continuing to
15 address the fall risk needs --- fall reduction
16 needs in the elder population.

17 So, recognizing the opportunity in
18 relationship to the gap, there's a lot of
19 opportunity to be able to improve practice. And
20 in addition to usability, it helps us to be able
21 to appreciate that.

22 The reduction of fall risk really

1 requires more than balancing, gait, mobility and
2 calcium, Vitamin D.

3 The AGS guidelines, BGS guidelines,
4 American Orthopedic Surgery, there is a
5 multifactorial approach and there's lots of
6 opportunity to be able to reduce risk.

7 And this is to make -- help elder
8 patients be healthier. It's not just about
9 whether or not they fell. It's being able to
10 reduce their risk. And that's the focus of these
11 guidelines.

12 So, there's a lot of opportunity for
13 usability of this if we could get this into the
14 hands of providers.

15 CO-CHAIR THRAEN: Questions.

16 Yes. Go ahead.

17 DR. YU: I have two questions. One is
18 about the comments about there have been little
19 variation in performance across providers which
20 was to report.

21 This tied to the previous statement
22 that payment program, and said that the measure

1 is the currently used payment program.

2 So, I would just -- can you describe
3 or explain it why -- how you tie to payment
4 program when you have so little variation among
5 the performance.

6 DR. GIOVANNETTI: So, the payment
7 program that this is tied to, there's two
8 different programs.

9 One is the PQRS voluntary reporting
10 program in which it is a pay for reporting. So,
11 you are not paid based off of your performance.
12 You are paid because you've reported the measure
13 and providers choose which measures they want to
14 report on.

15 And so, what you end up with is
16 providers that are doing well in a particular
17 area, choose to report on that measure.

18 And so, in the two measures that look
19 at risk assessment and plan of care we see high
20 rates with not a huge amount of variation
21 primarily because the providers choosing to
22 report on them are doing those things and

1 documenting them.

2 The other one, the screening, is
3 actually being used in the GPRO program, which is
4 not voluntary. That one is for the Medicare
5 shared savings programs and group practices are
6 required to report on that.

7 And that is actually something where
8 we're starting to see more of the pay for
9 performance. And so, we see more variation in
10 that measure.

11 There is movement of the PQRS program
12 to move from a voluntary reporting program to
13 become more of a mandatory reporting program with
14 payment for performance as opposed to payment for
15 reporting, but we're not there yet.

16 DR. YU: Yeah. Okay. Thanks for
17 clarifying.

18 My other question is definitely you
19 want to see more people or physicians, you know,
20 to encourage them to report.

21 And there are comments that PQRS
22 involved in the reporting, you know, increase is

1 expected, I just wondering what is the plan or do
2 you have any, you know, explanation what is the
3 improvement down the road that you would
4 encourage more reporting on this type of thing

5 DR. GIOVANNETTI: So, NCQA does not
6 run the PQRS program. That's run by the Centers
7 for Medicare and Medicaid.

8 They have put forth several proposals
9 for improving that program that actually many of
10 which I believe were laid out in the -- some of
11 them in the MACRA legislation. The SGR.

12 So, unfortunately, that's not a
13 program that's within our control, but CMS is
14 working towards more of a value-based purchasing
15 model in which the measures that are in the PQRS
16 program will be used in that way.

17 DR. YU: Okay. Thank you.

18 CO-CHAIR THRAEN: Laura.

19 MS. ARDIZZONE: Yes. Would you be
20 able to comment on some of the -- there seems to
21 be a lot of competing measures and there's
22 actually one that really sounds similar, NQF

1 0035, Fall Risk Management for All Older Adults
2 Across All Settings.

3 I'm concerned about the burden of
4 reporting on, you know.

5 DR. GIOVANNETTI: I'd be happy to.

6 So, 0035 is a measure for health plans
7 as opposed to providers. It does look at the
8 similar concepts and we've actually -- we also
9 stored that measure in CQA. And so, we harmonize
10 it in terms of concepts, but that measure is
11 actually collected through a survey, not through
12 physician reporting.

13 So, if a physician is doing the things
14 to meet this measure and the patient is
15 understanding what's going on, ideally the
16 patient will report on the survey that those
17 things happened.

18 So, it's not adding to physician
19 burden in terms of having to report on two
20 different measures.

21 The reason that we collected for a
22 survey for the health plan has to do with some of

1 these issues around the burden of data
2 collection.

3 So, as we noted before, a lot of this
4 information has yet to go to the medical record
5 to find it.

6 And so, physician that may do that in
7 the PQRS program we felt that for the health plan
8 reporting rather than health plans having to go
9 back out and do this again, this could be better
10 captured through a survey.

11 The survey also gets some other
12 elements, which is how much is the patient
13 actually understanding that this has happened for
14 them.

15 So, if they don't know that anyone has
16 actually advised them on how to prevent falls,
17 that's a kind of other end of the spectrum.

18 So, they tell you slightly different
19 things about the same underlying measure concepts
20 that are aligned.

21 CO-CHAIR THRAEN: Kimberly on the
22 line, you had a comment?

1 DR. APPLGATE: Oh, it was actually a
2 comment about the PQRS program. My understanding
3 is that it's actually a penalty program now in
4 2015 and it will pay out -- I mean, it will
5 assign penalties in 2017 for the 2015 program
6 reporting of those PQRS metrics. It's just a
7 comment.

8 CO-CHAIR THRAEN: All right. Any
9 other -- Laura, did you have a -- any other
10 conversation, questions?

11 (No comments.)

12 CO-CHAIR THRAEN: Shall we vote?

13 MS. IBRAGIMOVA: Usability and use.
14 The votes are one, high; two, moderate; three,
15 low; four, insufficient information.

16 (Voting.)

17 MS. IBRAGIMOVA: The results are 17
18 percent high. 74 percent moderate. Nine percent
19 low. Zero percent insufficient information.

20 CO-CHAIR THRAEN: All right.
21 Endorsement. Yes/no.

22 MS. IBRAGIMOVA: Overall suitability

1 for endorsement. Does the measure meet NQF
2 criteria for endorsement? One, yes. Two, no.

3 (Voting.)

4 MS. IBRAGIMOVA: Results are 96
5 percent yes. Four percent no.

6 CO-CHAIR THRAEN: Good. All right.
7 Moving on to the next one is -- hold on.

8 MS. KEANE: 0567.

9 CO-CHAIR THRAEN: Yeah. Thank you.

10 MS. KEANE: It's Nicole Keane from Abt
11 Associates, one of the measure developers.

12 CO-CHAIR THRAEN: Hold on. Excuse me.
13 Hold on. There's been some reordering. Hold on
14 a minute.

15 (Comments off record.)

16 CO-CHAIR THRAEN: 0097. We have
17 National Committee on Quality. Their second one.
18 I apologize. There it is. Medication -- 0097,
19 Medication Reconciliation Post-Discharge.

20 NCQA, yes.

21 DR. GIOVANNETTI: Hello again.

22 So, this measure is a measure that

1 looks at the reconciliation between a hospital
2 discharge medication list and an outpatient
3 medication list occurring within 30 days post-
4 discharge for adults 18 and older.

5 This is actually we have preemptively
6 taken the move to combine two measures into a
7 single measure here.

8 So, we have a provider-level measure
9 of medication reconciliation post-discharge
10 that's reported through the PQRS program, and a
11 health plan-level measure of exactly the same
12 that's reported in the HEDIS set for Medicare
13 advantage plans.

14 So, this measure is not necessarily
15 based off of a systematic evidence review, but
16 really that best practice that medication
17 reconciliation post-discharge is a critical
18 component of transitional care.

19 Older adults are discharged -- older
20 adults, and younger adults as well, are
21 discharged from the hospital often with multiple
22 medication lists that can be conflicting with

1 their outpatient medication list. And it is
2 critical that the outpatient provider understand
3 what medications were they prescribed from the
4 inpatient setting and then reconcile that with
5 the outpatient list to determine what's the
6 appropriate list the patient should be on.

7 So, the measure uses medical record
8 review once again to identify whether or not the
9 two medication lists were reconciled within 30
10 days of discharge.

11 You'll notice that there are two
12 different testing forms for this because this is
13 tested at both levels. So, the provider level
14 where we have done inter-rater reliability
15 between different abstractors looking at the
16 records and then at the health plan level where
17 we've done construct validity analysis where
18 we've compared the measure with other measures of
19 medication management and found strong
20 correlations, as well as reliability of the
21 overall score of the precision of the estimate
22 and found that the measure is highly precise.

1 As I said, it's used in different
2 programs depending on if you're using the
3 provider level or the health plan level.

4 So, for providers it's used for the
5 PQRS program. For health plans it's used for
6 Medicare advantage reporting.

7 The data that you have in here
8 actually for the health plan-level reporting
9 comes from special needs plans reporting, because
10 that is up until -- actually, have they approved
11 --

12 DR. BARTON: Yes.

13 DR. GIOVANNETTI: Okay. Good. I can
14 say this. Up until a few days ago this measure
15 was only approved for special needs plans
16 reporting. But as of a few days ago, it has been
17 approved for reporting by all Medicare advantage
18 plans, not just the special needs plan.

19 And reported for all age groups in
20 Medicare advantage 18 and older so that we are
21 capturing that 18 to 64 dual-eligible population
22 in the Medicare.

1 So, those were two significant
2 improvements to the measure that we just got
3 approved.

4 CO-CHAIR THRAEN: Chris.

5 DR. COOK: Yeah, this is Chris Cook.
6 And going through this from the evidence
7 standpoint as you pointed out, there is not any
8 overall systematic review from what's there, but
9 all the studies do consistently point towards the
10 benefits of performing medication reconciliation
11 particularly for patients who are at that risk
12 standpoint of transferring between facilities.

13 Studies have all been primarily linked
14 to medication reconciliation to reducing
15 medication errors. However, no studies have
16 actually linked medication reconciliation to
17 morbidity or mortality simply because you have a
18 number of steps that are within that.

19 And the developer states that most of
20 those studies are basically just underpowered to
21 get to that level.

22 As a personal note, when I look at

1 this overall being a pharmacist, when we look at
2 what we spend in the national from a healthcare
3 we're looking at 2.7 trillion dollars.

4 Drugs have consistently been
5 approximately ten percent of that. So, that's
6 270 billion dollars that we spend on medications
7 each year.

8 Back in 2009 NEHI actually did a
9 report around medication non-adherence or
10 medication misadventures. And their estimation
11 at that point was 290 billion dollars.

12 So, in essence, as a society and as a
13 healthcare system, we are spending basically one
14 dollar fixing drug errors for every dollar that
15 we spend on medications.

16 So, if you look at it from a purely
17 economic standpoint or an economist would look at
18 it, the question would be why in the world do we
19 even pay for any drugs whatsoever?

20 As we are all practitioners in this
21 room, I think if we took away that tool in our
22 toolkit to improve patient care it would be

1 considered ridiculous.

2 So, to me, the next thing that we have
3 to do is we have to put this as a national
4 priority to pay better attention to the
5 medications that we use, minimize the adverse
6 effects that are there and be proactive in
7 pursuing patient care in this area.

8 CO-CHAIR THRAEN: Lisa.

9 MS. MCGIFFERT: Thanks. What we're
10 measuring here is actually that a check was done,
11 but is there any indication that when a check was
12 done there was actually reconciliation?

13 DR. GIOVANNETTI: So, this is
14 something we actually in our past reevaluation of
15 the measure looked into in depth of how can we
16 get at the quality of the medication
17 reconciliation, which includes more than just,
18 you know, were they reconciled. Did you do
19 education with the patient about it? Did you
20 actually identify that each medication was
21 indicated?

22 As we looked through all of our

1 options for actually getting down into this level
2 of detail, it was just not feasible with a
3 quality measure. And this may be one of the
4 areas where the limits of measurement are
5 actually you can't get up with this.

6 So, one area that we did actually we
7 didn't look at this, but we looked at some
8 research of others where they compared the
9 hospital discharge medication list to the list in
10 the outpatient record to then say, okay, well,
11 what was the number of discrepancies?

12 The challenge with that is that you
13 can't tell if the discrepancy was intentional or
14 not. So, someone might have actually -- a
15 provider in their outpatient list might have
16 discontinued something that someone was
17 discharged with because they didn't feel it was
18 appropriate. And that was an intentional
19 discrepancy versus an unintentional discrepancy.

20 And so, getting down into that level
21 of detail what's documented right now in medical
22 records we really can't get to that level of

1 detail.

2 And so, where we are right now is with
3 a measure that does just say, did you look at
4 both lists and compare them?

5 It, I agree, doesn't get at the level
6 of quality we want to, but I will point out that
7 in special needs plans this low level is only
8 being done in 35 percent, on average, of
9 discharges.

10 So, we see a need to significantly
11 improve performance on this measure and then look
12 at other things potentially like structural
13 measures and quality improvement efforts that can
14 be used to help bolster this whole concept of
15 medication reconciliation.

16 MS. MCGIFFERT: Thank you.

17 CO-CHAIR THRAEN: Ed, and then Josh,
18 and then Yanling, and then Steve.

19 CO-CHAIR SEPTIMUS: It looks to me as
20 reading this that this could be reconciled by any
21 number of three professionals; is that correct?

22 I'm just going to tell you

1 philosophically something. It says that any one
2 of three practitioners can do this.

3 It seems to me by doing it this way,
4 that you've taken the physician off the hook for
5 his or her primary responsibility for patients.
6 So, I have a concern about that.

7 And then secondly, you've said within
8 30 days; is that correct? Is there a particular
9 reason you picked 30 days? That assumes that a
10 patient discharged will see a practitioner in 30
11 days, which of course is not always the case.

12 DR. GIOVANNETTI: So, I'll first
13 address the three different practitioner types.
14 This can be done by a physician, any type of
15 prescribing practitioner, including a nurse
16 practitioner, a clinical pharmacist or a
17 registered nurse.

18 And this is based off of several
19 interventions that have shown that these
20 different professions can actually do medication
21 reconciliation very effectively as part of team-
22 based care. And so, actually there's a lot of

1 evidence that clinical pharmacists can play a
2 very critical role in medication reconciliation.

3 What we look for is that it's
4 documented in the outpatient record so that it
5 can't be that a clinical pharmacist does a
6 reconciliation and does it over here and it never
7 gets documented back to the central record.

8 And so, that's kind of where we are
9 looking for -- we don't want to say this has to
10 be the physician that does this, but it has to be
11 documented in the record.

12 CO-CHAIR SEPTIMUS: I'm not
13 disagreeing with the value of other
14 practitioners, but it seems to me that somewhere
15 in the medical record that the physician has to
16 sign off that medications have been reconciled.
17 That's what I'm saying.

18 I know that pharmacists play a
19 valuable role. I know that nurse practitioners
20 and nurses, I mean, physician assistants can play
21 a valuable role, but that's generally under the
22 supervision of a physician.

1 And so, my only concern about this is
2 not that they don't play a valuable role, but
3 that I think we have to have someplace in there
4 that that is acknowledged by the physician.
5 That's my only thought.

6 CO-CHAIR THRAEN: So, I want to remind
7 people that we're talking about the evidence
8 right now. So, if your questions are related to
9 the evidence --

10 CO-CHAIR SEPTIMUS: Based on the
11 evidence, it sounds like you have the evidence
12 supporting --

13 (Comments off record.)

14 CO-CHAIR THRAEN: Josh.

15 DR. RISING: Hi. Thanks. This is
16 Josh Rising. I just wanted to make sure I was
17 understanding the numerator and the denominator
18 correctly on this.

19 So, if you have a patient discharged
20 from the hospital who never follows up with his
21 or her primary care physician, so -- then so med
22 rec is never done. So, presumably that would

1 show up for both the health plan and for
2 integrated delivery system as no med rec being
3 done. And then would it also show up for the
4 physician who has been assigned to that?

5 So, for the physician it's only when
6 you see a patient who has been discharged from
7 the hospital, did you do med rec at that
8 particular visit?

9 DR. GIOVANNETTI: Yes, you're entirely
10 right. There's different accountability models.

11 DR. RISING: Now, is there a reason we
12 wouldn't want to be assigning it to a primary
13 care physician assuming that the patient has a
14 primary care physician as well?

15 DR. GIOVANNETTI: I think you just hit
16 the nail on the head as identifying who is the
17 accountable physician for a patient that never
18 followed up with a physician.

19 And so, that's just a limitation of
20 the PQRS program.

21 CO-CHAIR THRAEN: Yanling.

22 DR. YU: Yes. I didn't hear Ed's

1 question about 30 days. I do have a concern
2 about that, too, because I understand that
3 sometime you document it not right at the time or
4 maybe have a little short window, but how do you
5 distinguish between someone delayed their
6 documentation versus, you know, not just the
7 reason that, you know, got 30 days.

8 To me, I don't see any -- in most
9 cases you don't need 30 days to -- because, you
10 know, to verify the medical records, adequate
11 patients and, you know, their caretakers.

12 DR. GIOVANNETTI: So, you're correct.
13 The evidence for 30 days versus 15 versus seven,
14 you know, there's not enough evidence to really
15 say this is the one threshold.

16 30 days is the -- a lenient time. And
17 as I said before, we still see performance at 35
18 percent for just even reaching medication
19 reconciliation within 30 days.

20 So, when we've talked about this with
21 our advisory panels and they've suggested
22 shortening the follow-up time, they've actually

1 said maybe we should see performance improve
2 before we make this a more difficult measure.

3 I'll also point out that two of the
4 administrative codes that can be used to meet
5 this measure are transitional care visits that
6 were recently approved by CMS, which can occur
7 within 30 days of discharge.

8 And so, part of this is aligned with
9 the billing that CMS has said transitional care
10 occurs within the 30 days post-discharge.

11 And so, those visits -- so, we're in
12 some ways trying to align to minimize burden in
13 that way as well, but it's definitely on the
14 future when we see performance get to a certain
15 level that we would want to raise the bar and
16 makes this something that looks at a more
17 stringent time level.

18 DR. YU: Thank you.

19 CO-CHAIR THRAEN: Steve.

20 DR. LAWLESS: The evidence that -- or
21 the numerator/denominator excludes observation
22 patients, or includes observation patients?

1 X percent of patients who are there
2 within -- or seen out of the hospital within 48
3 hours for observation do not categorize as
4 inpatient. They are not part of the denominator?

5 DR. GIOVANNETTI: Give me one second
6 here as I'm thinking through. So, this is a
7 discharge from an inpatient facility.

8 DR. LAWLESS: Uh-huh.

9 DR. GIOVANNETTI: So, if they are
10 considered -- if they are observation and
11 considered hospital outpatient, they are, you are
12 correct, not included in this measure.

13 DR. LAWLESS: Okay.

14 DR. GIOVANNETTI: We have been
15 definitely going through the efforts of how do
16 you distinguish hospital outpatient claims that
17 are observation stays that are actual stays
18 versus hospital outpatient that is not a stay.
19 And that's one of the challenges we've been
20 struggling to overcome.

21 DR. LAWLESS: Okay. So, you're
22 looking at it.

1 And the other question is, is one of
2 the exclusions are patients who are readmitted
3 before the reconciliation is done.

4 I would consider was the evidence --
5 that the reconciliation was not done caused the
6 admission -- the readmission.

7 DR. GIOVANNETTI: I think that's a
8 very good point. So, I will say that if they're
9 readmitted, they get picked up in the measure the
10 next time they're discharged. So, they don't
11 eliminate from the measure whatsoever.

12 You are correct the readmission could
13 be the result of the medication reconciliation,
14 but we can't necessarily determine if they did
15 have an appointment scheduled where this was
16 going to happen and they came back to the
17 hospital before that appointment could happen if
18 it was a readmission within 24 hours, within 48
19 hours.

20 And so, we do exclude those
21 readmissions assuming they'll be captured the
22 next time they're discharged from the hospital.

1 CO-CHAIR THRAEN: All right. Any
2 other -- should we vote on the evidence?

3 MS. IBRAGIMOVA: Importance to measure
4 and report, 1(a), evidence structure process
5 intermediate outcome. The votes are one, high,
6 only eligible if QQC submitted; two, moderate;
7 three, low; four, insufficient evidence.

8 (Voting.)

9 CO-CHAIR SEPTIMUS: Lunch is here.
10 So, some of you have already -- so, I think if
11 you want to peel off and just grab your lunch and
12 come back to eat, that would be great.

13 MS. IBRAGIMOVA: The results are 36
14 percent high. 55 percent moderate. Nine percent
15 low. And zero percent insufficient evidence.

16 CO-CHAIR THRAEN: All right.
17 Performance gap. Chris.

18 DR. COOK: Yes. As already mentioned,
19 there is definitely a performance gap especially
20 with the special needs plan beneficiaries.

21 It is interesting to see that they're
22 going to be expanding that to Medicare advantage

1 plans and having it all the way across the board.

2 And of course Medicare advantage plans
3 do take into the totality of the patient care
4 both from the medical and the pharmacy side. So,
5 I think I see that as a good thing.

6 The special need plan beneficiaries
7 were an average of 36.6 percent. The tenth
8 percentile reported 9.4 percent. And the 90th
9 percentile reported only 62 percent showing clear
10 room for improvement both from the mean, as well
11 as the variance across what's going on.

12 Within the PQRS system, interesting to
13 me here is that only 1.6 percent of eligible
14 providers chose to report on this measure. And,
15 again, this is one of those to where physicians
16 are able to choose which measures. It's not
17 mandatory for them to choose on it.

18 And so, what you see there is that
19 those who did report obviously have systems in
20 place that allow them to do this in a very
21 structured fashion.

22 And so, you saw a mean performance

1 there of 96.3 percent. So, I think it clearly
2 shows this can be done. It's just not being done
3 by most. And so, we have a lot of room for
4 improvement.

5 CO-CHAIR THRAEN: Go ahead, Yanling.

6 DR. YU: Thank you. That's just one
7 of my question. The statements that only 1.6
8 percent of eligible provider choose to report.
9 So, I guess this performance gap is really how to
10 make them to report.

11 So, I wonder if you have any thoughts
12 on that how to make people to do things that you
13 make measures on.

14 DR. BARTON: I'm glad to say that from
15 what I understand of the MACRA legislation, there
16 will be -- CMS is looking to hold physicians
17 accountable either through what they've called
18 APMs, alternative payment mechanisms, which means
19 like an ACO or some sort of actual risk
20 arrangement, or if not that, then through what
21 they call MIPS, the merit-based incentive
22 program, which is going to ratchet up over time

1 the requirements for clinicians in practice,
2 wherever they're in practice, to organize
3 themselves for reporting on quality and for
4 quality improvement.

5 So, I think that there's a lot of
6 reasons to be very hopeful. Of course, the
7 distance between legislation that's passed and
8 the regulations that get written can sometimes be
9 as we're suffering in the Supreme Court even
10 today so that it's not a slam dunk, but I think
11 that there's reasons to be hopeful.

12 And also reasons if you're so
13 inclined, to be active with professionals
14 organizations to try and influence how this gets
15 written in regulation.

16 DR. YU: Thank you.

17 CO-CHAIR THRAEN: Jason, then Susan,
18 then Charlotte.

19 DR. ADELMAN: I'm not sure that I
20 believe the performance gap. And that is to say
21 that I'm not sure that I believe in the validity
22 of the measure.

1 And so, they're intertwined, my
2 comments, but I do believe that I think it was
3 somewhere like around 35 percent of the time
4 people are checking the box.

5 I just don't believe that 30 percent
6 of the time when people are discharged from the
7 hospitals, doctors consider the medicines that
8 they're on.

9 I think that what's more likely is
10 that they just don't care about checking the box.
11 There's not enough meaning and, you know, it's
12 egregiously bad care to, like, not consider the
13 medicines that a patient that was just in the
14 hospital was on. And I don't think that 60
15 percent of our providers are egregiously that
16 bad. I just think they don't care about checking
17 the box.

18 And so, you can call that a validity
19 comment, which I can circle back around and make
20 it again for a performance gap, but I just don't
21 -- I don't believe it.

22 CO-CHAIR THRAEN: Susan.

1 DR. MOFFATT-BRUCE: I think just from
2 the perspective of physicians -- so, as a CQO for
3 a large academic medical center, PQRS is not very
4 -- not been in our wheelhouse at all. PQRS
5 measures have been chosen by administrators that
6 find them easy to report on the behalf of the
7 physicians.

8 As MIPS is rolled out, I am encouraged
9 because I think the docs are going to have to pay
10 attention and they are going to be made
11 accountable, because money talks. And I think
12 that's the first incentive for physicians,
13 unfortunately, to get kind of on board.

14 I think the more PQRS measures that
15 are meaningful, that are put in place and
16 endorsed will be helpful, because we can choose
17 the ones that will impact patient care and
18 ultimately improve, you know, the systems
19 approach to care.

20 So, I think that is encouraging. I
21 think that is important. I think the MIPS
22 program with the right PQRS measures are going to

1 be very influential in providing the care we want
2 for our patients.

3 MS. MCGIFFERT: Can you tell me what
4 that acronym stands for?

5 DR. MOFFATT-BRUCE: I'm just trying to
6 remember. What is it? Merit-based incentive
7 program.

8 And so, I think it's encouraging
9 because they took away this idea that they were
10 going to reduce all the Medicare reimbursement,
11 but rather put in pay for performance and
12 accountability metrics at the physician level.

13 Right now it's very much at the
14 institutional level so they think it's my job,
15 whereas now it's going to be down to the
16 provider. It's going to be their job, which is
17 great.

18 CO-CHAIR THRAEN: Charlotte, and then
19 we have someone on the line that has a comment.

20 DR. ALEXANDER: So, I have a concern
21 that this is not meaningful, because it's too
22 easy to check a box and not do the activity, do

1 not really reconcile.

2 And even more important is to find out
3 whether the patient filled the prescription, is
4 taking the medicine, is taking it appropriately.
5 And that needs to be looked at for disparities.

6 I don't know that this will be
7 applicable for disparities, but I think it misses
8 what we need to do.

9 CO-CHAIR THRAEN: And online is it
10 Kimberly or Ann? It's Kimberly. Kimberly, you
11 have your comment about PQRS?

12 DR. APPLGATE: I already made it.

13 CO-CHAIR THRAEN: Sorry. Thank you.

14 Any other conversation about
15 performance gap?

16 (No comments.)

17 CO-CHAIR THRAEN: Okay. Should we
18 vote?

19 MS. IBRAGIMOVA: Importance to measure
20 and report, 1(b), performance gap. The votes are
21 one, high; two, moderate; three, low; four,
22 insufficient.

1 (Voting.)

2 MS. IBRAGIMOVA: The results are 36
3 percent high. 36 percent moderate. 23 percent
4 low. Five percent insufficient.

5 CO-CHAIR THRAEN: All right.
6 Reliability.

7 DR. COOK: The measure developer has
8 done testing at the level of the measure score.
9 It was performed both, as I said, at the
10 physician level. So, that was done through
11 charts. And then also from electronic medical
12 level testing for the plan level. So, two
13 samples were done for data element reliability.

14 In one sample, it was from four
15 practices using 62 patients. And then in the
16 PQRS system, 38,000 plus patients were used to
17 examine.

18 The nominator rate of agreement was
19 96.8 percent, which indicates that the
20 abstractors almost came to the same conclusion.

21 And then the numerator had a kappa
22 score of 0.97. Obviously very high.

1 CO-CHAIR THRAEN: All right. Any
2 questions?

3 Yes, Yanling.

4 DR. YU: Yes. Thank you.

5 I have concerns about how the
6 documentation would consider as the fact that
7 medication reconciliation had been done.

8 I think on Page 21 it says any five --
9 what it said that the data on which you perform
10 any of the following evidence need criteria.

11 So, you document a list of five
12 things, but my concern is that things missing is
13 very important for medication reconciliation is
14 to document any there's contraindication, have
15 had a drug reaction, have had a, you know,
16 communication with the patients and caretakers,
17 you know, about, you know, it's a process to me
18 rather than just a single document said I done,
19 check the box.

20 So, the whole thing is how this
21 process went through that makes sure that
22 everyone on the team, including patient

1 caretaker, is on the team and understand this
2 thing.

3 So, I'm concerned about that just
4 single check box.

5 DR. GIOVANNETTI: I think that this
6 panel has raised one of the central challenges
7 with measuring medication reconciliation, which
8 is this balance between we want to see that many
9 things were done.

10 Like you mentioned, all of this
11 process was done. As Charlotte mentioned, you
12 know, all of the things happened to help people
13 actually understand their medications.

14 What's actually documented, though, as
15 -- sorry, I don't see your name down there, but
16 what's happening -- Jason. What's happening
17 versus what's document is -- there's a disconnect
18 there.

19 And so, we try to strike a middle
20 ground where we look for these types of
21 documentation that is reasonable with what we
22 expect a provider to actually write in the note

1 section of I looked at the, you know, here's the
2 discharge list, here's the things that were
3 changed, or here's a copy of the discharge list
4 or, you know, or, as you say, checking the box or
5 just a notation of reviewed and reconciled.

6 Those types of things are what we look
7 for as kind of the bear minimum that we would
8 expect of providers to document, but they may be
9 doing much more that they're not documenting.

10 And we want to strike that balance
11 between not asking providers to spend all of
12 their time documenting 15 steps of I educated the
13 patient, I, you know, I looked for
14 contraindications, I did this, I did this, I did
15 this, because that turns into 15 boxes we have to
16 check versus also trying to have some type of
17 minimum documentation.

18 DR YU: I just think that, you know,
19 to ask for providers to check whether they have
20 been, you know, indicated in the medical records
21 in term of a cancellation that, I mean, a
22 contraindication, a drug potential interaction of

1 and adequate patient, I think, is a huge
2 investment actually in the time spent, because
3 that can happen.

4 That can have a medical error and
5 have, you know, that can cause more actually to
6 fix the medical error. So, I think that that
7 shouldn't be a, you know, a burden, look at it as
8 a burden.

9 You can just make boxes, make
10 prioritize what needs to be done and check the
11 box. Thank you.

12 CO-CHAIR THRAEN: Chris, then Missy.

13 DR. COOK: Yeah, I think, Yanling,
14 what you're bringing up is absolutely true. And
15 the pharmacy profession, I know, is definitely
16 working on this.

17 I'm involved with the Pharmacy Quality
18 Alliance, where we are trying to answer and to
19 create measures and to build more robust
20 measures.

21 This current measure right now is sort
22 of that basic first step that is where we are

1 currently.

2 There are a number of CMMI grants that
3 are going on around the nation, which definitely
4 deal with medication use and trying to get from
5 where we currently are to medication
6 optimization.

7 And so that work is currently being
8 done, but we don't have the solutions yet to
9 bear. And a lot of it comes into what are the
10 data limitations, both from EHR as well as claims
11 data, a number of different things that are
12 happening that are the barriers.

13 And I think overall our healthcare
14 system is trying to build that infrastructure to
15 get past that bridge, but as of right now, this
16 is the best we can do.

17 CO-CHAIR THRAEN: Go ahead, Missy.

18 MS. DANFORTH: Given, I think, the
19 Committee has really warranted concerns about
20 doctors just checking the box and the fact that
21 the measure has been endorsed since 2007, have
22 there been any efforts to just do some random

1 observations in some of these practices that are
2 voluntarily reporting on this measure to actually
3 see if the physicians or the providers, I guess,
4 are just checking the box or actually going
5 through the steps, and is that a consideration?

6 DR. GIOVANNETTI: So, we do not
7 actually run the PQRS program, so we don't know
8 which providers are reporting on this measure.
9 That's a CMS effort.

10 Where we do know that there is effort
11 is around the special needs plans. And
12 particularly, because this is a HEDIS measure
13 reported by special needs plans, and we've worked
14 with CMS to actually better understand their
15 quality improvement efforts around medication
16 reconciliation and understanding what are some of
17 the things that they are doing to try to improve
18 this process overall, particularly as it leads to
19 better outcomes for patients in the end.

20 So, I have not personally done any
21 observations. It's not a study that we have
22 done, but it is something that CMS is actively

1 interested in and is understanding what are the
2 efforts going on in special needs plans to do
3 medication reconciliation.

4 MS. DANFORTH: Wait, but I think my
5 question is slightly different in terms of the
6 reliability of the measure.

7 And so, this is giving physicians
8 and/or health plans credit every time a box is
9 checked.

10 And so, like, to Jason's earlier
11 point, if they're just checking the box and not
12 doing anything, that does speak to the
13 reliability of the measure.

14 DR. GIOVANNETTI: So, just to be
15 clear, this is not --- there's no box. This is
16 actually looking for notation, as we said here,
17 of they signed off saying, I reconciled this.

18 And we have not actually done an
19 observational study of the reliability. I don't
20 know, Mary, if you want to build on that.

21 DR. BARTON: Well, I'll just say the
22 health plan measure requires chart review. And

1 the special needs plans are called upon, if
2 audited, to document what words notated in a
3 chart are supporting their supposition that this
4 is a numerator hit.

5 So, I am less likely to be concerned
6 about this use in a health plan setting than I am
7 in a physician setting. And I can appreciate the
8 wide frustration with the PQRS program, but I
9 guess I would just echo what Susan said earlier
10 that there's hope that things are going to
11 change, and that this is a good time to see
12 change.

13 CO-CHAIR THRAEN: Charlotte, did you
14 have something, or is that left over? Okay.
15 Let's vote. Reliability.

16 MS. IBRAGIMOVA: Scientific
17 acceptability of measure properties, 2(a),
18 reliability. The votes are one, high; two,
19 moderate; three, low; four, insufficient.

20 (Voting.)

21 MS. IBRAGIMOVA: The results are: zero
22 percent high; 68 percent moderate; 27 percent

1 low; 5 percent insufficient.

2 CO-CHAIR THRAEN: All right.

3 Validity.

4 DR. COOK: Within validity, there was
5 testing done as well. A systematic assessment of
6 face validity was done very similar to some of
7 our other measures in this area, where there was
8 an AMA convened PCPI standardized process using
9 33 members.

10 The mean rating for face validity was
11 4.0, with 73.91 percent of respondents either
12 agreeing or strongly agreeing that the measure
13 can accurately distinguish good and poor quality.

14 When you look at the threats to the
15 validity, there are no exclusions to this
16 measure, and it is not risk adjusted.

17 When you do look, there is a 33
18 percent gap in the performance between the 25th
19 and the 75th percentile. So, you do see a
20 distinguishable difference.

21 And there was definitely a gap among
22 the low and the higher performing Medicare

1 special needs plans when looking at it from that
2 standpoint.

3 CO-CHAIR THRAEN: Jason.

4 DR. ADELMAN: So, they're primarily
5 relying on face validity that had --- and please
6 correct me if I have this wrong --- that had some
7 30 experts that were asked the question, do they
8 think the measure would be valid? And the
9 majority said yes.

10 However, I think, you know, depending
11 on how you couch the question now that that has
12 happened, they have some data. And as I said
13 before, 35 percent are compliant.

14 I bet if you went back to the same
15 group and said, do you believe that 35 percent of
16 our doctors are not doing med rec, that they
17 would all now find it not valid.

18 And so, I think that, in this case,
19 face validity is not acceptable and perhaps
20 investing in doing a more thorough validation is
21 worthwhile.

22 And also to the point --- I'm sorry.

1 You didn't know my name, and now I don't know
2 your name.

3 DR. GIOVANNETTI: Erin.

4 DR. ADELMAN: Erin. To Erin's point,
5 you know, it would be one thing if the measure
6 was about documenting of med rec.

7 And, in that case, if the numerator
8 didn't claim it's actually measuring med rec, but
9 it's measuring the documentation of med rec, then
10 we can say, okay, we're at 30 percent and people
11 have to, you know, improve their documentation.

12 But since it's claiming it's an actual
13 measure of med rec, I just don't believe it's
14 valid, and I don't believe the face validity test
15 of 30 experts at that time without this
16 information is good enough.

17 CO-CHAIR THRAEN: All right. Other
18 thoughts?

19 CO-CHAIR SEPTIMUS: Erin, I want you
20 to meet Jason.

21 DR. GIOVANNETTI: I just want to put
22 out one thing, which is that it's not based

1 solely on face validity.

2 We did do a test of empiric validity
3 where we looked at construct validity and its
4 correlation with another measure of medication
5 management, medication review, and we see strong
6 correlations there. So, we actually are seeing
7 this behave the way we would expect it to behave.

8 I would also say that this measure
9 just --- this was the original panel that did the
10 face validity assessment, but we just went
11 through this whole process with our panel again
12 because this went through reevaluation, and they
13 continue to support the face validity of it.

14 So, I agree with your assessment, and
15 they echoed the same concerns that there is a
16 problem with documentation of medication
17 reconciliation; however, I don't necessarily
18 think that is unique to this measure.

19 I think that is a problem with all
20 quality measures that are based off of chart
21 review when you are getting at something that is
22 not routinely documented, similar to what we had

1 around falls.

2 You may be asking about falls, but not
3 documenting asked about falls, no falls
4 documented.

5 I think it is something that is a
6 challenge with all quality measures; they are
7 really no measures of what's documented.

8 And we want documentation to improve,
9 because that in and of itself is an important
10 component of patient safety.

11 CO-CHAIR THRAEN: Steve.

12 DR. LAWLESS: Real quick. In your
13 validation studies, did everybody agree to what
14 medication reconciliation actually was?

15 DR. GIOVANNETTI: They agreed to what
16 we could measure, which is what is documented
17 here.

18 CO-CHAIR THRAEN: Should we vote?

19 MS. ARDIZZONE: I'm sorry. There was
20 one comment on here that we got pre-reading this
21 from the --- what is it? I'm so sorry --- oh,
22 from the Nursing Home and Assisted Living

1 Consortium, saying that they should be removed
2 from the denominator because it -- I guess it
3 wasn't generalizable to their kind of group.

4 Could you comment on that, or have you
5 seen that comment?

6 DR. GIOVANNETTI: So, this is the same
7 comment that was made on the falls measure; it's
8 the same organization.

9 When providers are providing care in
10 the -- a non-acute inpatient setting like a
11 custodial nursing home, they may be eligible to
12 report this measure if it is selected for them to
13 be reported on.

14 And I think that they recognize that
15 it is a challenge, it's a burden, but I don't
16 think they provided very good clinical evidence
17 that because someone is discharged to a nursing
18 home they are not --- they shouldn't have
19 medication reconciliation done.

20 CO-CHAIR THRAEN: All right. Let's
21 vote for validity.

22 MS. IBRAGIMOVA: Scientific

1 acceptability of measure properties, 2(b),
2 validity. The votes are one, high; two,
3 moderate; three, low; four, insufficient.

4 (Voting.)

5 MS. IBRAGIMOVA: The results are: 0
6 percent high; 59 percent moderate; 41 percent
7 low; 0 percent insufficient.

8 CO-CHAIR THRAEN: All right. We're in
9 the gray. Moving forward. Feasibility.

10 DR. COOK: There are no concerns
11 within feasibility. This is not an eMeasure, but
12 the data is captured from electronic clinical
13 data that is being used to report for CMS
14 meaningful use program.

15 Let's see. At the health plan and
16 physician level, it's obtained through the
17 administrative claims, electronic clinical claims
18 for patient --- or paper medical records. So, no
19 concerns overall.

20 CO-CHAIR THRAEN: All right. Any
21 questions?

22 (No questions.)

1 CO-CHAIR THRAEN: Shall we vote?

2 MS. IBRAGIMOVA: Feasibility. The
3 votes are one, high; two, moderate; three, low;
4 four, insufficient.

5 (Voting.)

6 MS. IBRAGIMOVA: And the results are:
7 32 percent high; 59 percent moderate; 9 percent
8 low; 0 percent insufficient.

9 CO-CHAIR THRAEN: All right.
10 Usability. Chris, do you have any comments?

11 DR. COOK: Just what's already been
12 stated in the fact of its NCMS Medical Part C
13 special needs plans. And apparently we've just
14 been told it's been extended to all of Part C
15 Medicare advantage plans.

16 Also, it's within the NCQA ACO
17 accreditation program, and that may also be
18 expanded to be used in the State of the
19 Healthcare report, as well as the Quality Compass
20 reports for public reporting.

21 CO-CHAIR THRAEN: Yanling.

22 DR. YU: Yeah, I just have one

1 comment, a question. The measure was first
2 endorsed in 2007 and is then recent endorsement
3 is 2012.

4 And since 2007 and, you know, with the
5 time progress, have you seen any efforts being
6 taken or any progress in transparency
7 accountability once you started to see
8 endorsement?

9 DR. GIOVANNETTI: So, in the special
10 needs plans, we've definitely been seeing an
11 improvement in performance, particularly when the
12 payment has been attached to this as part of the
13 CMS Stars program. That has definitely led to an
14 improvement in performance on this measure, which
15 I think we demonstrated.

16 I think it's been about a 10 percent
17 -- just over the last year, it was a 10 percent
18 improvement in performance.

19 In the PQRS program, I think we've
20 talked at length about the challenges there where
21 we don't see the variation to see the
22 improvement, but we hope to see it as the program

1 itself improves.

2 DR. YU: Thank you.

3 CO-CHAIR THRAEN: All right. Shall we
4 vote?

5 MS. IBRAGIMOVA: Usability and use,
6 the votes are: one, high; two, moderate; three,
7 low; four, insufficient information.

8 (Voting.)

9 CO-CHAIR THRAEN: We're missing two.
10 Try again.

11 MR. ANDERSON: Kimberly, we need your
12 vote.

13 DR. APPLGATE: Hi. I'd like to vote
14 high.

15 (Pause.)

16 MS. IBRAGIMOVA: The results are: 33
17 percent high; 48 percent moderate; 19 percent
18 low; 0 percent insufficient information.

19 CO-CHAIR THRAEN: And the last one is
20 suitability for endorsement. Yes or no.

21 MS. IBRAGIMOVA: Overall suitability
22 for endorsement. Does the measure meet NQF

1 criteria for endorsement? One, yes; two, no.

2 (Voting.)

3 MS. IBRAGIMOVA: The results are: 60
4 percent yes; 40 percent no.

5 CO-CHAIR SEPTIMUS: Okay. Well, that
6 one was a close one, wasn't it?

7 (Comments off record.)

8 CO-CHAIR SEPTIMUS: Okay. Skipping
9 around based on people's needs and flights, we're
10 going to go to 0537.

11 MS. KEANE: Hi. This is Nicole Keane
12 with Abt Associates. We are the measure
13 developer; CMS is the measure steward. And I
14 have on the phone as well my colleague from
15 Colorado, Dr. Gene Nuccio, and also Dr. Angela
16 Richards.

17 Dr. Richards will start us off with an
18 introduction.

19 DR. RICHARDS: Thank you.

20 CO-CHAIR SEPTIMUS: If you can make
21 your introduction very brief, we'd appreciate it.

22 DR. RICHARDS: Yes, I can make it very

1 brief. Thank you.

2 Older people receiving home healthcare
3 have relatively higher rates of falls. And those
4 are, in turn, associated with injuries,
5 healthcare resource use -- including ED use and
6 hospitalization --- and increased mortality
7 rates.

8 We talked in review of a previous
9 measure about the American Geriatrics Society and
10 the British Geriatrics Society clinical practice
11 guidelines which make -- recommend use of a
12 multifactorial fall risk assessment.

13 We also have evidence based on a
14 Cochrane Review that found that risk assessments
15 associated with reduced rate of falls from health
16 providers are in a unique position to assess the
17 environmental and other circumstances within the
18 patient homes that may increase falls risk, and
19 then to provide interventions and
20 recommendations to mitigate those risk factors.

21 This process measure encourages use of
22 a systematic multifactorial assessment for falls

1 risk and provides home health agencies and
2 consumers with information that will enable them
3 to monitor the extent to which fall risk
4 assessment is conducted for ambulatory patients.

5 It is not limited to older adults;
6 however, we should short of note that 82 percent
7 of home health agency users are over 65. So, it
8 does really hit on that population pretty well.

9 The measure is calculated based on
10 data from the mandated OASIS-C data set that the
11 home health agencies collect as part of their
12 comprehensive patient assessments.

13 And then the definition of the measure
14 is the percentage of home health episodes in
15 which patients who can ambulate had a
16 multifactorial fall risk assessment at start or
17 resumption of care.

18 So, I think I'll just kind of conclude
19 that there since we've already heard a lot of the
20 evidence as it supports other falls risk
21 measures.

22 CO-CHAIR SEPTIMUS: Thank you. So,

1 who's going to do this one?

2 CO-CHAIR THRAEN: Pat Quigley gets to
3 do this.

4 CO-CHAIR SEPTIMUS: Pat does it? All
5 right. So, let's go through the evidence, Pat.

6 DR. QUIGLEY: Sure. Thank you. And
7 I'd also like to thank the developers so much for
8 that brief overview.

9 And what I would like to say, in
10 relationship to the evidence, is that this is a
11 home healthcare indicator.

12 And the evidence that is presented is
13 essentially for those who are community-dwelling
14 adults not in home care.

15 So, putting that aside, I will say,
16 though, that I did go ahead and add to the
17 literature review to support this. Because --
18 because this is a home health indicator, that
19 there is evidence to address falls beyond those
20 who are ambulatory especially, you know, in
21 looking at those who are not ambulatory, but
22 there's different risk assessment that has

1 advanced since 2012 when this was endorsed that
2 looks at intrinsic and extrinsic risk factors
3 inside the home and outside the home.

4 So, even though the evidence that's
5 here is good in relationship to why it's
6 important to identify fall risk in older adults,
7 I think, you know, the evidence in home care is
8 really emerging.

9 So, that being said, lack of evidence
10 is not evidence that something is lacking. So,
11 it's still an important indicator because there's
12 a lot of opportunity there, but this is a very
13 important measure for home care.

14 And I hope my CMS colleagues, if you
15 want to comment on my comments, that's okay.

16 CO-CHAIR SEPTIMUS: This is an
17 endorsed measure, correct?

18 DR. QUIGLEY: Yes.

19 MS. KEANE: Yes, it is.

20 CO-CHAIR SEPTIMUS: So, are you trying
21 to tell me we have an endorsed measure on no
22 evidence?

1 DR. QUIGLEY: No, it is, but it's
2 based on AGS guidelines, which is for ambulatory
3 care people in the community, but this is a home
4 care measure.

5 CO-CHAIR SEPTIMUS: Right.

6 DR. QUIGLEY: Right --- which is an
7 extension into the home setting.

8 CO-CHAIR SEPTIMUS: Any comments on
9 the evidence?

10 (No comments.)

11 CO-CHAIR SEPTIMUS: Okay. Well, I
12 guess -- well, we got to wait for Laura to come
13 back. Take your time, Laura.

14 MS. IBRAGIMOVA: So, importance to
15 measure and report, 1(a), evidence structure
16 process and intermediate outcomes. The votes are
17 one, high, only eligible QQC submitted; two,
18 moderate; three, low; four, insufficient
19 evidence.

20 (Voting.)

21 MS. IBRAGIMOVA: The results are: 10
22 percent high; 70 percent moderate; 10 percent

1 low; 10 percent insufficient evidence.

2 CO-CHAIR SEPTIMUS: Okay. We will
3 move on. Gaps in care.

4 DR. QUIGLEY: Yes. In terms of the
5 opportunity for improvement, the data that was
6 submitted on this did not indicate much
7 opportunity for improvement.

8 The data for the year ending in June
9 of 2014 for the agencies indicated they had 20
10 valid episodes in which there was 98.4 percent
11 performance, but recognizing that this measure is
12 that for those who can ambulate in home care that
13 they have a multifactorial assessment done. So,
14 it's really yes or no.

15 DR. NUCCIO: This is Gene Nuccio from
16 the University of Colorado. Just to clarify, we
17 have close to six million episodes of care
18 annually from 2011 through 2013 calendar years.
19 So, we have more than 20 episodes on which these
20 data are based.

21 And the --- for the --- it's a three-
22 part --- it's --- we have --- while the measure

1 specifically looks at the assessment piece, we
2 also have data elements that look at whether or
3 not that information was used in the plan of
4 care, and whether or not it was used --- if it
5 was implemented -- that is, that actions were
6 taken.

7 And those data show that all across
8 those three years approximately between 96 and 98
9 percent of agencies are doing the assessment, the
10 plan and the doing of this.

11 DR. QUIGLEY: Thank you.

12 MS. ARDIZZONE: So, 98 percent of the
13 people are already doing this?

14 DR. NUCCIO: --- of agencies are, in
15 fact, assessing the fall risk.

16 CO-CHAIR SEPTIMUS: Yes, go ahead.

17 DR. NUCCIO: Just to give you some
18 context, we have two historical --- one
19 historical piece of data for the patients.
20 Approximately between 28 and 30 percent of
21 patients come to home health with a history of
22 falls, defined as two or more falls, or a serious

1 fall in the last 12-month period.

2 After the fall risk assessment,
3 approximately 88 percent of patients in home
4 health are judged to be at risk for falls.

5 So, the assessment process is
6 identifying patients who indeed are at risk using
7 that multifactorial falls risk assessment. And
8 agencies are taking action, again, at a rate of
9 about 98 percent to put it in the plan of care
10 and to do something about it.

11 As a result of this, the actual
12 percentage of patients who go to the hospital for
13 emergency care due to a fall, a serious ---
14 obviously a serious fall -- is only about 7
15 percent of those patients who go to emergency
16 departments for any reason.

17 So, the entire assess, plan and do
18 process that we have in place seems to be very
19 effective in reducing that potential risk
20 population that is 88 percent, down to about 7
21 percent who actually experience a fall that
22 requires an emergency department help.

1 CO-CHAIR SEPTIMUS: Lisa.

2 MS. MCGIFFERT: So, is this a measure
3 that's been topped out and --- it sure sounds
4 like it. And what do we do with that?

5 CO-CHAIR SEPTIMUS: Well, I think the
6 first thing we ought to do is vote on the gap.
7 And then if people think it's topped out, then
8 we'll discuss next steps. Does that make sense?

9 So, I don't see any other hands up, so
10 let us now vote on the gap.

11 MS. IBRAGIMOVA: Importance to measure
12 and report, 1(b), performance gap. The votes are
13 one, high; two, moderate; three, low; four,
14 insufficient.

15 (Voting.)

16 MS. IBRAGIMOVA: And the results are:
17 5 percent high; 25 percent moderate; 60 percent
18 low; 10 percent insufficient.

19 CO-CHAIR SEPTIMUS: It didn't pass.
20 Okay.

21 DR. PINES: Right. So, at this point
22 we would decide whether or not to put it on

1 reserve status or, I guess, do we go through all
2 the other measures?

3 Okay. So, we go through all the other
4 ones first, and then we can decide at the end.

5 (Pause.)

6 CO-CHAIR SEPTIMUS: If it didn't meet
7 1(a) and 1(b), then that was an automatic stop.
8 So, okay. Let's keep going then.

9 DR. QUIGLEY: For reliability, because
10 this is electronic clinical data is the source of
11 this data. So, for reliability, as mentioned by
12 the additional comments, it was electronic
13 clinical data that was used for this testing,
14 from July 3rd, 2013 to June of 2014, at the
15 facility agency level. And this is where there
16 was the 9,443 agencies that tested 3.8 million
17 patients.

18 And they had the critical elements,
19 and they did the reliability testing interclass
20 correlation of 0.91. So, there's good
21 reliability.

22 CO-CHAIR SEPTIMUS: Comment. Lisa,

1 it's your --- okay.

2 (No comments.)

3 CO-CHAIR SEPTIMUS: Seeing none, let's
4 vote on reliability.

5 MS. IBRAGIMOVA: Scientific
6 acceptability of measure properties, 2(a),
7 reliability. The votes are one, high; two,
8 moderate; three, low; four, insufficient.

9 (Voting.)

10 MS. IBRAGIMOVA: The results are: 41
11 percent high; 50 percent moderate; 9 percent low;
12 0 percent insufficient.

13 CO-CHAIR SEPTIMUS: Okay. Now, we go
14 to validity.

15 DR. QUIGLEY: Thank you. There's no
16 issues with validity. It's a yes or no indicator
17 of whether or not assessment was done. So,
18 there's no issues with validity.

19 CO-CHAIR SEPTIMUS: Comments.

20 (No comments.)

21 CO-CHAIR SEPTIMUS: Seeing none, we
22 will vote.

1 MS. IBRAGIMOVA: Scientific
2 acceptability of measure properties, 2(b),
3 validity. The votes are one, high; two,
4 moderate; three, low; four, insufficient.

5 (Voting.)

6 MS. IBRAGIMOVA: The results are: 27
7 percent high; 64 percent moderate; 9 percent low;
8 0 percent insufficient.

9 CO-CHAIR SEPTIMUS: Feasibility.

10 DR. QUIGLEY: The data is easily
11 collected. It's collected in the clinical
12 electronic data elements, as I had mentioned.
13 And it's collected through the clinical registry,
14 the nursing home MDS, the home health OASIS
15 program. So, it's feasible to get this, and it's
16 not an eMeasure.

17 CO-CHAIR SEPTIMUS: Comments?

18 MS. ARDIZZONE: Sorry. I had a
19 question for the developer. I had brought this
20 up at another measure. So, again, there are some
21 competing measures. There's 0035, 0101. I know
22 each of the developer's responses has been,

1 "Well, I'm looking at a very specific or a very
2 different aspect, or literally a different
3 piece."

4 A patient goes through all pieces as
5 they're going through their healthcare. How do
6 we -- again, I'm concerned about the burden on
7 people reporting, and we're measuring all
8 different aspects of one fall, or one person.
9 So, is there any talk, especially as we need to
10 make sure that measures follow a patient through
11 all transitions of care?

12 DR. RICHARD: Yes, it's a very good
13 point. We have been using this particular one
14 now since 2009, and it has been in the chart to
15 remind home care staff particularly to do their
16 risk factor assessment, and just focus on that.

17 This is not -- this is a process
18 measure. This isn't an impact measure. There is
19 help and work on developing a measure that
20 crosses care settings for an outcome measure.
21 And so, that may be where some of the
22 harmonization comes in.

1 So, it is a very good point. At this
2 point, this is a measure that the home care
3 agency population is very comfortable with, very
4 familiar with, and is -- you know, whatever
5 question you're answering from a provider
6 perspective, the burden doesn't really fall on
7 the patient so much as it does the provider, and
8 this is the item that the providers have been
9 collecting for many years now.

10 DR. NUCCIO: Also, the fact that this
11 is the community, if you will, measure. That is
12 that the assessment is done in the patient's
13 home, which is far different than the other
14 settings that the patient comes from, like a
15 hospital or nursing home. And so, there are many
16 other factors that need to be assessed in a
17 unique way for -- by our nurses when they do in
18 and do this assessment as part of the
19 comprehensive assessment in home care.

20 The data has mentioned part of the
21 OASIS instrument, and have been on the instrument
22 since 2010. So, we're very comfortable with

1 assessing it, but looking forward to
2 harmonization across post-acute care settings
3 with the impact measures.

4 CO-CHAIR SEPTIMUS: Iona?

5 CO-CHAIR THRAEN: So, we have to
6 enforce that. So, these have a three-year cycle.
7 I would anticipate in three years that the impact
8 work should be close to being done, and that all
9 of these various measures that are either all
10 related to falls or all related to nutrition, or
11 all related to whatever came across the sectors,
12 the impact measures should be compared, and we
13 should see some retirement going on as we go to a
14 common measure that might have multiple
15 attributes.

16 So, part of that problem is because of
17 the information systems that are different across
18 each sectors. Also, the information systems are
19 going to have to change in order to be able to
20 yield that new type of measure. So, I think in
21 three years, we will be at that place. At least
22 starting.

1 CO-CHAIR SEPTIMUS: Okay, I don't see
2 any other hands. So, we'll vote on feasibility.

3 MS. IBRAGIMOVA: Feasibility: The
4 votes are one high, two moderate, three low, four
5 insufficient. The results are 48 percent high,
6 52 percent moderate; 0 percent low, 0 percent
7 insufficient.

8 CO-CHAIR SEPTIMUS: Okay, now,
9 usability?

10 DR. QUIGLEY: Thank you. I think that
11 everybody has discussed -- described adequately
12 that this is being done.

13 So, how it is being used to now move
14 into quality of practice I think is the next
15 step, and that was also my comments in getting to
16 present this is that there is emerging evidence
17 in the home health arena that the falls that
18 happen inside the home are different than outside
19 the home, and maybe they'll use this as an
20 opportunity to do something different and build
21 upon a yes/no measure, and also look at the
22 emerging fall risk assessment tools for the home

1 population.

2 The Missouri Alliance of Home Care has
3 done extensive work in this area. So, I think
4 there's an opportunity to really build upon this
5 clinical setting where patients are vulnerable,
6 and not just those who can ambulate.

7 CO-CHAIR SEPTIMUS: Thank you, Pat.

8 DR. YU: Thank you. I have a
9 question. Currently the measure is used for
10 healthcare public reporting. What if this
11 measure was not approved; would the data continue
12 to be collected? Would there continue to be
13 public reporting?

14 DR. QUIGLEY: Well, it's in OASIS.
15 So, it is something that's being done anyway. I
16 don't know about public reporting, but it's an
17 OASIS element, because OASIS has been requiring
18 this, as mentioned, since 2010. This measure was
19 originally adopted in 2009 before the OASIS.

20 DR. YU: So, my question is it has
21 been -- I've been thinking about the re-
22 endorsement. What is new? When you look at the

1 time change and what has been changed, do you
2 compare the improvement now days and compare it
3 with data from back in 2008 when you first
4 endorsed?

5 So, I just -- I guess my question is
6 what is new in this endorsement that when you
7 continue public reporting? Will the public say
8 there's something different or improved since
9 2007?

10 DR. QUIGLEY: I'm not the developer,
11 but I'm say what's new is that they are doing it.
12 People are being assessed for falls; those who
13 are ambulatory. Back in 2007, it wasn't. Now
14 they are being assessed, and maybe the developers
15 would want to comment as well.

16 DR. NUCCIO: Yes, yes. We are.
17 There's always been a very strong level of
18 assessment, but that has actually improved
19 slightly across the three years of data. Three
20 complete calendar years of data that we have.

21 Also, I would like to point out that
22 -- you raised the question about whether or not

1 the outcome measure would be -- well, in this
2 case it's a process measure. Would be posted on
3 Home Health Compare.

4 CMS has the option, as I understand
5 it, to post measures on Home Health Compare that
6 are not NQF endorsed, and one of those was the
7 dyspnea measure that was not endorsed by NQF, but
8 continues to be reported on Home Health Compare
9 because we believe in the value of that
10 particular outcome measure.

11 But I'm a contractor. I can't speak
12 directly for CMS.

13 CO-CHAIR SEPTIMUS: Go ahead.

14 DR. RICHARD: This is Angela Richard,
15 one of the measure developers. I'd like to point
16 out that one of the big differences in this
17 measure is that it requires a multi factorial,
18 and standardized validated assessment instrument.

19 So, I think since 2007, not only are
20 they doing it, but they're doing it in a more
21 systematic way and using evidence-based tools
22 actually and recommendations.

1 So, it really has -- we've seen not
2 only an improvement in what people are doing, but
3 in how they're doing it we believe.

4 DR. NUCCIO: Including the Missouri
5 Tool that you referenced.

6 DR. RICHARD: Right.

7 DR. NUCCIO: We know that there was a
8 major push by another private commercial
9 contractor to create or find a multi factorial
10 instrument that was validated and standardized,
11 and they settled on and have highly touted the
12 Missouri document.

13 We know that many agencies make use of
14 that. CMS does not require a specific tool.
15 Only that it is standardized and elevated.

16 DR. QUIGLEY: Thank you. I did add
17 that. This is Pat Quigley's voice. I did add
18 that to the comments in the review.

19 CO-CHAIR SEPTIMUS: I think this
20 committee knows that I think people prefer NQF
21 endorsement, but it is not a requirement. So, I
22 think it's going to be up to the decision of CMS

1 if we reserve this because it may have topped out
2 whether or not they want to continue to have
3 reporting. So, let's go to usability.

4 MS. IBRAGIMOVA: Usability: The votes
5 are one high, two moderate, three low, four
6 insufficient information. So, the results are 14
7 percent high; 67 percent moderate, 19 percent
8 low, zero percent insufficient information.

9 CO-CHAIR SEPTIMUS: Okay, now we'll go
10 to the last one, which is should we overall
11 suitability for endorsement?

12 MS. IBRAGIMOVA: Overall suitability
13 for endorsement: Does the measure meet NQF
14 criteria for endorsement? One yes, two no.

15 CO-CHAIR SEPTIMUS: Just vote yes or
16 no, and then go to the next step. We have to go
17 through the whole process. If you decide to
18 endorse it, we'll go back and say whether we want
19 to put it on reserve status, okay? Just to let
20 you know, okay?

21 DR. RISING: My understanding is that
22 it can't be endorsed because it didn't qualify

1 for that -- it didn't meet --

2 CO-CHAIR SEPTIMUS: That's -- that --

3 DR. RISING: We still have to go
4 through the other steps though because it's still
5 eligible.

6 CO-CHAIR SEPTIMUS: That's how you
7 should go to the rest. It didn't pass the gap.
8 Why don't you introduce yourself since you've
9 joined.

10 MS. MUNTHALI: Hi. My name is Elisa
11 Munthali. I'm Vice President for Quality
12 Measurement at NQF. I'm stepping in for Helen.

13 We do need to apologize about the
14 process you went through for reserve status
15 yesterday. It was a misstep. What you should
16 do, the friction you're sensing and the vote
17 reflected that there wasn't an opportunity for
18 improvement there.

19 It sounds like from how the votes are
20 falling that you still think it is a good
21 measure. So, what we're going to do is vote on
22 the overall suitability, which you have just

1 done, and it has passed. Now, we're going to go
2 to a yes or no on reserve status.

3 CO-CHAIR SEPTIMUS: That's just what
4 I said. Of course, it's not what I thought
5 yesterday.

6 MS. IBRAGIMOVA: So, the results are
7 67 percent yes; 33 percent no.

8 CO-CHAIR SEPTIMUS: Passes the
9 consensus. So, now we have to go to whether or
10 not we want to retire this to reserve status. Do
11 you have -- oh, you've got it. Look at this.
12 Not yet. Wait a minute. Okay, so now we get to
13 say do you want to endorse the maintenance
14 potential to reserve status.

15 The votes are one yes; two no. The
16 results are 95 percent yes; 5 percent no.

17 CO-CHAIR SEPTIMUS: All right, it's on
18 reserve.

19 CO-CHAIR THRAEN: So, because of
20 scheduling issues, we're not going to go back and
21 re-visit the old one yet. We might end up doing
22 that on the phone after the fact.

1 We're going to go to 419 because we
2 have the developers on the phone, who have to
3 leave at what time? Developers have to leave at
4 1:30, and it is now 1:30. So, are they leaving?

5 Okay, so which one is it? It is 419.
6 They have to leave at 2:00. 419, please step up.
7 This is Quality Insights of Pennsylvania. Good
8 afternoon. Please introduce yourselves.

9 DR. BERG: Is the microphone working?
10 Well, I was prepared to say good morning, but
11 good afternoon to the group here. I'm Sven Berg.
12 I'm the Chief Medical Officer at the West
13 Virginia Medical Institute, which is the parent
14 organization for Quality Insights.

15 I am joined by Alyssa Crawford from
16 Mathematica, with whom we work now. On behalf of
17 CMS, and as the measures developer for this
18 measure, Quality Insights of Pennsylvania is
19 pleased to introduce NQF 0419: Documentation of
20 Current Medications in the Medical Record for
21 Consideration of NQF re-endorsement.

22 This measure was developed to promote

1 medication safety by requiring physicians to
2 review patients' most current medications list at
3 every encounter.

4 This allows for more effective
5 monitoring for medication errors, and is a
6 critical activity to prevent adverse events.

7 The measure received initial
8 endorsement from NQF in 2008. It was implemented
9 into the Physician Quality Reporting System,
10 beginning in 2010, and into the Meaningful Use
11 Program, beginning in 2013.

12 In 2013, over 100,000 eligible
13 providers who participated in the PQRS program
14 reported to this outpatient measure using either
15 claims or registry data.

16 The intent of this process measure is
17 for all eligible medical professionals to
18 document a list of current medications, using all
19 immediate resources available at every encounter
20 or patient visit.

21 This list must include all known
22 prescriptions, over-the-counters, herbals and

1 vitamin/mineral dietary nutritional supplements,
2 and must contain the medication's dosage,
3 frequency and route of administration.

4 This measure focuses on the adult
5 population, those 18 years and older, and the
6 denominator includes all visits occurring during
7 the 12 months reporting period.

8 Patients in an urgent or emergent
9 medical situation, in which time is of the
10 essence and the delay in treatment would
11 jeopardize their health are excluded or exempt
12 from this measure.

13 Evidence suggests that frequently
14 identifying document DNA, maintaining a list of
15 patients' medications requires -- reflects high
16 quality care. The process this measure assesses
17 is foundational to multi component approaches to
18 decrease ADE's, which in turn reduces unnecessary
19 medical treatment, and minimizes the financial
20 burden on patients and payers.

21 Eligible professionals see this as an
22 important measure and many have opted to report

1 it in the PQRS and Meaningful Use programs.

2 Furthermore, recent testing has shown that the
3 measure is feasible, valid and reliable.

4 Unfortunately, our colleagues at CMS
5 may not have been able to join us for this
6 discussion of this measure due to the change in
7 time, which was considered. However, based on
8 our recent conversations with them, I believe
9 they would want us to reiterate that this measure
10 has an important part of a comprehensive approach
11 to quality improvement and a key component of the
12 GPRO, PQRS, and Meaningful Use BP programs.

13 Thank you for this opportunity to
14 discuss the measure today.

15 CO-CHAIR THRAEN: Kendall?

16 DR. WEBB: So, I had one general
17 question. I didn't find -- in this, you talk
18 about eligible professional as part of this. Who
19 do you consider an eligible professional?

20 DR. BERG: Sure. The EP's are those
21 defined by CMS under the Physician Quality
22 Reporting Program. I can give you an entire

1 list, if you like. I can read it, but it's a
2 quite extensive list and it is defined by CMS.

3 MS. CRAWFORD: I would just add that
4 the list includes physicians, as well as a number
5 of other types of practitioners, including PA's,
6 nurse practitioners, social workers, dietitians,
7 audiologists, and also therapists including
8 physical, occupational and speech therapists.

9 DR. WEBB: How about medical
10 assistants?

11 DR. GREEN: This is Dan Green from
12 CMS. Medical assistants would not be included in
13 this.

14 DR. WEBB: So, licensed practitioners,
15 anybody who carries a license it sounds like?

16 DR. BERG: That would be correct.

17 DR. WEBB: I just wanted to make sure
18 we knew what we were talking about and who this
19 applies to. So, 419 --

20 CO-CHAIR THRAEN: Steve?

21 DR. LAWLESS: Certified medical
22 assistants cannot do this, correct?

1 DR. GREEN: We're looking for people
2 who are submitting billing claims, if you will,
3 to CMS.

4 CO-CHAIR THRAEN: Go ahead, Kendall.

5 DR. WEBB: I had one more quick
6 question. Is this an e-measure?

7 DR. BERG: Yes.

8 DR. WEBB: All right, so evidence.
9 They provided a great introduction. I don't
10 think we need any more introduction. So, for
11 evidence, this is a process measure. There was a
12 systematic review, and NQZ presented.

13 There is good evidence that adverse
14 drug events are a problem, especially in the
15 outpatient setting. Of note, this is an
16 attestation process, where the practitioner
17 attests that they have reviewed or provided this
18 documentation.

19 It does not tie back, actually. They
20 have seen an improvement in performance just from
21 an evidence perspective, but it has not tied back
22 to a decrease in adverse drug events, as they

1 have seen an increase in attestations. I just
2 want to make that note as we go through the
3 evidence.

4 I think otherwise, the evidence is
5 excellent. It does tie med rec to ADE's, but I -
6 - what they're trying to do is decrease the
7 ADE's, and they don't have that tie back in
8 there. So, as we're voting, I want that to be
9 noted.

10 CO-CHAIR THRAEN: Steve, did you still
11 have a question? Questions? Josh?

12 DR. RISING: Hi there. This is Josh
13 Rising. Certainly, there is a lot of evidence
14 about the frequency of adverse drug events that
15 is documented.

16 I guess what I didn't see, and I was
17 hoping you could talk me through a little bit,
18 was a sense of whether this frequency of med rec
19 will help address the ADE challenge. Because
20 that was something that I didn't see in the
21 evidence, and presumably is an essential part of
22 why to have the measure.

1 DR. BERG: Let me begin by making a
2 slight modification to your statement, but this
3 is not a medication reconciliation measure. This
4 is a documentation of medications.

5 So, it is -- this is not a med rec
6 measure in and of itself. One of the things that
7 is difficult about any analysis of this type of
8 measure is that this is a quality best practice,
9 and to design a study that would compare two
10 groups: one doing this and one not doing this, we
11 really feel would be an unethical proposition.

12 So, obtaining the type of evidence
13 that you're looking for is difficult for us to
14 do, and could be unethical.

15 However, at the same time, we believe
16 that a -- that it is logical to draw a conclusion
17 that it is necessary to have the complete list of
18 medications if you're really going to assess
19 whether there could be adverse drug reactions,
20 and then to be able to avoid those reactions.

21 MS. CRAWFORD: A number of the studies
22 cited in our evidence back up the statement that

1 a lot of current documentation of medications is
2 inaccurate. I think that's pretty clearly noted.

3 Sorry about that. I was saying in
4 connection with the point that Dr. Berg just
5 made, there's some pretty clear evidence that
6 current medication lists are inaccurate, and that
7 there's often incomplete or inaccurate
8 information, not only about which medications a
9 patient is taking, but the dose of the medication
10 and administration, and other very important
11 details.

12 I think Dr. Berg said it well in terms
13 of the inability to devise a randomized
14 controlled trial that would actually determine
15 the effectiveness of this particular practice. I
16 wanted to add that in addition, it is difficult,
17 if not impossible, to design an analysis that
18 could control for all of the other variables that
19 might be inherent in the process, even if you
20 wanted to look at whether there was a correlation
21 with decreased and adverse events, it is very
22 difficult to be able to control for all of the

1 other factors that influence that kind of an
2 outcome.

3 So, it's the reason why our evidence
4 and testing approach did not consider looking at
5 that kind of a predictability assessment because
6 of the fact that it would be very difficult to
7 devise one that would accomplish that
8 effectively.

9 MS. MCGIFFERT: So, just to follow up
10 on that, is there evidence presented that doing
11 this action leads to accurate lists as opposed to
12 inaccurate lists that we have lots of evidence
13 there is inaccurate listing?

14 DR. BERG: I'm not aware that we have
15 anything to that effect.

16 MS. CRAWFORD: I would add that I
17 think part of the reason why we don't have
18 anything to that effect is because nobody is
19 looking for that evidence because it is a sort of
20 understood part of the process.

21 I was saying I think part of the
22 reason why we weren't able to find evidence that

1 clearly made that statement is because of the
2 unethical issue that Dr. Berg pointed out, which
3 is that if this is such an established part of
4 care that should be occurring in all visits, but
5 which our test results show is not, that it would
6 be very difficult to devise.

7 Nobody is going to do a study to show
8 that connection because you would have to stop
9 doing it for a certain number of patients.

10 MS. MCGIFFERT: You could have a third
11 party verify the accuracy of the list versus
12 inaccuracy of the list. There wouldn't be
13 anything unethical about that.

14 MS. CRAWFORD: True. There are a
15 number of studies that have looked at adverse
16 medication reconciliation. Again, this is a
17 medication documentation measure, but after
18 medication reconciliation, there are studies that
19 show that doing that process improves care, and
20 that looking at the medication and discussing
21 medication lists with patients does identify a
22 number of discrepancies.

1 CO-CHAIR THRAEN: Lisa?

2 MS. DANFORTH: I just want to make one
3 more comment, and I don't know if the other
4 committee members who were here last year would
5 agree with me, but I remember some radiology
6 measures where the measure was basically, "Do you
7 document this thing, or do this thing?"

8 What we agreed was that exposure to
9 radiology is extremely important. It is
10 something that should be measured and we need to
11 measure. But this particular one was really too
12 distant from the outcome.

13 This measure kind of reminds me of
14 that, where medication errors are extremely
15 prevalent, and we need good measures of
16 medication errors. We don't have a good outcome
17 measure. So, we're seeing these processes'
18 structural measures.

19 But to me, the distance from the
20 outcome is too far. In the case of those
21 radiology measures, we said, "We're going to say
22 no today, and we hope that encourages you to come

1 back with something better."

2 I'm just thinking that in my opinion
3 that is what I'd like to see the committee do
4 today. I think if we endorse this as a measure
5 but we don't push this any further, three years
6 from now this is going to be up for reendorsement
7 and we're not going to be any further along.

8 We know medication errors are frequent
9 and dangerous, and is this really the best way to
10 improve on it? I just wanted to mention that.
11 To be consistent also with the way we've treated
12 some of our measures, I think.

13 DR. GREEN: This is Dan Green from
14 CMS. Completely respect what you just said, but
15 I would suggest that in the absence of a perfect
16 or better measure, not to necessarily discount
17 this measure.

18 I mean as a physician, it kind of
19 shocked me as we were developing this measure
20 that we even needed a measure to tell providers
21 that they should be assessing what medication,
22 herbals and botanicals that their patients are on

1 when they're caring for them.

2 As an OB/GYN, you'd be surprised how
3 many folks, for example, are taking botanicals
4 that could interfere with their clotting, but
5 their docs have absolutely no idea about, or even
6 the primary care doctor thinks, "Oh, you are on
7 the same June 26, 2015 medications."

8 But in the mean time they see someone
9 different, and they put them on something
10 different. We talked about different types of
11 practitioners. I mean even taking it, for
12 example, to a dietitian who is trying to help
13 somebody, perhaps, with weight loss.

14 It would be helpful for them to know
15 if the patient is on an SSRI medication. They
16 may be fighting a little bit of an uphill battle.
17 So, again, it surprises me that we need the
18 measure, but we do need the measure. And until
19 something better is created, I would suggest this
20 is important.

21 CO-CHAIR THRAEN: This is Iona. So,
22 I guess the argument we just made talks about

1 individual practitioners, who are using
2 supposedly CPOE kinds of tools and digital
3 prescribing, and a variety of data sets that are
4 out there.

5 On behalf of that, their individual
6 expertise, they are documenting that in their
7 individual EHR's. So, the argument that you made
8 is that that should be available to the next
9 provider, which is an interoperability question,
10 and a transfer of information question, and not a
11 documentation question, in my mind, of the
12 provider that is doing the service at that point
13 in time.

14 So, does this really get at that
15 argument that you just made about the dietitian
16 being able to see that you're on an SSRI, when
17 it's really an interoperability question as
18 opposed to a documentation question?

19 DR. GREEN: Again, you make an
20 excellent point, and certainly at CMS and HHS in
21 general as I'm sure you do, we all strongly
22 support the use of electronic health records.

1 And equally or more important, the
2 interoperability of the records.

3 Unfortunately, as you painfully know
4 probably, we're not there with interoperability.
5 I mean, things are improving. Pharmacies are
6 starting to be able to communicate to electronic
7 health records. Not just the pharmacy where the
8 patient fills medication A, but if they go to a
9 different pharmacy to fill another medication.

10 With the payers and what have you
11 becoming, we'll eventually get to the point where
12 that information will be fed back to the
13 rendering docs system. But unfortunately,
14 between that and the interoperability, we are
15 just not there yet.

16 DR. BERG: I think to tag onto that,
17 I would argue that the reason we're asking all
18 eligible providers to do this is for that very
19 reason: that the interoperability isn't there.

20 So, we're asking all of them to ask
21 these questions, and to document that, and that
22 makes that connection where interoperability

1 isn't there.

2 DR. GREEN: One last quick thing. As
3 I'm sure you all know, the level of update of EHR
4 use is different among different types of
5 providers. Psychiatrists, for example, are some
6 of the later adopters, the numbers aren't as high
7 for them, for example.

8 Dietitians, if they're working in a
9 hospital: Obviously, they're likely to be on EHR.
10 But if they're in independent consultant? Not
11 necessarily because many per say doesn't apply to
12 them.

13 MS. CRAWFORD: This is Alyssa Crawford
14 again from Mathematica. I just wanted to address
15 a point that was raised about developing measures
16 that get farther than this current measure. I
17 wanted to just state that I think it is a measure
18 that has been very clearly heard, and something
19 that -- perhaps I should note that this measure
20 is being maintained under a contract from CMS to
21 develop and maintain electronic quality clinical
22 measures for eligible professionals.

1 So, we have currently in the pipeline
2 a number of measures that are under development.
3 Some of which are very highly related to patient
4 safety and go beyond the documentation of
5 medications.

6 I would add that in order for those
7 measures to be able to work, we need to make sure
8 that the data that's going into those measures is
9 accurate. Right now, the fact that a number of
10 those providers are still not updating the
11 medication lists at every visit suggests that
12 those measures may be based on bad data, which
13 calls into question not only their validity but
14 their feasibility moving forward.

15 So, I think in many ways, this measure
16 is foundational to that measure and what we're
17 currently seeing in the performance doesn't
18 suggest that we're at a point where this measure
19 is ready to go away. We still need to make sure
20 that this data is going to be accurate so we can
21 measure the important things that you've brought
22 up. They're really what we should be focusing on

1 moving forward.

2 CO-CHAIR THRAEN: Chris then Charlotte
3 then Michelle.

4 DR. COOK: I think all the points that
5 have been brought up, and this comes back to the
6 previous measure when we were talking about
7 medications is that we don't have great measures
8 currently.

9 I think it hits on that face validity
10 that there's no way to accurately find out what
11 the patients are if you're not asking. Much like
12 Dr. Dan Green was saying, it is shocking that
13 people aren't doing this as an automatic part of
14 their process.

15 It is not that you're seeing one
16 physician. It is that most of our patients are
17 seeing a multitude of physicians. So, whether
18 you're the primary care who is looking at it and
19 not getting the information back from their
20 endocrinologist or their cardiologist or the
21 podiatrist, if you're one of the specialists who
22 is not on the primary care, then you still have

1 to be able to catch all the different points that
2 are ongoing.

3 So, to me, it is almost as hard to
4 believe that somebody would put in a central line
5 without using aseptic technique, and I cannot
6 believe that we have to put that as a measure,
7 but it is something that is absolutely necessary
8 now to help us avert further adverse drug events
9 that we know are occurring and we have great
10 documentation that is out there and is prevalent.

11 DR. LAWLESS: I'm going to give you
12 the other side. This is just as much of a
13 patient as a provider issue. So, before we just
14 get on physicians on saying, "How dare you not
15 enter the data." Evidence is out there.
16 Articles published. Half the patients, more than
17 half the patients, don't even know what
18 medications they are on.

19 If you ask a family member, "What are
20 you taking?" They are getting it wrong over half
21 the time. Unless you ask them to bring the
22 medicines in with them. You still get to about a

1 90 percent rate of accuracy.

2 So, I think what you're asking is
3 you're trying to get a central repository of
4 medications that we know you are taking from
5 pharmacy data and from other stuff.

6 So, I think it is a great goal. But
7 I also think quite honestly sometimes with
8 medication listing the less data you have is
9 better because it helps people question at the
10 time of validity. "What medications are you
11 actually taking? I have very minimal here."

12 So, the reality is the surgeries and
13 that kind of stuff. That's why they ask at the
14 last minute. It's because you can't trust the
15 list. Even if you're asking, half the time the
16 family doesn't even know what they're all taking.

17 Is it better to prompt the question at
18 the time of delivery? Is it better to have a
19 central repository that people can go to do this?
20 Before we get on physicians only, it is just as
21 much a patient and provider issue.

22 DR. GREEN: Well, there's no doubt

1 that that's true. I don't think that should let
2 the provider off from making the effort to try to
3 find out. We've even added language in the
4 measure last time we went before NQF. I think it
5 was something to the providers' best efforts or -
6 - I mean if somebody forgets to tell the doc that
7 they're on a particular medicine, they are not
8 going to go revoke their Medicare or billing
9 privileges or something like that.

10 I mean, everything in a medical
11 record, as you will know, is based on the history
12 that you're given. So, you can only do what you
13 can do. But you're right; it definitely works
14 both ways, but at least we can adjust the doctor
15 part.

16 CO-CHAIR THRAEN: Charlotte and then
17 Michelle.

18 DR. ALEXANDER: So, I'm hearing what
19 everyone is saying, and I agree to a great
20 extent. What I find is that none of us are
21 perfect historians, and patients are not perfect
22 historians.

1 They will come in one day and tell me
2 one thing, and then on another day another. I
3 get great benefit when I go to the operating room
4 and my anesthesiologist has asked what drugs
5 they're on and what allergies they have and I can
6 compare it to what I have, and it's not always
7 the same.

8 So, I think every time we ask is a
9 benefit. It gives us a chance to catch things
10 that may fall through the loops. It may not be
11 perfect in an ideal world. But we've got
12 transparency, so we can look.

13 My heparin office calls the pharmacy
14 if the patient can't tell what they're on. We're
15 really trying hard to capture this data. I know
16 I would say every time we can it's a benefit.

17 DR. SCHREIBER: Thank you. I fully
18 agree with you that we need a medication list and
19 it should be in there every time. I'm trying to
20 clarify about the documentation piece, and what
21 you're actually measuring. Because according to
22 what you've written, it's the licensed

1 professional who has to document the med list.

2 Well, in our clinic the MA documents the med
3 list, or a nurse, or a pharmacy technician.

4 Does that count when they do that and
5 the physician reviews it? Do they actually have
6 to do the documentation?

7 DR. GREEN: No. That's a great
8 question. It doesn't really matter who does the
9 documentation. Your medical assistant can do it,
10 as you said. We do expect for the doctor to
11 report this, but they would review it. "Okay, so
12 I see you're on, you know, whatever." But they
13 don't have to literally do the writing or the
14 typing in the health record.

15 CO-CHAIR THRAEN: All right, I think
16 it is time to vote.

17 MS. IBRAGIMOVA: Importance to measure
18 and report 1A evidence, structured intermediate
19 outcome. Votes are 1 high, only eligible if 2
20 QQC's submitted; 2 moderate, 3 low, 4
21 insufficient evidence.

22 Results are 19 percent high; 57

1 percent moderate; 14 percent low; 10 percent
2 insufficient evidence.

3 CO-CHAIR THRAEN: All right,
4 performance gap?

5 DR. WEATHERS: Performance gap: They
6 show interesting evidence that actually using
7 this attestation or they got better performance,
8 they increased from 75 percent using PQRS and
9 other measures but PQRS being the main one, from
10 75 percent attestation rate in 2010 to 88 percent
11 in 2013. Eighty-eight percent is not 100
12 percent. So, I would say that there is a
13 performance gap.

14 CO-CHAIR THRAEN: Any questions?
15 Let's vote.

16 MS. IBRAGIMOVA: The importance to
17 measure and report 1B performance gap: The votes
18 are 1 high; 2 moderate; 3 low, 4 insufficient.

19 The results are 43 percent high, 33
20 percent moderate, 19 percent low, 5 percent
21 insufficient.

22 CO-CHAIR THRAEN: The reliability?

1 DR. WEBB: So, for reliability, they
2 actually have -- using data from Part B Medicare
3 claims, PQRS, administering data from registries
4 and EHR reports: Used 3 outpatient physician
5 practices from 255 patients in the report there
6 for their testing.

7 MS. CRAWFORD: The 255 patients was
8 the number that was manually abstracted for the
9 validity comparison and recorded later for the
10 reliability. It was based on the full sample,
11 which included 40 providers with an average of
12 407 patients and 770 encounters per provider.
13 So, it's a fairly substantial size --

14 DR. WEBB: Okay, so, given that size
15 when they calculated out the reliability, they
16 had a reliability between 0.97 and 1, which is
17 good reliability.

18 CO-CHAIR THRAEN: Lisa?

19 MS. MCGIFFERT: Just quickly. The
20 data elements that we're looking at here are that
21 somebody said they checked it? Right? Okay.

22 DR. YU: I have a comment. One of the

1 criteria for physical -- oh, this is reliability.

2 I'm sorry. Never mind.

3 CO-CHAIR THRAEN: All right, we'll
4 vote.

5 MS. IBRAGIMOVA: Scientific
6 measurability of properties to reliability: The
7 votes are 1 high; 2 moderate; 3 low; 4
8 insufficient.

9 The results are 50 percent high; 52
10 percent moderate; 14 percent low; 0 percent
11 insufficient.

12 CO-CHAIR THRAEN: Sorry. Trying to
13 multi-task. Didn't work.

14 DR. WEBB: So, validity testing. The
15 specifications do align with the evidence. The
16 validity testing was done both on the element
17 level and the score level.

18 Again, we talked about it. Three
19 outpatient offices and 255 patients were manually
20 abstracted. It was noted in the discussion with
21 the previous committee meeting that as far as the
22 validity was concerned, face validity results at

1 the performance level were not reported and there
2 was no risk adjustment.

3 There was no power analysis for the
4 reported sample size either.

5 CO-CHAIR THRAEN: Any questions?
6 Comments?

7 MS. CRAWFORD: I just wanted to point
8 your attention to Question 2B 2.2, which
9 indicates that we determined via simulation that
10 our sample of 255 cases had a greater than 80
11 percent power to detect at least substantial
12 kappa scores between EHR extract and --

13 CO-CHAIR THRAEN: Any questions? All
14 right, vote.

15 MS. IBRAGIMOVA: Scientific
16 acceptability of measure properties 2B validity:
17 The votes are 1 high; 2 moderate; 3 low; 4
18 insufficient.

19 Results are 10 percent high; 71
20 percent moderate; 19 percent low; 0 percent
21 insufficient.

22 CO-CHAIR THRAEN: All right, next?

1 DR. WEBB: Feasibility: the have four
2 years of PQRS reporting. I don't see any issues
3 with feasibility.

4 CO-CHAIR THRAEN: Go ahead.

5 MS. ARDIZZONE: I just had a question
6 since this is four first e-performance measure.
7 When do we -- or e measure. Do we just look at
8 the technical review that you provided with the
9 comments, and that's it? Okay, thanks.

10 DR. YU: Under feasibility, the
11 criteria is "Can be implemented for performance
12 measure?" My concern is that we have this
13 discussion about how to really make this list as
14 accurate. I mean documenting is an excellent
15 idea, and you have to be accurate in order for
16 the list to be useful.

17 I can see either way. My personal
18 experience is I went to my mom's doctor, and the
19 medication she was not taking anymore was still
20 on there. So, it takes me going through with her
21 with the doctor and hasn't been there for some
22 time.

1 So, I'm just concerned about when you
2 try to do performance measurements, you don't
3 have a way -- or maybe you have a way and could
4 explain it. How do you really make sure that
5 list is accurate, updated and -- you know, so
6 it's useful?

7 DR. BERG: You make an excellent
8 point. Before coming to my current position, I
9 worked in the DoD system, and we dealt
10 significantly with medication reconciliation and
11 the electronic medical record that we had, and it
12 was very difficult. Medication lists were often
13 wrong.

14 So, it really took repeated encounters
15 with the patients, going through the list of
16 everything that we have, striking those things
17 that were on the list and adding new drugs,
18 etcetera.

19 So, in this specific measure, there is
20 no mechanism built into it to ensure that
21 everything is correct. What I would argue is
22 that if we don't ask at each encounter, we're

1 less likely to actually find those items that we
2 need to find as we go along.

3 MS. CRAWFORD: I would just like to
4 add to that that there's a lot of promising
5 practices for how to improve the accuracy of
6 medication lists, and we've talked a little about
7 some of them: encouraging patients to bring their
8 medications with them to their visit.

9 I think the reality is there's a lot
10 of different ways of doing that, and rather than
11 being prescriptive in this measure and directing
12 providers to one type of workflow for how to
13 accomplish it, we want to make sure that they're
14 documenting it at every visit.

15 I think there's a lot of other work
16 going on to ensure that they're using the right
17 processes, which may not be at the level yet
18 where you can call them best practices, but that
19 help to encourage the collection of the right
20 types of data at that point of care.

21 I think I agree with the points Dr.
22 Berg raised. It is a very valid question, and I

1 think this measure won't fully accomplish the
2 point that you're trying to make but I think it
3 gets it into the workflow in a way that
4 encourages providers to be thinking about how to
5 maximize that interaction with their patient.

6 CO-CHAIR THRAEN: Jason, you had
7 something?

8 MR. GOLDWATER: Sure. So, since this
9 is an e measure, and I know one of the things I
10 said this morning was to look at how feasible it
11 is to do in the daily workflow of care; what I
12 would say is these are a lot of excellent points
13 that have been raised here, but if you have
14 really looked at electronic health records over
15 the past several years, the functionality that is
16 probably the most robust at the moment is
17 electronic subscribing.

18 It has been for some time, largely
19 because it relies on a singular code set and a
20 singular method of transport: getting information
21 from one system to another.

22 It is remarkable that we're doing that

1 with medications, and we can't seem to do that
2 with anything else.

3 CO-CHAIR SEPTIMUS: Jason, it is also
4 required.

5 MR. GOLDWATER: Right, right.

6 CO-CHAIR SEPTIMUS: That's one of the
7 three elements in it: Accountability and how it
8 drives change.

9 MR. GOLDWATER: That is correct. I'm
10 talking from a purely technical standpoint
11 because I'm essentially referred to at NQF as a
12 gearhead. Take that for however you'd like, as
13 have I, usually by Helen.

14 So, I think the functionality is
15 robust enough that even though we're not at the
16 point where there's 100 percent accuracy on the
17 list because we're still waiting for full bi-
18 directionality between a patient and multiple
19 prescribers based on where care is delivered, and
20 that needs transmitted back to the primary care
21 physician.

22 We are, as it was stated earlier by my

1 colleague at CMS, moving closer to that idea.

2 And we will be there probably before we will be
3 there with anything else at the moment.

4 So, even though there is the question
5 of is there a way to guarantee 100 percent
6 accuracy, which I think is probably an
7 unreasonable goal in any element of this, I think
8 we're much closer to that electronically than we
9 will be on anything else, and it also goes back
10 to even though this measure almost seems as if,
11 "Why do we need something that almost seems so
12 obvious?" At this moment, we definitely need a
13 measure like that, and the functionality will
14 catch up to deliver exactly what you want,
15 probably sooner than it will on any other level.

16 CO-CHAIR THRAEN: All right, any other
17 comments? Lisa is thinking about it.

18 MS. MCGIFFERT: Well, I do want to --
19 I mean I think I've heard about these kinds of
20 measures for at least five years. Maybe eight
21 years. I hear what you're saying about, "It's
22 coming around the bend."

1 But I kind of feel like as long as we
2 keep endorsing these measures that really don't
3 tell us what we need to know, we're not going to
4 be developing the measures that we really need to
5 have that tell us what we want to know.

6 So, I see it as sort of a delay
7 tactic. I understand what you're saying, but I
8 just feel like this doesn't move us forward. It
9 just is telling us that -- it's telling us a
10 conversation took place maybe but it doesn't give
11 us any sense of whether or not it helps a
12 patient, improves care, avoids adverse events, is
13 accurate. All of those things I'm not seeing
14 here. So, that's my biggest concern.

15 CO-CHAIR THRAEN: Any more comments?
16 Shall we vote?

17 MS. IBRAGIMOVA: Feasibility: The
18 votes are 1 high; 2 moderate; 3 low; 4
19 insufficient. Results are 15 percent high; 75
20 percent moderate; 10 percent low; 0 percent
21 insufficient.

22 CO-CHAIR THRAEN: Usability?

1 DR. WEBB: Use and usability: Again,
2 we've covered most of this. It is currently in
3 use. Has been for four years. We've seen
4 improvement. It is also a meaningful use
5 criterion. So, it's used in meaningful use. A
6 little bit different in meaningful use, but used
7 just the same.

8 It is publically reported. There is
9 information on improvement over time that we've
10 already discussed, and so as far as unintended
11 consequences, the only unintended consequence I
12 can see from the way that this is worded is that
13 anybody in the office can document these meds,
14 and nowhere is it stated that the physician
15 actually sees it before they write the
16 prescription, and they write at least one
17 prescription per visit based on the evidence.

18 So, you know, are we documenting but
19 more having the most important person review it?
20 It's not covered in here. That would be by only
21 concern.

22 CO-CHAIR THRAEN: Any questions?

1 Let's vote.

2 MS. IBRAGIMOVA: Usability and use:
3 The votes are 1 high; 2 moderate; 3 low; 4
4 insufficient information.

5 Results are 15 percent high; 55
6 percent moderate; 30 percent low; 0 percent
7 insufficient information.

8 CO-CHAIR THRAEN: All right, and
9 suitability for endorsement.

10 MS. IBRAGIMOVA: Suitability for
11 endorsement: Does the measure meet NQF criteria
12 for NQF endorsement? 1 yes; 2 no. Just missing
13 one.

14 CO-CHAIR THRAEN: Missing one.

15 MS. IBRAGIMOVA: Results are 70
16 percent yes; 30 percent no.

17 CO-CHAIR SEPTIMUS: Okay, I'm going to
18 turn this over to Jessie is just a second. I
19 think I hear a theme about measures like this
20 that cannot be directly tied to an action, but
21 directly impacts patient care. Is that what
22 other people are hearing?

1 I said there seems to be a theme
2 emerging with some of these measures that it
3 doesn't necessarily link to an action. I'm
4 talking about an action by the physician -- I'm
5 sorry.

6 The theme I'm hearing is that we're
7 checking off a box, or we're doing something for
8 the measure. We can't really guarantee it links
9 to an action by the physician, which in turns
10 links to better outcomes in patients. That seems
11 to be a theme.

12 I don't want to take this as a
13 criticism, but I think we're getting, and I think
14 Jason has articulated this. We are getting to
15 the point now where maybe we can start making
16 some of those links.

17 Right now, we're left with measures
18 that leave us a little bit unsatisfied for what
19 really matters, and that's what's actionable and
20 affects patient care. Other people think
21 differently. It's whether we send that message.
22 I don't know how we do that, but I think unless

1 other people -- it is one of the things that I
2 hear coming out of this meeting.

3 DR. LAWLESS: This is also to Lisa's
4 point, which emphasized the same thing. In some
5 of these, you can't say no to them, because you
6 feel like you're going against motherhood or
7 something. At the same time, we're not really
8 raising the bar, and saying, "Let's be leaders
9 rather than laggards in this."

10 The technology can do this fairly
11 easily, but is this really leading healthcare to
12 a better place versus, "Okay, we're going to
13 gradually get to this?" I think it's saying what
14 you said. Lisa's point was well taken on that
15 too.

16 DR. BURSTIN: And again, anything you
17 guys state that is sort of conceptual, we will
18 include in the report. I think the developers
19 pretty clearly heard it is highly unlikely
20 measures like this that point through the next
21 time they come up for maintenance unless we've
22 moved significantly forward, and also just to

1 plead all of you: If you know of innovative
2 measures that are actually pushing the needle and
3 kind of getting us closer to that place we want
4 to be, please encourage people to bring them in.

5 Talk to us. We can work with those
6 folks. Again, we just want to keep making sure
7 there are better and better measures coming in.
8 Some of these are great measures. They are kind
9 of legacy measures in some ways, and I think
10 there's a place for them.

11 We don't want to throw the baby out
12 with the bath water, but we do want to continue
13 to bring in the innovative ones that I think push
14 the envelope more.

15 CO-CHAIR SEPTIMUS: Everybody agrees
16 we will make that comment in our report, and
17 maybe Helen or others can comment. NQF really
18 has moved the bar into innovation to help
19 innovate new measures, and you may want to
20 comment on that relatively recent effort by NQF
21 to do that.

22 DR. GREEN: Sorry. This is Dan Green

1 from CMS. I'm going to drop off but I just
2 wanted to thank you all for your consideration of
3 this measure and certainly suggestions to improve
4 it we would be all ears. Thank you again. Good
5 luck with the rest of your meeting.

6 DR. BURSTIN: Thanks, Dan.

7 CO-CHAIR THRAEN: So there's lots of
8 efforts. We are trying to both be involved in
9 the measurement side. Like, for example, the
10 issue this morning we talked about antimicrobial
11 stewardship.

12 We've got an action team that has
13 launched with help from Ed and lots of support to
14 really begin thinking about not just what the
15 measures are but what are the evidence-based
16 strategies, how do we pull together the
17 remarkable NQF membership to be much more focused
18 on action.

19 How do you take a measure and run with
20 it. How do we really drive meaningful
21 improvement. It's been pretty unsatisfying at
22 times. To feel like, okay, here's the measure and

1 it's kind of thrown over the transom and we
2 should wait to see things happen. I think there
3 is definitely a sense we would like to be more
4 engaged.

5 The standing committee can be engaged
6 in all those efforts really helping us think not
7 just about the measures but how they get used.
8 Even the CDC measure this morning we actively
9 reached out for, not sort of passively waiting.
10 It's really important. It's a national priority
11 where do we get those measures working with Ed
12 and others to really go after it.

13 DR. BURSTIN: I want to make a comment
14 about that, Helen. So for the maintenance
15 measures that are scheduled that we know and can
16 anticipate, I'm wondering if there has to be
17 another set of criteria that makes an evaluation
18 of these issues that we are identifying sort of
19 up front to say, "Okay, this measure has been in
20 play for six or eight years and it's still too
21 far away from the goal," and whatever, whatever.
22 But there is at least some sort of assessment of

1 that.

2 CO-CHAIR THRAEN: Yeah and actually, I
3 believe we're going to launch it with the new
4 project? Elisa is shaking her head. When our
5 new projects begin in the fall, we hope, all of
6 our CDP work will actually -- we'll actually have
7 a different process for measure maintenance. We
8 shall see.

9 We have found this sort of painful as
10 you have to go laboriously through some of these
11 older measures in great detail. In the future
12 maintenance first of all will move from every
13 three years to four years just to lighten that
14 load a bit in terms of these maintenance
15 measures.

16 The emphasis on it will be
17 overwhelmingly around gap in care and usability
18 and use. We will only re-evaluate evidence if
19 it's changed and we will only really look at the
20 testing and scientific reliability, validity,
21 etc. We keep either change level of analysis,
22 change data source, made it an e-measure.

1 We are really trying to streamline
2 that because we feel like we have to, first of
3 all, give us a break. This is all intense at
4 times. But also really emphasize that point;
5 measures coming back to us should really be about
6 are you helping to move the needle on quality.

7 If you're not, why not, and it'll be
8 trying to sort of move it to more feasible data
9 sources and get much more emphasis from the
10 field. Is this measure helping? Is it hurting?
11 Just part of usability as well as evidence of
12 unintended consequences and hopefully give a
13 little more breathing room to try to bring in
14 more newer innovative measures.

15 MS. DANFORTH: I had a quick request
16 for that. So in doing that, there are some
17 measures we looked at today where when the
18 measures were first endorsed disparities were
19 identified. When the measure was brought back to
20 us for maintenance, the disparities are still
21 noted so it didn't seem like there had been any
22 work on the disparities in between.

1 Can that be part of the performance
2 gap piece, that like it's expected that if the
3 disparities are identified that within the three
4 or four years something is done to address that.
5 I think that is really important. I think it
6 looks strange if the committee keeps re-endorsing
7 measures for these noted disparities, like 12
8 years later they're still there.

9 CO-CHAIR SEPTIMUS: Well I think it
10 gets to the concept is that when we see that we
11 want to know that the measure is actually
12 changing or moving the needle and that is
13 something that we did not necessarily see. So I
14 don't want to labor this but I just thought
15 conceptually that what I'm hearing and it sounds
16 like everybody seems to be really invested in out
17 of this meeting and going forward.

18 Now, we have -- it depends upon when
19 people are leaving and how long we have a quorum,
20 how many measures. I'm going to let Jesse sort
21 of walk you through some things.

22 Oh, I'm sorry. Yanling, did you have

1 --- I'm sorry.

2 DR. YU: I just want to make a quick
3 comment. Since I'm new, when I'm looking at all
4 the measures, there's a endorsed since 2007, for
5 example, and then re-endorsed 2012. Then I start
6 looking at what has been done, what is new, what
7 accomplishments.

8 I really like to have your ideas where
9 you have them talk about in the spreadsheets,
10 really list what has been done, what is new, what
11 accomplishments, and that would be the gap
12 actually, what re-endorsement is needed.

13 DR. PINES: Thanks. So we have two
14 more measures that are on the agenda. We have 45
15 minutes. We want to see if we are going to lose
16 quorum before 3:00 so can you please raise your
17 hand if you are going to have to walk out before
18 3:00 to get on a flight. How about 3:30? We are
19 going to lose --

20 And for Ann and Kimberly?

21 DR. APPLGATE: I'm here. I'm okay.
22 It's still early here in California.

1 DR. PINES: Okay, great. So we will
2 try to get through the last two measures if
3 possible.

4 CO-CHAIR SEPTIMUS: Okay, Iona.

5 CO-CHAIR THRAEN: 2732. Is that
6 correct? INR Monitoring for Individuals on
7 Warfarin after Hospital Discharge. CMS and
8 Mathematica are the developers. Who is the
9 representative?

10 DR. RISING: I am for that one.

11 CO-CHAIR THRAEN: Josh is. Okay.
12 Thank you. You want to introduce, please?

13 MS. CULLEN: Yes. Thank you again.
14 This is the second measure developed by FMQAI
15 under previous contract with CMS. As the current
16 contractors Mathematica is representing CMS'
17 interest. We'll note any questions we are unable
18 to answer at this time we work with CMS and FMQAI
19 to get answers for you.

20 Measure under consideration, INR
21 Monitoring for Individuals on Warfarin after
22 Hospital Discharge. That's the percentage of

1 adult in-patient hospital discharges to home for
2 which the patient was on warfarin and discharged
3 with a non-therapeutic INR who had an INR test
4 within 14 days of hospital discharge.

5 This process measure is a hybrid with
6 data source from both an electronic health record
7 and Medicare administrative claims. Use of the
8 hybrid meets two goals; the use of novel
9 techniques for measure reporting, as has been
10 discussed here, and they reduce burden on
11 providers.

12 Warfarin continues to be widely
13 prescribed. It has a narrow therapeutic range
14 and needs to be monitored closely to lower the
15 risk of complications such as thromboembolism or
16 bleeding. Current guidelines recommend follow-up
17 for out-of-range INRs, particularly those less
18 than two and greater than three.

19 This measure is focused on these at-
20 risk patients out of the therapeutic range as
21 they transition from the in-patient setting to
22 the home from a controlled to a less-controlled

1 environment.

2 Public comment raised a question of
3 attribution of post-discharge care to hospitals.
4 This was discussed with this committee yesterday.
5 Dr. Ahlen mentioned -- had talked about this so
6 hospitals should be concerned and held
7 responsible for this type of follow-up.

8 FMQAI undertook extensive field
9 testing at seven geographically and
10 characteristically diverse hospitals. The
11 liability scores calculated at the hospital level
12 provided an indication of the ability to
13 distinguish between signal and lies and
14 Mathematica augmented FMQAI's work in this area
15 like calculating a measure level reliability
16 score that indicated the ability to distinguish
17 performance among hospitals.

18 Criteria and validity tests showed
19 strong agreement between electronic and manual
20 abstraction for all of the data elements required
21 to be captured by the EHR. Although discharge
22 status showed slightly lowered strength of

1 agreement.

2 Field testing identified issues
3 related to the accuracy in identifying discharge
4 medications in the EHR. As a result of this, the
5 measure was modified to include a proxy to look
6 for the administration of warfarin in the
7 hospital on the day of or day prior to discharge.

8 Construct validity tests confirm the
9 specification captured patients discharged from
10 warfarin that nearly all patients should have had
11 a follow-up INR. Feasibility tests demonstrated
12 that all data elements were found to be available
13 in the EHR systems and used by the hospitals
14 which included Epic, Cerner, and McKesson
15 products.

16 This measure is not yet in CMS
17 programs, nor has it been reviewed by the MAP.
18 Planned use is for CMS' hospital and patient
19 quality reporting program. There are four
20 measures that address warfarin and INR monitoring
21 and this measure uniquely addresses the care
22 transition and need for appropriate post-

1 discharge follow-up. Thank you for your
2 consideration.

3 CO-CHAIR THRAEN: Josh.

4 DR. RISING: Hi. I think that is a
5 very helpful summary. Should we just start right
6 in on discussing the evidence? Sounds great.
7 All right. We'll keep things moving forward.

8 I think the big question for me that
9 I would like to hear the developers talk about a
10 little bit is the selection of the INR range that
11 is used here in particular. I think we all know
12 that your target is two to three for most
13 patients and the evidence presented kind of looks
14 at -- well, there is evidence that looks at a
15 number of different ranges at which adverse
16 events occur.

17 A lot of studies kind of at five and
18 above. Some look at anything outside the two to
19 three range. So I would like to hear a little bit
20 kind of on the selection of the 1.5 to four as
21 the area to target the follow-up because I didn't
22 see a lot of studies that did target that range

1 in particular as where to be focusing priorities.

2 DR. CROGHAN: Sure. So the short
3 story is that's a synthesis of a lot of different
4 studies that you mentioned. One cut of it is
5 that for people with heart valves the therapeutic
6 range is 3.5, so a little bit higher. You will
7 recognize that this is now .5 above and below
8 that broader range two to three and a half.

9 Having said that, a lot of the
10 evidence is built upon sort of standards of your
11 three to five, five and above, particularly for
12 bleeding events. This was selected by the expert
13 panel as sort of a conservative estimate of where
14 that line ought to be but there is no clear
15 standard.

16 But the lower end I think the standard
17 is pretty clear. That's where the cuff links are
18 for a real jump in the adverse outcome. The
19 robotic events at the lower range. It's a little
20 bit less clear at the upper range where there's a
21 jump in the number of bleeding points.

22 DR. RISING: I'm curious to hear

1 anything you can share about why the panel didn't
2 choose five because it does seem that there are a
3 number of studies that really kind of use five
4 and above as the -- where they look at the
5 adverse events.

6 DR. CROGHAN: That may be a nuance I
7 can't provide you since we weren't in the room.

8 CO-CHAIR THRAEN: Lynda.

9 DR. SMIRZ: I have a question for the
10 developer when I was reading through this. One
11 of those is I don't see a correlation with
12 picking 14 days. Some of the evidence that you
13 cited said that there was an increased rate in
14 mortality at one year if it was 45 days between
15 the time that the INR was drawn, not 14 days. So
16 is there something that I missed where there was
17 a correlation between 14 days and extra adverse
18 events or is that when the adverse events
19 occurred?

20 DR. CROGHAN: The 14-day standard was
21 chosen based upon the American College of Chest
22 Physician Guidelines where if you had a slightly

1 out-of-range INR that you should be tested --
2 retested within seven to 15 days. That was felt
3 like it was giving providers a benefit of the
4 doubt using the best available evidence.

5 DR. SMIRZ: In this measure here there
6 was no evidence that was cited that showed that.
7 Was that --- you're just basing that on --

8 DR. CROGHAN: No. That's right. It's
9 based upon the guidelines.

10 DR. SMIRZ: Okay. Thank you.

11 CO-CHAIR THRAEN: Other questions
12 about the evidence? All right, we'll vote.

13 MS. IBRAGIMOVA: Importance to measure
14 and report on an evidence-structure process and
15 to media outcome. The votes are one high, only
16 eligible if QQC submitted; two moderate, three
17 low, four insufficient evidence.

18 CO-CHAIR THRAEN: Vote again. Did we
19 get 21?

20 MS. IBRAGIMOVA: Twenty-one.

21 CO-CHAIR THRAEN: Twenty-one. We're
22 there.

1 MS. IBRAGIMOVA: The results are 33
2 percent high, 52 moderate, 14 percent low, zero
3 percent insufficient evidence.

4 CO-CHAIR THRAEN: Performance gap.

5 DR. RISING: Okay. So the evidence
6 that's presented by the measure developer show
7 that when they tested this in seven hospitals,
8 they found -- I'm sorry, a mean rate of around 50
9 percent for meeting the measure. It certainly
10 shows that there is room for improvement in this
11 particular measure.

12 CO-CHAIR THRAEN: Any questions?

13 Lynda, you still have your card up.
14 Do you have a question? Okay.

15 Anybody else? All right. Let's vote.

16 MS. IBRAGIMOVA: Importance to
17 measuring and report 1(b) performance gap, the
18 votes are one high, two moderate, three low, four
19 insufficient. The results are 33 percent high,
20 57 percent moderate, ten percent low, zero
21 percent insufficient.

22 CO-CHAIR THRAEN: Feasibility.

1 Reliability. Sorry. It takes two.

2 DR. RISING: Great. So on the
3 reliability testings, again, there were seven
4 hospitals that were assessed and five of them
5 have scores that were above the acceptable
6 threshold when it came to reliability. Two of
7 the seven that did have smaller sample sizes were
8 below the specified threshold for reliability.

9 CO-CHAIR THRAEN: Any questions?

10 Missy.

11 MS. DANFORTH: So it looks like the
12 reliability testing was dated from 2011 to 2012
13 used CMS data. I know that measure is not being
14 like actively used in any programs, but is it
15 actually being used by a health plan or state?

16 DR. CROGHAN: Not that I'm aware of.

17 MS. DANFORTH: So you just -- so
18 because you had access to the CMS data, is that
19 the reason we did seven hospitals?

20 DR. CROGHAN: Remember this is a
21 hybrid measure so we had to know who was
22 discharged on warfarin using EHR data. The CMS

1 data is to determine the numerator.

2 MS. DANFORTH: Okay.

3 CO-CHAIR THRAEN: Any other questions?

4 Pat.

5 DR. QUIGLEY: Thank you. I would just
6 make a quick correction. On page nine for the
7 numerator is says the patients are the
8 denominator so if this goes anywhere, that would
9 be the patients in the numerator.

10 CO-CHAIR THRAEN: Note to staff, or
11 developer.

12 All right. Any other questions?

13 Let's vote.

14 MS. IBRAGIMOVA: Scientific
15 acceptability of measures not released to a
16 reliability. The votes are one high, two
17 moderate, three low, four insufficient. The
18 results are 14 percent high, 71 percent moderate,
19 14 percent low, zero percent insufficient.

20 CO-CHAIR THRAEN: All right.
21 Validity.

22 DR. RISING: Great. There were a

1 couple of interesting questions here. I would be
2 curious to get the developers' thoughts here.
3 The first had to do with discharge status so they
4 went back to look to see because there were some
5 important exclusion criteria including if you
6 were going to a skilled nursing facility so they
7 wanted to only look at individuals who were being
8 discharged to go home or a few other places and
9 it varied by hospital.

10 One hospital in particular there was
11 only 70 percent accuracy between what was in the
12 EHR and kind of where the patient was ultimately
13 found to be going if I was reading correctly. I
14 did have one other question but wanted to get the
15 developers' thoughts on how that may challenge
16 the measure.

17 DR. CROGHAN: My recollection is that
18 where there was disagreement it was largely based
19 upon chart reviews and that had to do with
20 several where there was disagreement within the
21 chart where the patient was actually discharged.
22 For example, some patients were discharged to

1 home healthcare where other people were
2 discharged home.

3 That was often based upon different
4 recorders. For example, the social worker may
5 discharge one person so it was sort of within
6 that category. Overall I don't think that
7 changed the overall assessment or the validity of
8 the measure.

9 CO-CHAIR THRAEN: Lynda.

10 DR. SMIRZ: I had some concern for the
11 developer that you might be able to answer. One
12 of those goes back to exclusions as far as the
13 threat to validity. A patient that was re-
14 admitted within 14 days they may have been re-
15 admitted because of a problem with not having
16 their INR checked and they were on too much or
17 too little Coumadin. Also patients that died
18 within 14 days.

19 DR. CROGHAN: I can deal with the
20 second one first. Very few people died probably
21 does not have a significant impact, a measurable
22 impact on the measure. We don't know the reasons

1 why people were re-admitted. That does make up
2 about 25 percent of the exclusions.

3 CO-CHAIR THRAEN: Any other questions?

4 Josh.

5 DR. RISING: One other, I think,
6 exclusion criteria to note is the readmission to
7 the hospital. You look at how many patients were
8 excluded because of that particular criteria, it
9 was between 40 and 50 percent of patients were
10 excluded because they were coming back from the
11 hospital.

12 That may or may not be related to the
13 fact their INR was so out of whack when they were
14 discharged but it does seem like it's a lot of
15 the population that we are trying to target with
16 this measure who are being excluded.

17 By the time you add up, you know,
18 people who are going to skilled nursing
19 facilities or who have died or who have gone back
20 to the hospital I think it's over half the
21 patients who are being discharged with out-of-
22 range INRs who are then excluded from the

1 measure. That did kind of raise a couple of
2 flags for me.

3 MS. CULLEN: One of the reasons that
4 this exclusion was included was because it was
5 assumed that once the patients were readmitted
6 they were going to get the INR so the onus of the
7 follow-up was no longer on the hospital because
8 of the readmission.

9 CO-CHAIR THRAEN: All right. Any
10 other questions? Vote, please.

11 MS. IBRAGIMOVA: Scientific
12 acceptability of measure that relates to
13 validity. The votes are one high, two moderate,
14 three low, four insufficient.

15 CO-CHAIR THRAEN: I need one more it
16 looks like. Someone's got a lazy remote. Oh,
17 she's gone. We've got one who stepped out.
18 That's fine. Okay. Thank you.

19 MS. IBRAGIMOVA: The votes are 15
20 percent low, 60 percent moderate, 25 percent low,
21 zero percent insufficient.

22 CO-CHAIR THRAEN: It takes a team.

1 All right, feasibility.

2 DR. RISING: The only things to speak
3 to on feasibility are that, again, this is a
4 measure that is drawn both from claims data and
5 the EMR data but it seemed to be done
6 successfully by the measure developers in this
7 case not tried other questions on feasibility.

8 CO-CHAIR THRAEN: Questions? Vote.

9 MS. IBRAGIMOVA: Feasibility, the
10 votes are one high, two moderate, three low, four
11 insufficient. The results are 40 percent high,
12 55 percent moderate, five percent low, zero
13 percent insufficient.

14 CO-CHAIR THRAEN: Usability.

15 DR. RISING: I do think the main
16 question in my mind on usability has to do with
17 because of the very small sample sizes that
18 you're going to have from a lot of hospitals in
19 part due to those exclusion criteria kind of how
20 much -- how useful kind of it's going to be.

21 I know we discussed this a bit in the
22 reliability section. We did have, you know, about

1 a quarter of the hospitals that had too few
2 patients to feel like reliability was
3 particularly good. So I do think there is going
4 to be a challenge just on the sample size of this
5 measure.

6 CO-CHAIR THRAEN: Ed and then
7 Victoria.

8 CO-CHAIR SEPTIMUS: Just quickly I
9 think we need to measure this. One of the
10 unintended consequences of this measure is
11 driving people to use other oral anticoagulants
12 that do not require monitoring and whether or not
13 that we have anything in place to look at.

14 DR. RISING: Ed, can you say that one
15 more time and speak up a little bit?

16 CO-CHAIR SEPTIMUS: I'm sorry. I said
17 one of my concerns is that even before this
18 measure is that since you don't have to measure
19 INRs that some of the new oral anticoagulants,
20 are we going to drive increased use of oral
21 anticoagulants and do we know what the relative
22 comparisons are with those through the safety

1 methods.

2 DR. CROGHAN: I'm sure, Ed, that's a
3 question you will be asking us for years and
4 years.

5 CO-CHAIR THRAEN: Victoria.

6 DR. RICH: I have a question. I think
7 it's related to usability. It might be the whole
8 thing. In my 30 years of practice, primarily
9 inner-city academic medical centers and a
10 struggle with minorities, with INR clinics, and
11 on and on and on. And so I thought it was
12 interesting that you didn't find any difference
13 there perhaps not looking at that.

14 But I think moving forward with the
15 minority populations I think would be so key to
16 see if we could stratify that or do something
17 with it. I don't know if you have any comments.
18 I think many people have seen that within the INR
19 maintenance and trying to keep this going, even
20 in the first 14 days.

21 DR. CROGHAN: Are you referring to the
22 notion that there are some hospitals, and there

1 are some hints in the data that didn't point to
2 statistical significance in regards to hints that
3 there were some hospitals that had more troubles
4 that had larger minority populations?

5 DR. RICH: I'm just looking at the
6 usability to expand how we're using it.

7 DR. CROGHAN: Right. Sure. So, yeah,
8 I think it does tell you that if you're not
9 getting follow-up.

10 DR. RICH: Right. I just thought it
11 might be an extra kind of add-on as time goes
12 forward.

13 DR. CROGHAN: Hopefully that's a
14 useful thing. Great.

15 CO-CHAIR THRAEN: Lynda.

16 DR. SMIRZ: Can I ask the developer
17 just one final comment? I guess it falls under
18 usability. I released a patient from the
19 hospital and want them to have an INR. They were
20 in town and they moved to a different place.
21 What are your suggestions on how that -- what
22 kind of a mechanism is the hospital going to put

1 in place to ensure that that happens? Any
2 thoughts?

3 DR. CROGHAN: So as in any
4 transitioning care what this measure tends to do
5 is to have the hospital take proactive steps to
6 improve outcomes before discharge. I think the
7 term that we heard yesterday was the hospital
8 should own that transition period as best they
9 can.

10 If you have a patient who you know is
11 moving and is not going to be able to get good
12 medical follow-up, then the recommendation is
13 that they stay as an in-patient until they do.
14 You don't have to be a real -- they could go to
15 the hotel across the street for that matter. But
16 there are ways that you can help people get the
17 appropriate follow-up so they are not out of
18 range. Does that answer it?

19 DR. SMIRZ: Well, that is an answer.
20 I don't know how satisfying an answer it is. I
21 have the number of a company that has a number of
22 hospitals along the border in Texas and they go

1 back to Mexico.

2 Then they come back when they have a
3 problem because the care is better there. They
4 come as our readmissions, etc., etc. But once
5 they are across the river, we don't have that
6 much control over them.

7 CO-CHAIR THRAEN: Kendall.

8 DR. WEBB: I agree with Lynda. I work
9 in an inner-city -- as you guys know, an inner-
10 city population. I think owning your own
11 healthcare to some extent is what needs to be
12 done here.

13 I have a lot of patients who I work in
14 several of the hospitals in town and I'll see
15 them at each hospital because they didn't get
16 what they wanted at the last hospital and I'll be
17 like, "Mr. Jones, I just saw you yesterday at
18 this other hospital for this same problem."

19 And they are not following up. At
20 what point do we not put necessarily all the onus
21 on the hospitals but figure out a way to give the
22 patients control back of their own healthcare in

1 some way, shape, or form.

2 CO-CHAIR THRAEN: Michelle.

3 DR. SCHREIBER: Thank you. I do
4 agree. I work in an inner-city hospital as well
5 and our patients travel but I have to admit I
6 think that we do have the burden of
7 responsibility if we discharge a patient with an
8 INR out of range to find them. Maybe that's
9 harder in some populations but I think that it is
10 our responsibility.

11 CO-CHAIR THRAEN: Victoria, did you
12 have another comment? Victoria, did you have
13 another comment? Okay.

14 Anybody else? Vote, please.

15 MS. IBRAGIMOVA: Usability and use,
16 the votes are one high, two moderate, three low,
17 four insufficient information.

18 CO-CHAIR THRAEN: And finally,
19 suitability for endorsement. Overall suitability
20 for endorsement, does the measure criteria for
21 endorsement, one yes, two no. The results are 90
22 percent yes, 10 percent no.

1 CO-CHAIR THRAEN: So, we're at the end
2 of the hour, and we also have to have a public
3 comment period so I don't think --

4 DR. PINES: So, I think we do want to
5 do --- if our measure developer is here, we do
6 want to see if you can tell us one more measure.

7 MS. DAVIES: This is Sheryl Davies.
8 We're here with AHRQ. Can you verify for us that
9 you will not be doing the ad hoc measures today?

10 CO-CHAIR SEPTIMUS: That's correct.

11 MS. DAVIES: Thank you.

12 CO-CHAIR SEPTIMUS: Appreciate your
13 patience.

14 Now, Josh is going to present this so
15 I don't want you to influence -- Jason. Jason is
16 going to do this so I don't want you to influence
17 your results.

18 MS. ARDIZZONE: I just want to let you
19 know I'm going to leave at 3:00 so I don't know
20 what quorum, what it needs to look like or --

21 CO-CHAIR SEPTIMUS: There's 20 minutes.

22 MS. ARDIZZONE: Okay. And I do want

1 Jason to get his full, not hurried.

2 DR. BURSTIN: If nothing else, it might
3 be useful to at least allow Jason to present so
4 people can hear it even if we don't run through
5 the evaluation. I think it's easier if you go
6 with the asking questions in person. It's always
7 more awkward on the phone. So, even if you're
8 not finished with the evaluation you can do that,
9 I think. And then make sure to save a few
10 moments for public comment for sure.

11 DR. ADELMAN: Okay, sure. I'm going to
12 start.

13 All right, thank you everybody. On
14 the phone with me are two folks from the
15 Montefiore team, Dr. Will Southern who is the
16 Chief of the Division of Hospital Medicine for
17 Einstein and Montefiore who collaborated with me
18 on the development of the measures as well as the
19 research we've done with it. And Dr. Brandon
20 Young who is a statistician and the Senior
21 Epidemiologist from Montefiore.

22 So, I have some slides. So, if you

1 look forward, I'm going to explain the measures
2 very clearly and quickly.

3 So, first, some of these slides have
4 some animation, so I'll just tell you next and if
5 you could advance. I'll tell you when. Okay.
6 All right.

7 The measure very simply, it's looking
8 for an automated method for identifying wrong
9 patient errors. It looks for when a doctor
10 places an order as you can see on the slide in
11 front of you and then cancels the order. Next.

12 Within 10 minutes and then immediately
13 after, same doctor orders the exact same -- or
14 not the exact, places the same order on a
15 different patient. Next.

16 So, the programmer who helped develop
17 it used to call it the oops career, like oops I'm
18 on the wrong patient, let me catch it and fix it.
19 We call it the retract and reorder measure. Next
20 slide.

21 So, prior to our work, the most wrong
22 patient errors anybody ever identified was around

1 nine or ten by voluntary reporting. You could
2 see when we developed this, we found 6,885 in one
3 year. And even though I showed you we set a
4 limit for 10 minutes for retraction, on average
5 it was retracted within one minute and eighteen
6 seconds. So, if you track yourself it's usually
7 pretty quick. Next.

8 To validate this, we got IRB approval,
9 got a precision analysis and we called 243 people
10 in near real time, shortly after they made the
11 error, and we asked them was it in fact a wrong
12 patient error. And 170 or 76.2 percent confirmed
13 it was. Next.

14 So, if you correct for that it was
15 still over 5,000 in one year. Fourteen a day.
16 One out of every six providers. Next.

17 So, validity. First of all, I just
18 want to point out that this is a unique measure.
19 We talked earlier about creative new measures.
20 It's very different than almost everything I
21 think we've seen in the last two days and that is
22 measuring actual actions of providers. It's not

1 what somebody charted and then a chart reviewer
2 extracted or abstracted. It's not the doctor's
3 documentation. It's, in fact, the doctor's
4 action. Like you must place an order, and then
5 it has to see that that order was actually
6 canceled. And that allows for some special
7 things.

8 So, first of all, we hardly heard
9 today before the ability to call people an hour
10 after they made an error and said, did you just
11 make an error? So, when we validated we really
12 validated. Next.

13 And it uses very basic data. I mean,
14 there's nothing more fundamental than who placed
15 an order, what time that order was placed, and
16 what was the order and then was it DC'd. That's
17 all the data that it uses. Next.

18 And I guess I made this point.
19 There's no human interpretation. It's just
20 actually what happened. There's no ICD-9 codes.
21 No chart retraction. No voluntary reporting.
22 Next.

1 So, I cut and pasted from, you know,
2 I guess I have the manual that we get, too, so I
3 cut and pasted some of the rules for validation.
4 It says another authoritative source for the same
5 information. So, as I said, we got to call
6 people in real time and positive prediction of
7 76.2 percent with a very narrow competence
8 interval plus or minus five percent.

9 I didn't put this in the packet, but
10 I saw some of the comments about reliability and
11 validation and the VA in New York, I gave them
12 the exact instructions of the measure. I gave
13 them my IRB protocol. I gave them my script for
14 making phone calls. And they made not as many as
15 us. They made 35 and 26 out of 35 so their
16 positive predictive value was very similar to
17 ours. It was 74.3 percent.

18 And then another hospital used chart
19 review. Now chart review is different because in
20 that case, they look for -- if somebody orders
21 insulin on a patient and cancels it and then
22 orders it on another patient, if the first

1 patient has no diabetes, no insulin and then they
2 cancel it and then the second has diabetes and
3 insulin, they decide it's a good chance it was a
4 wrong patient error. But if by chance both had
5 diabetes, then it was hard to determine. So,
6 you'll see by chart review, they looked at 200
7 charts, 61 percent were valid, but another 38
8 percent were indeterminate. So, it's probably
9 more than 61 percent and in the range of what saw
10 in the other slides. And each one of these was
11 done at a different hospital with a different
12 EMR. Next.

13 So, face validity, a lot of experts
14 have endorsed this. So, yesterday you heard the
15 chair of the NQF Health IT Committee. He and
16 David Bates also wrote a letter that's in the
17 folder there. Actually there's a JAMIA article
18 that suggests that we submit these measures to
19 ONC on a quarterly basis. Actually, ONC has the
20 SAFER Guides which you could all see on line, and
21 they recommend using the measure now. And then,
22 of course, the Health IT Committee as I

1 mentioned. That's why I decided to submit it.
2 I'm also on that, and NQF Health IT Safety
3 Division, and they kept using this as an example
4 of a good health IT safety measure, so we
5 decided to submit. Next.

6 Also it says, performance scores
7 resulting from the measure as specified can be
8 used to distinguish good from poor quality. Well,
9 we've been using this measure a lot and
10 publishing a lot to test intervention. It was
11 not possible to do any of the work that we would
12 do beforehand because hospitals would have like
13 seven errors. You couldn't test because there
14 wasn't enough, and they were voluntary reported.

15 When you have 5,000, you can do
16 randomized controlled trials, which we did, and
17 we showed that alerts decreased errors. We
18 showed that if you type in initials, age and
19 vendor that decreased errors. We just got a
20 paper accepted in pediatrics that shows that when
21 you name children, baby boy, baby girl
22 temporarily, that that increases errors, and if

1 you use the mother's first name like Wendy that
2 decreased errors. And we're funded by AHRQ to
3 study how many records are in our state. So,
4 we've been using it successfully a lot to show
5 that we can decrease these errors. Next.

6 So, I said this already. As far as
7 reliability, you know, some of the rules are,
8 they have to be well-defined and precisely
9 specified, and it uses very basic data, and I
10 showed you with the graphic at the beginning. It
11 just looks at when orders are placed, canceled.
12 Next.

13 And it asks if it can be consistently
14 implemented, and we think it can be for the
15 reasons we said, and I'll show you, we've been
16 sharing it. But also our system that we tested
17 with GE. We're going to Epic, and we built it in
18 Epic, but we haven't yet, but when we're ready
19 we're just going to share it with the entire Epic
20 community which, you know, Epic says, well 50
21 percent of the patients in the United States are
22 going to have it, and we can just share it.

1 Next.

2 So, this is the exact quote, if you
3 look under 2a. Reliable testing demonstrates the
4 measure data elements are repeatable, producing
5 the same results a high proportion of the time
6 when assessed in the same population. So,
7 essentially, if you re-run it, will you get the
8 same results? So, if it's chart extraction of
9 doctor's notes, and doctors document differently
10 and the chart inspectors read it differently.
11 our infection control preventionists are trying
12 to figure out if there's a CAUTI. You know, the
13 inter-rater reliability may vary. Here, it's
14 computers pulling direct actions of doctors. So,
15 it's just very -- and it was hard to describe how
16 to do the reliability, so I consulted with Andrew
17 and others at NQF, and initially we just said,
18 it's reliable for these reasons. Next.

19 And these are some of the options that
20 NQF offers. You can to inter-rater reliability,
21 but there's not people extracting, so how do you
22 do it? You could do test, re-test. Next.

1 What we did in the end is we just ran
2 it. We did test, re-test. We ran it a couple of
3 times to show that because it's using this data,
4 it always, you know, repeats itself almost
5 identically, and if you compare, the comparisons
6 are identical. Next slide.

7 We shared it with many hospitals, all
8 on different EMRs and, you know, we give them the
9 requirements. It's anywhere from a couple of
10 hours to a couple of days to write the brief
11 because it's relatively simple, and the results
12 are remarkably similar. They're not exactly the
13 same because the EMRs are different. Some allow
14 for a couple of records open. Some, you know,
15 have different fonts, patient photos. So, that's
16 the whole point of all this is that we need to
17 see the safety of EMRs and then push them to put
18 in photos and limits of one and different things
19 to have protection. Next slide.

20 So, this was, and I mentioned this
21 before, but before our research, the most errors
22 that I could find that were quantified was in the

1 MedMARx database, 120 facilities. Checked off
2 that CPOE was the cause, and they found a mean of
3 9 wrong patient errors, and then next slide.

4 I found one study that did a large
5 chart review, and they found many errors, but
6 only two were wrong patient errors. So, with
7 voluntary reporting and chart review, you just
8 can't ascertain what's going on. Everybody knew
9 it was a problem, but it wasn't until we came up
10 with the automated measures that we could do all
11 the research that we did that led to all the
12 national recommendations. Next slide.

13 So, I'm almost done. So, all of this
14 started in 2011, the Institute of Medicine came
15 out with a report about Health IT and Patient
16 Safety. That led to AHRQ funding more grants,
17 which I got funded by NQF to make other HIT
18 Safety Committee. Next.

19 So, ONC made a HIT Patient Safety
20 Action & Surveillance Plan. As I said, AHRQ, ONC,
21 and they're all recommending we need Health IT
22 Safety Measures, and then they're, you know,

1 highlighting this one as the first, really, as an
2 example.

3 And as I mentioned the SAFER guides
4 are already recommending on line that people do
5 this. Next.

6 And then there's all these letters of
7 support. Next.

8 So, I kind of went over scientific
9 acceptability and importance, but I think in that
10 that I discussed feasibility like it's basic
11 data. I talked about usability. I think it will
12 be used for more research and for surveillance
13 like David Hunt from ONC was going to call in
14 yesterday but because of the time change -- but
15 in this JAMIA article that several of our Health
16 IT national experts, they said we should send
17 this data quarterly so that people will be
18 compelled to put in photos and have them type in
19 initials and do all these things to keep driving
20 down the rate. Next.

21 So, I'm pretty much over. It's unique
22 for the reasons I told. We've already done

1 current use research, and research was not
2 possible for it. And it can be used for
3 surveillance. I think it's valid, reliable. I
4 think it's important, and I think it's feasible.
5 I think it's usable, and there's no competing
6 measures or anything like it.

7 Thank you.

8 CO-CHAIR SEPTIMUS: Well, that was an
9 actual incredible job. Outstanding job.

10 DR. ADELMAN: Thank you.

11 CO-CHAIR SEPTIMUS: That doesn't mean
12 when we have our phone call, we're going to
13 endorse it, but it was a great presentation,
14 Jason. It really was. I don't know whether or
15 not you'd share that presentation with the
16 committee.

17 DR. ADELMAN: Oh, yes, sure, we can
18 share it.

19 CO-CHAIR SEPTIMUS: Yes, that would be
20 great. Put it on SharePoint, yes.

21 So, we have about five minutes for
22 people to ask Jason questions. We'll go through

1 the data elements when we have our follow-up
2 phone call, and then we'll take about five plus
3 minutes, and then we have to have public
4 comments.

5 So, Laura.

6 MS. ARDIZZONE: Just two quick
7 questions.

8 So, you presented some data that most
9 people correct their near misses within a minute
10 and 18 seconds. How many people are -- like what
11 is the harm? How many patients are we giving
12 wrong dosage and wrong medications? Because
13 inherent in this is a check and balance system.
14 So, there's a planned intervention to pick up
15 these near misses. There's a nurse check for
16 right patient, right medication, that sort of
17 thing. I think where we're really vulnerable is
18 where there is no check for that near miss.

19 DR. ADELMAN: Yes, so not as much is
20 known about the actual errors that reach the
21 patient and cause harm. It's, you know, I gave
22 you my very, very quick presentation. I have my

1 much longer one where I share some data on that
2 question like, for example, ECRI did a study and
3 showed that 15 percent of the adverse events that
4 were reported to their PSO were related to wrong
5 patient errors. And we started this whole thing
6 because we had many real wrong patient errors,
7 and most of the people that have used my measure
8 and shared it have had the same experiences. But
9 they haven't done as good of a job quantifying
10 the errors because it relies on voluntary
11 reporting, and people just don't like to report.

12 That's what makes this measure so powerful. So,
13 it is after near misses which allows for the
14 research to study it, but we still have to use
15 like voluntary reporting to find out the really
16 bad things, and so we have enough to know that
17 they're out there and when they happen they're
18 bad. But we don't have enough information to
19 quantify it.

20 CO-CHAIR SEPTIMUS: Okay, Josh, then
21 Louie, and then Charlotte and then we'll go to
22 public comment.

1 DR. APPLGATE: And then Kimberly, too.
2 I'm on the line. I have a --

3 CO-CHAIR SEPTIMUS: Well, I'll tell you
4 what. Kimberly, since you've been so patient on
5 the line, Josh, if you don't mind. Kimberly, I
6 didn't know. I apologize. Kimberly, go ahead.

7 DR. APPLGATE: Thank you so much.
8 And, Jason, I would love to talk to you offline
9 further about this because I really support the
10 measure without having all the details of it, but
11 I will say that I want to support this by saying
12 that I'm doing my own research from an imaging
13 perspective trying to get photo IDs into the
14 CAHPS record. I know about the Denver Children's
15 Hospital work, and I also know about Hardeep
16 Singh's work at the VA in Texas. And I support
17 what you're trying to do. I think it is somewhat
18 of a connectivity issue and interoperability
19 issue. In that I've done some research at Emory
20 trying to get photos of patients into the record
21 with some publications in the imaging side and at
22 SIIM, the Society for Imaging Informatics in

1 Medicine, which we presented this year and last
2 year. And I will say that you're right. There's
3 very little wrong patient error research, and we
4 have done some on the imaging side to show that
5 even though there are low rates of it, the
6 consequences can be quite negative for patient
7 safety, and we continue to look at it in our
8 institution. And when the technologists have the
9 drop-down list where they can send patient
10 imaging to the wrong folder, nobody can find it.
11 And so we have no idea how often it occurs, and
12 nobody wants to talk about it. And I would just
13 strongly support this work, and I'm trying to get
14 support for more research on the imaging side.
15 And as we do millions and millions and millions
16 of imaging tests, and we continue to ask our
17 workers to do more and more, you can imagine that
18 even one of these cases can lead to very bad
19 consequences. And we are finding that we may
20 have a joint commission, two-patient identifier
21 requirement. But when we have many demands on
22 our technologists to hurry up and do the test,

1 they do not follow that requirement, particularly
2 on our portable studies, and that's our most
3 common event that we have where they're not
4 following it. And you can imagine that they are
5 low on the totem pole, and when people are
6 demanding they take the image without double-
7 checking, this happens more than you think.

8 So, I commend Jason for doing this
9 research.

10 Thank you.

11 CO-CHAIR SEPTIMUS: Thank you very
12 much. So, we will be quick so we can everybody's
13 answers in before we have to go to public
14 comment. So, Josh is next.

15 DR. RISING: Great. Very quick
16 question.

17 So, when you called the quarter of the
18 people, right, you know, you determined it was
19 not kind of an error. So, what so those 25
20 percent of people say that, you know, convinced
21 you that, yes, this was not a kind of erroneous
22 order in the first place?

1 DR. ADELMAN: Sometimes people are
2 placing a couple of orders in bulk like we just
3 talked about Coumadin. At the end of the day
4 before they go home they check the INR, and they
5 order Coumadin. So, they order it for the first
6 patient. They order it for the second, and then
7 they realize, oh, the attending said, don't order
8 Coumadin because the patient is going to the
9 operating room. So, they order it, and they
10 cancel it, and then they order on the third. So,
11 it was a type of error. It just wasn't a wrong
12 patient error. But it looks like a retract and
13 reorder event. A false positive.

14 CO-CHAIR SEPTIMUS: Lillee, do you
15 still want to make a comment? Yes.

16 MS. GELINAS: First of all,
17 congratulations, really. I look forward to when
18 we have the phone call to vote.

19 But my question has to do when you
20 talk about spread and interoperability. We're a
21 large system including internationals. So, we
22 have to report measures, not only domestically

1 but internationally. Our two largest systems are
2 Cerner and MEDITECH. I find when we try to
3 introduce new measures, our new reporting
4 mechanisms, Cerner is much more amenable than
5 MEDITECH.

6 Have you quantified the financial
7 burden to systems who have to pay for the -- I
8 would say the updates. I forgot how MEDITECH
9 puts it, upgrades, but I just find that that is a
10 piece when we move to really important components
11 like this, we just run into some buzz saws with
12 the vendors that haven't been quantified so it's
13 really hard to sell to the CMIO and CIO.

14 That said, we do have Midas. And so
15 we have a good event reporting system, but I know
16 we don't have anything like this. Have you also
17 thought about anyway we can be collecting this
18 through some of our normal mechanisms?

19 CO-CHAIR SEPTIMUS: Josh hold that. We
20 have to get public comment before 3:00, and then
21 we'll come back. I hate to do this but, no.

22 So, public comment. Operator?

1 OPERATOR: If you would like to make a
2 comment please press star, then the number 1.

3 There are no further comments from the
4 phone line.

5 CO-CHAIR SEPTIMUS: Thank you,
6 Operator.

7 I'm sorry about that.

8 DR. ADELMAN: That's okay.

9 One of the questions was, you said
10 there were two. One of them was about the cost.
11 So, one of the slides I had there showed multiple
12 systems that we implemented. We started it in
13 GE, moved it to Epic. There's a Cerner.
14 Allscripts is there. The VA system is there.
15 The Brigham's home-grown system is there. And
16 what I can tell you is, it uses -- in none of
17 those systems did we actually work with the
18 vendor meaning like all of them allow you to get
19 the very simple reports of like medications and
20 orders. And so the data comes out, and then a
21 programmer writes a query just to see was an
22 order placed, retracted, and so it's really a

1 report against the data as opposed to like some
2 code implemented within the vendor. And so I can
3 tell you, you know, we shared it with Dr.
4 Schreiber before coming here because she was
5 reviewing it, and she said, hey, how hard is
6 this? And we gave her the requirements and I
7 think it was like two hours of writing it, and so
8 it was not difficult at all.

9 CO-CHAIR SEPTIMUS: I want you to know
10 that we feel your pain since we're MEDITECH shop
11 also.

12 Yanling.

13 DR. YU: I just have quick question.
14 I really applaud your efforts to have this
15 measure. It's really cool.

16 DR. ADELMAN: Thanks.

17 DR. YU: Very creative. You have a
18 diagram that basically says yes or no, if
19 adequate human recover, it will go to a near
20 miss. If not, it goes to an adverse event.

21 DR. ADELMAN: Yes.

22 DR. YU: So, we all know that adverse

1 events sometime are under-reported or hard to
2 define, so they're not reported as an adverse
3 event.

4 Do you have any estimate how that
5 would have inflated your estimate or near miss?

6 DR. ADELMAN: I mean --

7 DR. YU: Is the error bar, you know --
8 or affect your error bar for near miss?

9 DR. ADELMAN: I think I understand your
10 question.

11 That diagram I took from the Institute
12 of Medicine report. I think it was just called
13 "Patient Safety." And, you know, that's a seven-
14 year old diagram about near misses. And
15 everybody believes in near misses. NQF has
16 another committee where they do common formats,
17 and we report adverse events and near misses.

18 Even though the evidence connecting
19 adverse events and near misses is not as strong
20 as we'd like. A lot of it comes from the
21 transportation industry. There's some in health
22 care. And there are these rules of thumb like

1 for every actual adverse event there's 100 near
2 misses, so you can make some estimates. I don't
3 know how well they hold up. So like everyone that
4 deals with patient safety believes in the value
5 of near misses because there certainly are many
6 more of them, so you can study things that will
7 then ultimately prevent the actual event. I'm
8 not exactly sure of the proportion of these self-
9 caught near misses and the actual errors. I just
10 know, you know, we started the whole thing
11 because we were having too many people getting
12 hurt from wrong patient errors, you know. It's
13 sort of like, you place the order on the wrong
14 patient, and then by the grace of God you
15 realize, oh, crap, I'm on the wrong patient, and
16 you cancel it. And if that happens which
17 obviously happens a lot, then it doesn't, you
18 know, reach the patient. And if you don't have
19 that thought it's not like a pharmacist checking
20 it or a nurse checking it. It's you in the back
21 of your mind realizing, oh, crap, I'm on the
22 wrong patient. It's not a very reliable safety

1 mechanism. And we saw that too often they were
2 reaching the patient.

3 CO-CHAIR SEPTIMUS: Charlotte.

4 DR. ALEXANDER: Well, first, I want to
5 commend you. This is really needed. It's outside
6 of the box. It's really great.

7 My angst is that when, from a patient
8 safety point of view, we look at near misses as
9 really great opportunities to learn. And it's
10 super, super, super important that there's no
11 punitive attachment to it. My concern is if this
12 rolls out as a measure, and hospitals are then
13 being measured by that, and then there's a pay-
14 for-performance problem with it, we're just doing
15 all the wrong stuff with a near miss.

16 DR. ADELMAN: Yes.

17 DR. ALEXANDER: And so this is one that
18 is perfect to use, to learn, to develop new
19 things, to --- if we were to counter and catch,
20 but I really hate to see near misses go down that
21 track of being punitive.

22 DR. ADELMAN: So, I taught Just Culture

1 at the National Patient Safety Foundation Annual
2 Congress the last two years in a row, so I'm a
3 big, you now, proponent of Just Culture and
4 differentiating human failure from system
5 failures. And this is all about system failures.
6 All the studies that have come from it taught us
7 how to make the systems safer. And to your point,
8 you know, one of the worst errors that we had
9 where, I think we're in a public comment, right,
10 so I won't say what happened at Montefiore, but
11 it was bad and --

12 CO-CHAIR SEPTIMUS: No, we're past
13 public comment.

14 DR. ADELMAN: We're past, but I just
15 don't know if they're --

16 CO-CHAIR SEPTIMUS: Right.

17 DR. ADELMAN: We had a bad wrong
18 patient that would really scare you, and at the
19 time we had a root cause analysis, and the theme
20 was, the intern must know what patient you're
21 placing orders on. And then we did a study, and
22 we showed everybody places orders on the wrong

1 patient and it's not the intern. It's the
2 system. And then we did all this research to show
3 if you have a pop-up that will decrease errors.
4 If you have them re-verify that they're on the
5 right patient with the initials, that will
6 decrease errors, and now even if you change the
7 name of children, so you don't call every kid in
8 the NICU, baby boy, baby girl, that decreases
9 errors. So, I think, you know, the point is
10 about making the system safer. And I guess what
11 we're trying to do is hold like vendors, not
12 individuals but vendors accountable and health
13 systems. It's time to invest in patient
14 photographs. You know, it's time to -- and I
15 think that will be the level of --

16 CO-CHAIR SEPTIMUS: And, Michelle.

17 DR. SCHREIBER: Thanks. As you know,
18 you and I have worked together in reviewing this,
19 and we actually did try it at the Henry Ford
20 Health System, so just a couple of comments.

21 I know Lillee is gone, but this is
22 entirely scalable. It took us only a couple of

1 hours to do it, and there's actually virtually no
2 cost to organizations in doing it. And there are
3 great lessons to be learned.

4 Wrong medication errors are almost
5 becoming endemic now with CPOE, and so I think
6 this is a really creative measure, and not only
7 that: you thought of how to do it from the very
8 beginning, so I just want to congratulate you.

9 Just one comment and a little bit of
10 a question. In some of how you looked at this,
11 it was all orders, and some of how you looked at
12 this and verified it was medications only. So,
13 if you can just clarify, is this always going to
14 be all orders or medication orders only?

15 DR. ADELMAN: Right. We did all orders
16 and then parsed it by all types of orders in our
17 JAMIA paper, which I think is attached to the
18 application. We showed how wrong patient errors
19 by medication orders, radiology orders, nursing
20 orders, and then there was a table where I showed
21 many different hospitals that implement it. Some
22 like the Brigham, for example, was funded by the

1 FDA to do a medication safety project so they ran
2 it with a particular interest on medications.
3 And it wasn't that they couldn't do it on all,
4 and I actually didn't go back and ask them. I
5 suspect that they did it for all and then only
6 reported the medications as part of that project.
7 And there was another hospital that similar
8 story.

9 I think it's intended and meant and
10 should be used for all orders, but you can parse
11 it any way you want.

12 CO-CHAIR SEPTIMUS: Yes, Jason and I
13 talked last night as we walked back in the rain.

14 Another thing to look at. I mean I
15 have been doing CPOE for a long time, and either
16 I have not recognized it but I've not had that
17 opportunity to put it on the wrong patient. I'm
18 sure that it can happen, that's for sure. You
19 proved that to me. But what I see more often is
20 not that the order is placed on the wrong
21 patient, but that the order is wrong. So, you
22 asked for a specimen from one site, but you

1 really meant another site. And I wonder whether
2 or not you might want to look at wrong order on
3 the right patient.

4 DR. ADELMAN: Yes, so interesting that
5 you say that because, you know, all this work, I
6 mean, for us it stems from actual wrong patient
7 errors. But the fact that NQF has a Health IT
8 Safety Committee and AHRQ, Congress gave AHRQ an
9 extra \$4 million to study Health IT Safety. And
10 I just submitted two weeks ago a new grant to
11 AHRQ saying that we want to expand this measure.
12 The concept of retract and reorder to find other
13 types of errors.

14 So, just very quickly, an example of
15 a wrong order would be a wrong medication would
16 be instead of looking for orders that are placed
17 on a patient, retracted and placed on another
18 patient, we took the IMCP list of similar
19 sounding medications and looked for when somebody
20 orders Clonidine on a patient, cancels it very
21 quickly and then on the same patient order
22 Klonopin, which often gets confused. So, it's

1 wrong drug and, you know, because I sit on this
2 committee, and I sit on the Health IT Safety
3 Committee, I sort of made the case in the funding
4 opportunity in the proposal that we want to
5 develop the measures, test them, and I'm
6 intentionally testing in such a way that it will
7 be -- we can demonstrate validity and reliability
8 to the NQF so it will be ready for endorsement.

9 So, if I get funded I will be back in
10 a few years with, you know, more Health IT Safety
11 Measures to address just what you asked.

12 DR. BURSTIN: To add in, you know, as
13 we are finishing up this work on Health IT and
14 Patient Safety, we'll also make sure we send that
15 draft report to all of you because part of what
16 you -- you remember Andrew from the last project.
17 Andrew has been leading this work and so we've
18 got -- they came up with a list of about 100
19 concepts that potentially could be measures that
20 reflect Health IT and Safety. So, we'd love to
21 get your input on that. There's a long list of
22 them, Michelle, beyond this one. This was the

1 first one that at least we knew there was
2 something in development and at least get a
3 chance to look at it.

4 DR. ADELMAN: Oh, can I please thank
5 Andrew in the back for helping me and guiding me
6 and the NQF staff, they were super helpful.

7 CO-CHAIR SEPTIMUS: And so, yes, we
8 should end the meeting by, first of all, thanking
9 the NQF staff for the support they provide this
10 committee. I mean, we know how much work it
11 takes to even get to this point. I know we're
12 not finished with their work, but they deserve a
13 really big round of applause.

14 There will be a follow-up phone call
15 as you know. I think there's going to be lots of
16 work done between now and whenever that phone
17 call is going to take place. And I can just say
18 I'm just amazed at the talent that's in this
19 room. You all make me feel awfully humble and
20 awfully inadequate because of all the talent
21 that's in this room. And I think that Iona may
22 have had to leave early, but I want to thank Iona

1 for -- we sort of support each other and made
2 sure we don't make too many mistakes. So, we
3 thank you from our perspective for being such a
4 great committee. And I know our work is not done
5 so safe travels to everybody.

6 DR. BURSTIN: Absolutely. Thanks from
7 us, too.

8 (Whereupon, the above-entitled matter
9 went off the record at 3:12 p.m.)
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This is to certify that the foregoing transcript

In the matter of: Patient Safety Standing Committee

Before: NQF

Date: 06-18-15

Place: Washington, DC

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