

NATIONAL QUALITY FORUM
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NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR
PATIENT SAFETY-COMPLICATIONS ENDORSEMENT
MAINTENANCE STEERING COMMITTEE

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FRIDAY,
DECEMBER 16, 2011

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The Steering Committee met at 9:00 a.m., at the National Quality Forum Conference Center, 1030 15th Street, N.W., 9th Floor, Washington, D.C., Pamela Cipriano and William Conway, Co-Chairs, presiding.

PRESENT:

PAMELA CIPRIANO, Ph.D., RNA, NEA-BC, FAA,
Co-Chair

WILLIAM CONWAY, M.D., Co-Chair

JASON ADELMAN, M.D., M.S., Montefiore Medical
Center

CHARLOTTE ALEXANDER, M.D., Memorial Hermann
Healthcare System

JOHN CLARKE, M.D., FACS, Drexel University
College of Medicine

JEAN de LEON, M.D., Baylor Specialty Hospital

VALLIRE HOOPER, Ph.D., R.N, CPAN, FAAN,
Mission Hospital

CAROL KEMPER, Ph.D., R.N., CPHQ, Children's
Mercy Hospital

STEPHEN LAWLESS, M.D., MBA, Nemours Foundation

LISA MCGIFFERT, Consumers Union

CHRISTINA MICHALEK, PharmD, RPh, BSc, FASHP,
Institute for Safe Medication Practices

PRESENT(Cont'd):

SUSAN MOFFATT-BRUCE, M.D., Ph.D., The Ohio
State University
JANET NAGAMINE, M.D., BSN, Permanente Medical
Group (via phone)
LOUISE PROBST, MBA, BSN, St. Louis Area
Business Health Coalition
GINA PUGLIESE, MS, R.N., Premier Healthcare
Alliance (via phone)
PATRICIA QUIGLEY, Ph.D., MPH, ARNP, FAAN,
Department of Veterans Affairs
MARY SIEGGREEN, MSN, APRN, Detroit Medical
Center
JIM SMITH, PT, DPT, Utica College
IONA THRAEN, MSW, Utah Department of Health
TRACY WANG, MPH, Wellpoint, Inc.
RICHARD WHITE, M.D., University of California
Davis

STAFF PRESENT:

HEIDI BOSSLEY, MSN, MBA, Vice President,
Performance Measures
AKINLUWA DEMEHIN
KAREN JOHNSON
JESSE PINES, MD, MBA, MSCE
ANDREW LYZENGA
JESSICA WEBER

ALSO PRESENT:

NONI BODKIN, Centers for Medicare & Medicaid
Services
JOHN BOTT, Agency for Healthcare Research &
Quality (via phone)
DALE BRATZLER, The Joint Commission

KYLE CAMPBELL, FMQAI
MAUREEN DAILEY, American Nurses Association
DEBORAH DEITZ, Centers for Medicare & Medicaid
Services (via phone)
JEFFREY GEPPERT, Agency for Healthcare
Research & Quality (via phone)

ALSO PRESENT(Cont'd):

DAN GREEN, Centers for Medicare & Medicaid
Services

SHARON HIBAY, Quality Insights of Pennsylvania

DAVID HITTLE, Centers for Medicare & Medicaid
Services (via phone)

PATRICIA HOLTZ, Centers for Medicare &
Medicaid Services

RABIA KHAN, Centers for Medicare & Medicaid
Services

DENISE KRUSENOSKI, The Joint Commission

SOEREN MATTKE, RAND Corporation

EUGENE NUCCIO, Centers for Medicare & Medicaid
Services (via phone)

MICHAEL PHELAN, Cleveland Clinic (via phone)

GARY REZEK, Quality Insights of Pennsylvania

PATRICK ROMANO, Agency for Healthcare Research
& Quality

KIM SCHWARTZ, Centers for Medicare & Medicaid
Services

DAVID SHAPIRO, ASC Quality Collaboration

DONNA SLOSBURG, ASC Quality Collaboration

ANN WATT, The Joint Commission

DON WILSON, Quality Insights of Pennsylvania

ALMUT WINTERSTEIN, University of Florida

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

2 (9:02 a.m.)

3 WELCOME AND RECAP OF DAY 1

4 CO-CHAIR CONWAY: We're going to
5 open the day, instead of a recap of yesterday,
6 which Pam did yesterday -- we don't need to
7 repeat that, but in the room next door, the
8 Measures Application Partnership was
9 deliberating on some general rules about the
10 hospital measures that they help our work.
11 And Heidi can give us an update on what
12 happens.

13 MS. BOSSLEY: Sure. So I don't
14 know if all of you are aware of some of the
15 other activities that NQF does, but one is we
16 serve as a neutral convener.

17 So we have the National Priorities
18 Partnership, who helps advise on the national
19 quality strategy priorities. And then we have
20 a new group that has been in existence for
21 just about a year. That is the Measures
22 Application Partnership.

1 And that is the group that is
2 advising HHS on what measures should be used
3 in payment programs, public reporting,
4 everything you see out there: The inpatient
5 quality report, all of those.

6 They have been sending the last, I
7 would say, nine months, providing overall
8 conceptual guidance and developing criteria on
9 how they would evaluate these measure sets
10 that come forward out of HHS. And in the last
11 week, it has been a marathon run for four
12 workgroups.

13 There's one more meeting today:
14 clinician workgroup, the post-acute care,
15 long-term care, and then the hospital
16 workgroup that met yesterday. And then there
17 is the dual eligible workgroup that is meeting
18 today.

19 All of them are looking at the
20 lists, the finalized rules that came out, and
21 providing final recommendations to HHS on
22 whether they think those measures are

1 parsimonious across the programs, if
2 appropriate.

3 Measures that are used in one
4 program perhaps should be used in another
5 program. They're putting those
6 recommendations forward, so basically have
7 gone -- some groups have gone -- and the MAP
8 Hospital Workgroup did it yesterday -- measure
9 by measure, saying they support, they do not
10 support, or they support the general
11 direction, but they don't think the measure is
12 quite there yet.

13 And so a lot of the work that you
14 have done today was being discussed yesterday
15 because a lot of these measures have been
16 included in a lot of the federal programs.

17 So what will happen next with that
18 group is it will go to the over-arching
19 Coordinating Committee, which is many
20 organizations and subject matter experts that
21 sit around the table. And they will come up
22 with some final recommendations to HHS.

1 But all of the decisions you make
2 today you may not see as a result because,
3 again, you haven't finished your process. It
4 hasn't gone out for comment, all of that. But
5 the recommendations that you do put forward
6 will eventually go to the Measures Application
7 Partnership and be used as a guidance of
8 whether or not that measure should continue to
9 be used in a federal program.

10 So it was a marathon run for them.
11 They had seven programs they needed to look at
12 yesterday. They got through all of them in
13 nine hours. So it was very fascinating to
14 kind of get the emails and find out what was
15 going on.

16 Lisa, I think you have a question.

17 MEMBER MCGIFFERT: So I'm always
18 trying to figure out how things work. So the
19 things we were discussing yesterday, which are
20 already on tap to be in the IPPS system in
21 2003, they were discussing -- so like they
22 were making another set of recommendations for

1 after 2013. I think I said 2003. After 2013?

2 MS. BOSSLEY: Yes. Rabia is from
3 CMS. She could probably provide even more
4 information on that for you because it does
5 vary by program as well.

6 MS. KHAN: Right. So this is
7 related to ACA section 3014. And it's a
8 pre-rulemaking process that involves a
9 multi-stakeholder group, which is the MAP.
10 And they are convened to provide their input
11 on our selection of measures for the federal
12 rulemaking, the next federal rulemaking
13 process.

14 So it's a pre-rulemaking input
15 that we would receive when considering new
16 measures for our reporting programs. And that
17 specifies or wheedles down to our programs
18 that go through the federal rulemaking process
19 that are publicly reported that fall under the
20 Social Security Act. And then within the
21 statute, there are some programs specifically
22 listed.

1 So the input that they were
2 providing or for new measures that were not
3 finalized in the past rulemaking process but
4 for the upcoming year.

5 MEMBER McGIFFERT: So after 2013?

6 MS. KHAN: Well, right. Well, it
7 would be the federal rulemaking process for
8 the calendar year 2012. So that could relate
9 to programs in future years depending on each
10 rule. So if --

11 MEMBER McGIFFERT: The rule will
12 come out in 2012?

13 MS. KHAN: Right. The rule comes
14 out in 2012.

15 MEMBER McGIFFERT: Okay. I was
16 just trying to get the timing straight.

17 So if they were discussing, like
18 if this group chose not to endorse certain
19 measures, that would go to them and they would
20 not recommend them or what would that --

21 MS. BOSSLEY: Again --

22 MEMBER McGIFFERT: Would they take

1 another bite at the apple?

2 MS. BOSSLEY: Right. So they
3 developed criteria that they are using. And
4 the first criterion is that it is NQF-endorsed
5 or at least eligible to be submitted to NQF if
6 it hasn't been prior. So anything that has
7 not been endorsed -- and literally that is why
8 Helen Burstin was not able to be here with us
9 today. She was over there advising.

10 As we know, recommendations are
11 coming out. And they're being ratified by the
12 Board. We're providing it directly to the
13 MAP. So they may very well decide that they
14 would propose that measures be removed off the
15 list because they're no longer endorsed.

16 We typically don't make that final
17 recommendation until the Board ratifies the
18 decision just because anything can change at
19 any point in time up until then. So this is
20 where it is truly an almost day-by-day update
21 that we are providing to that staff as well as
22 CMS and HHS.

1 CO-CHAIR CONWAY: Clear, right?

2 MEMBER THRAEN: Food in mouth. It
3 is more likely that the ones that we have
4 vetted and moved forward may not be approved
5 versus the ones that we haven't moved forward,
6 someone would advocate to bring it forward,
7 correct, the probability is?

8 MS. BOSSLEY: I think so. I think
9 we need to see how this plays out a couple of
10 more times to know for sure, but I think that
11 is a good assumption.

12 CO-CHAIR CONWAY: In a way, it is
13 a series of hurdles. The first ones have got
14 to get by a group like this to even be an NQF
15 measure. And then CMS may or may not select.

16 MS. BOSSLEY: Exactly.

17 CO-CHAIR CONWAY: Okay. Any other
18 questions on that background?

19 (No response.)

20 CO-CHAIR CONWAY: All right.

21 Thanks, Heidi.

22 Can the operator let us know if

1 panel members are on the phone today?

2 OPERATOR: We do have a few. We
3 have Gina, Janet, and John.

4 CO-CHAIR CIPRIANO: John, could
5 you identify yourself?

6 MR. BOTT: Yes. This is John Bott
7 with AHRQ. I'm not a Steering Committee
8 member, but I am here to respond to questions
9 that the Steering Committee may have, along
10 with Patrick and Jeff Geppert.

11 CO-CHAIR CIPRIANO: Great. Thank
12 you.

13 CO-CHAIR CONWAY: Great. So can
14 we open up Gina and Janet?

15 OPERATOR: Their lines are open.

16 CO-CHAIR CONWAY: Okay.

17 MEMBER NAGAMINE: Good morning,
18 everyone.

19 CO-CHAIR CONWAY: Good morning.
20 So we have Janet. And, Gina, are you on the
21 line, Pugliese? Operator, is Gina Pugliese
22 opened up?

1 OPERATOR: Yes, her line is open.

2 CO-CHAIR CONWAY: Okay. She must
3 be on mute. All right.

4 Other preliminaries? I think
5 that's that.

6 MEMBER PUGLIESE: I'm sorry. I
7 think I was on mute.

8 CO-CHAIR CONWAY: Okay.

9 MEMBER PUGLIESE: This is Gina
10 Pugliese. I'm sorry.

11 CO-CHAIR CONWAY: Good morning.

12 MEMBER PUGLIESE: Good morning.
13 How are you?

14 CO-CHAIR CONWAY: Wonderful.
15 Okay.

16 STEERING COMMITTEE REVIEW

17 0349: TRANSFUSION REACTION (PSI 16).

18 0350: TRANSFUSION REACTION (PDI 13).

19 AGENCY FOR HEALTHCARE RESEARCH AND QUALITY.

20 CO-CHAIR CONWAY: We're going to
21 start working on 0349 and 0350. They are
22 transfusion reaction measures from AHRQ. And

1 Patrick would like to say some opening
2 over-arching comments on this. And then we
3 will turn to our reviewers. And we welcome
4 Patrick back. We had a lot of fun yesterday.

5 (Laughter.)

6 DR. ROMANO: Okay. Good morning.
7 Well rested hopefully everyone is.

8 Yes. So I just wanted to say a
9 little bit in preparatory comments regarding
10 these two indicators of transfusion reaction
11 because these are both extremely rare events.
12 So we are literally talking about four events
13 reported across the entire country in 2008 for
14 the pediatric indicator, 64 events for the
15 adult indicator.

16 There were some complaints that we
17 received from users several years ago that
18 these codes were capturing some other types of
19 transfusion reactions related to minor blood
20 group antigens that were not AB/O or Rh.

21 And so we actually petitioned the
22 IC-9 CM, Coordination Maintenance, Committee

1 to revise the codes and to add additional
2 codes for non-other types of transfusion
3 reactions.

4 So these codes are now limited to
5 AB/O and Rh. And, hence, they're extremely,
6 extremely rare. So it does bend the concept
7 of importance. And I put that out to you just
8 initially as the overriding policy question
9 for the consideration of these indicators.

10 Also, of course, related to the
11 extreme rarity is the fact that we can't
12 organize any kind of a conventional validation
13 study to assess the accuracy of these codes.
14 Instead, we have to rely on feedback from
15 users to let us know if they find an event
16 that is false positive and to explain that.

17 And so that, in fact, resulted in
18 our petition for the new codes. We haven't
19 heard any complaints since then. But that
20 doesn't necessarily mean that the new codes
21 are working, despite the observed decrease in
22 the incidence.

1 So I will just put out that policy
2 question related to the extreme rarity of
3 these events and what that means and put it
4 forward to you for comments and discussion.

5 CO-CHAIR CONWAY: Okay.
6 Questions? John and then Richard?

7 MEMBER CLARKE: Just as a point of
8 clarification, one of the reason that these
9 reactions are rare is that the transfusion
10 community takes these things very seriously
11 and has been in the forefront of quality in
12 this area. And I assume they have had for my
13 whole career, in fact, their own system for
14 monitoring and correcting this.

15 And so I wonder to what extent you
16 feel that NQF guidelines are complementary or
17 are redundant to the standards within the
18 industry.

19 DR. ROMANO: While I certainly
20 agree that this has been an area of focus for
21 the industry for many years, you would
22 probably be better off addressing that

1 question to people in the industry.

2 There probably is some potential
3 for redundancy there. Hopefully there is
4 complementarity. This is obviously based on
5 a different data stream, again, public use
6 data, as opposed to confidential data that
7 would be reported to blood banks.

8 But aside from that, I welcome
9 comments and input from others or if anyone on
10 the phone has comments.

11 MEMBER WHITE: I missed what year
12 the new codes came into effect and what the
13 number of AB/O incompatibility there was after
14 the new codes. You said 64-something before,
15 but how many do we have of the new codes?

16 DR. ROMANO: I'll look that up
17 while the discussion continues.

18 CO-CHAIR CONWAY: Okay.
19 Charlotte, could you describe the -- summarize
20 the workgroup?

21 MEMBER ALEXANDER: That was not my
22 one.

1 CO-CHAIR CONWAY: Oh, sorry.

2 Steve?

3 MEMBER LAWLESS: I am Charlotte
4 today.

5 (Laughter.)

6 CO-CHAIR CONWAY: Yes.

7 MEMBER LAWLESS: Anyway, the
8 transfusion reaction, the measure we talk
9 about, obviously just for pediatrics, this was
10 mentioned. And the new readers are, as we
11 were discussing, AB/O and Rh compatibility.

12 With the numbers this low, with
13 the user group I come up with -- I missed that
14 meeting, but came up with, which was, again,
15 a discussion we had yesterday, which is counts
16 versus rates. And this is a way of looking at
17 rates here because literally if you look at
18 rates on this, this is near a six sigma level
19 or maybe even be better than a six sigma
20 level.

21 So it is unbelievably rare, but,
22 as mentioned by John, it's systems that have

1 got in place that are very rigid, actually,
2 with this. So that was a major discussion in
3 that regard from the user group.

4 From the measure itself, as
5 mentioned, there are 11 measures of these
6 incidents reported. Seven of them were
7 present on admission. So they probably
8 happened the year prior, obviously if it were
9 a year or two prior. And then, four, it
10 happened in the year 2008, when the data was
11 reported.

12 The data, the numerator is limited
13 to AB/O and Rh. And I would argue that from
14 a pediatric perspective, those are not the
15 errors that we are seeing.

16 In terms of -- and I'll elucidate
17 that. From the different organizations that
18 are actually following this and are rigid, if
19 you have an error at all with this, if the
20 American Red Cross, the FDA, it's never
21 events. So the payers and the states are
22 actually wanting to reporting this. This is

1 qualifying as a never event in some areas. It
2 is the sentinel event. And it is a national
3 patient safety goal. So besides that, nobody
4 is paying attention to it.

5 So it actually is a hugely
6 regulated, very dynamic, very, very, very
7 tight-knit, people are different from everyone
8 else.

9 The errors that we're seeing in
10 pediatrics, which are probably a little more
11 prominent, are things like where CMB negative
12 or positive; irradiated, "Yes" or "No"; and
13 minor grouping compatibilities and risk of
14 hepatitis C. Did you give blood that was
15 hepatitis C-positive but didn't know about it
16 or didn't follow up?

17 So in terms of scale -- and you
18 include it in the measures -- the exclusions
19 actually make -- those exclusions can actually
20 make this so unbelievably rare, it's almost
21 like why are we even -- this is redundancy
22 more than anything else versus those things

1 which are more the process-oriented, we tell
2 you how well the system is communicated. They
3 may not pop up into codes per se. But, again,
4 irradiation "Yes" or "No"; CMB, "Yes" or "No";
5 and things like platelets, single donor versus
6 multi-factor donor. These are the things that
7 are the communication items.

8 So that's it. I think one thing
9 in exclusion which was a little bit
10 bothersome, actually -- I'll just look at this
11 for a second. No. That's the summary.

12 CO-CHAIR CONWAY: So, Steve, is
13 that a summary of both of these: the adult
14 and the pedes?

15 MEMBER LAWLESS: I can't. I am
16 just speaking for the pediatric one right now
17 in terms of that. The incidence, as was
18 mentioned, is a little bit higher. The same
19 regulatory bodies are following the adults as
20 in pediatrics. So it's not much of a
21 difference.

22 I don't know if CMB -- I think CMB

1 and irradiated, those issues are only real
2 issues for, you know, compromised patients and
3 straightforward patients.

4 I would tell you just from a
5 personal note the trauma patients we are
6 seeing and the people who get blood in the OR
7 on type of -- just give it to them, that we
8 have only had four reported with even a trauma
9 getting them urgently. That even tells you
10 how tight the system is that even within
11 minutes, you could actually get -- this is not
12 an issue.

13 And so I cannot speak to the adult
14 part of it otherwise.

15 CO-CHAIR CONWAY: All right.
16 Questions or comments from the panel members?
17 Jason?

18 MEMBER ADELMAN: So forgive me.
19 I'm just going to do what I did yesterday. I
20 pulled one of the articles again. And I am
21 just going to read. There's a very, very
22 brief paragraph on transfusion reactions.

1 Sorry. This is the article that was given to
2 us, "Pediatrics: Evaluation of the AHRQ
3 Pediatric Quality Indicators." I think it's
4 three sentences. Give me a second.

5 So in this study, I will remind
6 you that it was 70-some odd hospitals over 3
7 years. It was almost two million discharges.
8 They picked up 15 transfusion reactions.

9 The denominator was all medical
10 and surgical patients aged 0 to 17 years
11 excluding neonates. The numerator is any
12 patient with a code for AB/O incompatibility
13 reaction, Rh incompatibility reaction or
14 mismatched blood. Twenty-nine percent were
15 present on admission. This is extremely rare:
16 15 cases in 3 years in 76 hospitals.

17 And none of the seven cases
18 reviewed were considered preventable. There
19 were reactions to correctly typed blood known
20 to occur, even with the best typing available,
21 because of untypable antigens or antibodies.
22 The reactions were usually transient fevers or

1 rashes. So they have it.

2 In this study that was given, they
3 found 15 cases. Half were present on
4 admission. And the rest were, you know,
5 nothing, not nothing but they were not -- this
6 is a quality indicator. And they, you know,
7 weren't a quality issue, minor adverse events
8 without any errors. So I just thought that is
9 something to consider.

10 CO-CHAIR CONWAY: Sure. John?

11 MEMBER CLARKE: I'm struggling
12 with this because I know it is extremely
13 important. I know it is also extremely
14 well-done. And, yet, so are we being
15 redundant if we have one of these standards or
16 is it valuable for public reporting since
17 maybe this is the only way it gets reported
18 out publicly?

19 And Steve's implication was
20 perhaps we should expand on that and that, in
21 fact, we should look at some of these minor
22 things since we seem, the industry seems, to

1 have solved the problem with the major things.

2 And so I raise those issues.

3 Should we not do it at all because everybody
4 else is doing it and doing it well or should
5 we do it because it constitutes public
6 reporting or should we recommend that more of
7 it be done because then more valuable
8 improvement would be done?

9 And I would actually not be swayed
10 by the fact that most of the problems right
11 now seem to be problems that are unavoidable
12 because yesterday's unavoidable problems are
13 tomorrow's avoidable problems.

14 CO-CHAIR CONWAY: John, since you
15 are active in the State of Pennsylvania
16 reporting, what measures --

17 MEMBER CLARKE: This is our least
18 common problem in Pennsylvania.

19 CO-CHAIR CONWAY: But what
20 definition are the states using for the
21 reporting? Is this --

22 MEMBER CLARKE: We get everything.

1 We get everything from people drinking back
2 rub solution, X-rays going out of the
3 helicopter, two cases, two different
4 institutions, by the way. And so we get every
5 minor mishap. But the major mishaps in
6 transfusion. Our transfusion category is the
7 smallest category we have.

8 CO-CHAIR CONWAY: Let me restate
9 my question. What definition does the State
10 of Pennsylvania use for transfusion reaction
11 reporting?

12 MEMBER CLARKE: Everything.
13 That's what I'm saying: everything from
14 mislabeled specimen -- see, we have near-miss
15 reporting. So if you just mislabel the
16 specimen and catch it, we get the report. So
17 we get every possible thing that might
18 potentially have affected the patient in the
19 way of the chain of blood custody.

20 CO-CHAIR CONWAY: Let me just
21 continue with this line of reporting.
22 Patrick, do you know if this measure was not

1 out there, what would happen? What is the
2 down-side risk of not having this available
3 for public reporting?

4 DR. ROMANO: I can't. My crystal
5 ball is weak on that. But probably again, you
6 know, the systems that are in place that have
7 been described I think have already
8 established a six-signal level of performance
9 in this area. So it would be hard for me to
10 predict a clear negative consequence, to be
11 frank.

12 There are some interesting
13 proposals on the table here. I would say that
14 it was Scanlon's work that has been cited as
15 well as other feedback that led us precisely
16 to petition for the separation of these codes.
17 So that was done.

18 The effective date of that was
19 October 2010. So, unfortunately, the data
20 that we have cited regarding the prevalence of
21 these events in hospitalizations predates the
22 change in the codes. So we would expect a

1 further dramatic decrease, even below the 4
2 and 64 events that are reported for the
3 pediatric and adult indicators, respectively.

4 CO-CHAIR CONWAY: Okay. Why don't
5 we do Charlotte, Lisa, Jason, and Iona?

6 MEMBER ALEXANDER: As I understand
7 it, one of the requirements is that there has
8 to be an opportunity for improvement. And I
9 don't see that here. I think we have done
10 what we need to do unless we change the
11 criteria to pick up some of these more
12 difficult-to-detect minor antigens.

13 CO-CHAIR CONWAY: Jason?

14 MEMBER ADELMAN: To me it is the
15 same as yesterday with the retained foreign
16 bodies. It's a mixture of somebody
17 accidentally giving blood to the wrong patient
18 versus much more commonly a minor antigen
19 causing something relatively insignificant.
20 And so it's hard to -- you can put in
21 bar-coding to try to prevent wrong patient
22 errors, at the same time be doing more blood

1 transfusions. And what is reported will be a
2 mix of the two.

3 And, despite the fact that
4 transfusion reaction does not say, "I gave the
5 patient the wrong blood," I am afraid that too
6 many people think that that is what this is a
7 measure of.

8 You had asked a question of John
9 of what information he collects. And they
10 collect everything. But they don't publicly
11 report everything and mix it all together.
12 And I think there is a distinction there.

13 And, again, even though it's not
14 anybody's fault that the term "patient safety
15 indicator transfusion reaction" because it's
16 a patient safety indicator is believed to be,
17 I think far too often, the wrong patient got
18 the wrong blood. It's just I'm afraid too
19 confusing. It's one of the goals of
20 usability, like, "Well, people understand what
21 this indicator means." And I think they will
22 think it is one thing, but it is actually

1 something else.

2 CO-CHAIR CONWAY: Iona?

3 MEMBER THRAEN: A couple of
4 observations. First of all, we wouldn't know
5 that we are at six sigma unless we have
6 collected this data. So that is the first
7 observation.

8 And we are always in patient
9 safety looking at what people do wrong. This
10 is an opportunity to celebrate, folks. I
11 think that if, in fact, we are at six sigma at
12 a population level on this particular issue,
13 that this is something that needs to be
14 communicated to the industry because when an
15 event like this occurs at a local hospital, it
16 is a big deal. And it is usually that kind of
17 event is not the reaction. It is the wrong
18 blood to the wrong patient kind of event. And
19 the hospitals and the staff suffer deeply when
20 an event like this occurs.

21 So, you know, I don't know that
22 that is within the scope of this Committee,

1 but if we are going to retire this indicator
2 or maybe reframe it based on the conversation
3 that you're talking about, at least rename it
4 possibly, that we need to also say to the
5 world out there that we have made some
6 improvement, significant improvement, in a
7 particular area that we can celebrate.

8 The other thing I want to say is
9 that I think this is an SRE. So separating
10 out the sentinel event issue, wrong patient,
11 wrong blood, from transfusion reaction rates
12 I think is worth exploring since we do have an
13 SRE already in place for the other side.

14 CO-CHAIR CONWAY: Steve?

15 MEMBER LAWLESS: I actually agree
16 in terms of the celebration of success. And
17 I think if you were retiring in terms of the
18 measure itself, this measure is saying, guys,
19 this is an example, just of something that
20 really worked. And now it is going to go
21 maybe to the next level or something else.
22 But that I think would give people hope out

1 there in terms of wow, it's not just
2 lingering, but it's actually something very,
3 very positive.

4 But, again, I think the bigger
5 issue, actually, people are grappling with is
6 things like how to handle blood transfusion.
7 It's the decision-making process about blood
8 transfusions. This is kind of an assumed "I
9 am going to get the right blood. Now what do
10 I do with it?" is where the bigger, major
11 issue is.

12 CO-CHAIR CONWAY: Louise?

13 MEMBER PROBST: If there's an
14 interest in having one place to go for
15 measures -- and so I know there is a lot of
16 discussion in our community among our
17 hospitals and others about trying to use
18 NQF-endorsed measures and having one place to
19 go. So I don't know if you start taking some
20 out, whether that means that it is just
21 multiple places folks have to go to find the
22 measures that they are using internally.

1 So I don't know if there is any
2 opportunity there for harmonization or
3 streamlining. That could be lost if we took
4 the measure out.

5 CO-CHAIR CONWAY: Okay. Other
6 comments? Patrick?

7 DR. ROMANO: John Bott might be
8 able to address this, but I would say that
9 AHRQ may decide to continue the indicator as
10 part of the PSI set, even if NQF endorsement
11 is withdrawn. So those two aren't necessarily
12 linked.

13 I might also ask Heidi to comment
14 on the link between the serious reportable
15 event program and this program because, yes,
16 this is a serious reportable event. It's
17 being defined through the SRE program. But
18 one of the interesting features of that
19 program is that it doesn't exactly have fully
20 operational specifications.

21 And so states then have to try to
22 implement those specifications. Some states

1 have mandatory reporting programs. Some
2 don't. There is a lot of variability there in
3 the extent to which they even follow the NQF
4 definitions.

5 So Heidi might be able to
6 illuminate the group on that question.

7 MS. BOSSLEY: Right. So one of
8 the things I think we have tried to continue
9 to work on the definitions for the SREs over
10 time, but they still remain somewhat open to
11 translation I think when you start looking at
12 some of the coding, et cetera. And there is
13 work underway to start putting a little more
14 meat on the bones, I would say, around the
15 SREs and everything.

16 It just occurred to me I never
17 thought this would come up in this Committee,
18 but there is an option for all of you, which
19 is putting the measure in reserve status.
20 This is a new status that we developed.
21 Patrick is a little surprised, but I am
22 throwing it out there. It is an option.

1 We have done it. And we just had
2 cardiovascular and surgery committees take a
3 look at this. This has been the first time
4 that we have really looked at measures
5 undergoing maintenance. And there have been
6 some measures where there has been clear
7 improvement to the point where the measures
8 meet all of the other criteria with the
9 exception of 1B, which is the opportunity for
10 improvement.

11 So there is actually little
12 variation. There is a small gap, if anything.
13 I think you would want to look and see the
14 disparities piece, if there continues to be
15 variation in that. And I'm not sure if we
16 have that data or not. I haven't looked to
17 see.

18 But you do have the opportunity to
19 say the measure remains endorsed, but it is in
20 reserve status. It is not the first one we
21 think that everybody should uptake and look
22 at, but it should be looked at periodically.

1 It would be reviewed again in three years.
2 AHRQ would continue to maintain it and provide
3 the updates to us.

4 And then in three years' time, we
5 would revisit and see if there's any new data
6 that would then make us realize maybe we need
7 to either say the measure is now gone, you are
8 doing great, or we need to actually move it
9 back into full maintenance again or
10 endorsement again and people need to actively
11 start reporting it.

12 It's an option. I am throwing it
13 out there because I can hear everybody kind of
14 struggling. That is an option or you can just
15 continue to move through and vote and either
16 vote the measure not to be endorsed or
17 endorsed.

18 CO-CHAIR CONWAY: So how would we
19 proceed? We would see if this hits the
20 threshold or importance? And if it fails
21 there, we could entertain a motion for reserve
22 status?

1 MS. BOSSLEY: So what we have done
2 -- and this is still a work in progress
3 because we have only done it a few times. So
4 we typically have you vote everything. So we
5 have you vote the importance.

6 You may vote the importance down
7 because, again, it needs to meet all three and
8 then go through and vote everything else:
9 scientific acceptability, usability, and
10 feasibility. And then we stop and say, "Okay.
11 Would you want to revisit the importance piece
12 because it is actually meeting everything but
13 1B, the opportunity for improvement?"

14 So we can run through that process
15 if that is something you all would like to do.
16 I don't want to cut off discussion, but I do
17 want you to know that is an option for all of
18 you to use if you'd like.

19 CO-CHAIR CONWAY: Thank you.

20 Let's just go around the table.

21 I've lost track. Jason?

22 MEMBER ADELMAN: I just want to

1 respond to one thing Patrick said. I think
2 that if it does not get endorsed, that AHRQ
3 should continue it. I see it has a great role
4 for widening the net, as John talked about
5 before.

6 If we get five cases and four of
7 them are nonsense but one of them is a real
8 bad medical error that slipped through the
9 cracks, we might pick it up.

10 I am just personally afraid the
11 public won't understand what exactly this is.
12 Many of these measures need an asterisk and a
13 paragraph below it explaining exactly what
14 this means.

15 CO-CHAIR CONWAY: Lisa?

16 MEMBER MCGIFFERT: The way this is
17 collected is not particularly labor-intensive,
18 right, because it's coming out of the
19 administrative data, right?

20 And the other thing that I was
21 wondering is I know there is a composite score
22 and I know that there is a lot of interest in

1 composites recently because of the multitude
2 of measures we have.

3 And I am wondering what benefit it
4 would have in a composite score looking at it
5 with a bunch of other rare events because we
6 have, you know, 15 rare events that might
7 happen or measures.

8 And then you have a cumulative
9 number. Is that valuable to look at whether
10 a hospital is taking these serious events as
11 seriously as they need to or whether they need
12 to improve?

13 And I think that taken
14 collectively -- I know we have trouble
15 communicating this, these kinds of measures to
16 the public because they are so rare, but I
17 think the public understands when things
18 aren't supposed to happen. And I think if
19 there was some way to move towards a more
20 composite look, that that might be beneficial.

21 CO-CHAIR CONWAY: John?

22 MEMBER CLARKE: First of all, I

1 have been curious, Lisa, the whole time. How
2 do you feel about the public reporting aspect
3 of this, the fact that this would allow public
4 reporting, rather than just within-industry
5 reporting? Is that important to you or do you
6 think the public has enough confidence in the
7 blood supply at the moment to not worry about
8 that?

9 MEMBER McGIFFERT: Well, I would
10 say there probably aren't a lot of people in
11 the public that say every day, "Gee, I am
12 worried about the blood supply. Let me go
13 look at this measure." But I do think when
14 these issues are presented, it is pretty
15 obvious to anybody that they are rare events
16 and that the public really understands there
17 are never events.

18 I mean, I am intrigued by what you
19 said about maybe there are some other things
20 that we should be measuring in safety with a
21 blood supply and that this is a never event or
22 a serious event but maybe there are some other

1 things we should be measuring.

2 But I do think people understand
3 that these things are things that shouldn't be
4 happening. And I think there is some comfort
5 in knowing that they are rare.

6 I think sometimes there is some
7 skepticism, but when you are pulling it from
8 codes and things like that, there is probably
9 -- you know, I don't know what to say. I do
10 think that there is a real need for us to get
11 to a point where we can have some good
12 composites that say overall this hospital is
13 safer or safe.

14 MEMBER CLARKE: Yes.

15 MEMBER MCGIFFERT: And I think we
16 are all looking for that and there is no magic
17 --

18 MEMBER CLARKE: Right. And that
19 is the other thing I wanted to comment on. We
20 looked at three never events in the -- are you
21 allowed to use the word "never" event in an
22 NQF building?

1 (Laughter.)

2 MS. BOSSLEY: You can. I can't.

3 MEMBER CLARKE: "You can. I
4 can't"? Okay.

5 We looked at three never events in
6 the operating room: wrong site surgery,
7 retain foreign objects, and surgical fires.
8 And we looked at institutions that had these
9 events. And the correlation between having
10 one of these three events and having another
11 one of these three events -- and for those of
12 you who know linear correlation statistics,
13 the r^2 on that is zero. That is, there is no
14 relationship between the facility for
15 operating on the wrong patient, setting the
16 patient on fire, or leaving something behind.
17 Those are totally unrelated aptitudes. And so
18 --

19 MEMBER MCGIFFERT: There was a
20 study that looked at all of the PSIs. And
21 they found that number 7, which was the
22 infection measure, was the canary measure.

1 MEMBER CLARKE: Yes. I would
2 think that would be true.

3 MEMBER McGIFFERT: Yes.

4 MEMBER CLARKE: So what happens is
5 that the rare events may, in fact, be
6 idiosyncratic. And they may not be a good
7 indicator of the overall quality of the
8 institution. I think that some of the things
9 like infections and readmissions, recovery
10 from complications, those things, particularly
11 recovery from complications, are very good
12 parameters of quality. But these rare events
13 probably aren't.

14 MEMBER McGIFFERT: My
15 understanding of the study was they looked at
16 how well it correlated with all of the other
17 PSIs so that, you know, it might be
18 interesting for you to look at that with yours
19 to see if that was a good indicator of some
20 correlate

21 CO-CHAIR CONWAY: Well, let's pick
22 up Iona. She has been waiting a while. And

1 then we will go to Patrick.

2 MEMBER THRAEN: I just wanted to
3 make sure that we are clear on the SRE versus
4 this type of event. So the SRE related to
5 this is defined as patient death, serious
6 disability associated with the wrong
7 transfusion.

8 So I think that, again, the SRE
9 definition is truly a definition of a sentinel
10 event, a very rare, rare event. This is a
11 transfusion reaction measure, which we have
12 already talked about is a broader capture of
13 information related, not necessarily related,
14 to death.

15 So the SREs are being reported,
16 mostly manually because the requirements for
17 reporting are in the moment where when you get
18 to ICD-9 code use, we're talking two-year
19 delays in terms of being able to capture data.

20 And that may not be true for CMS
21 in the future. But at the state level, by the
22 time we get the data, we have cleaned the

1 data, we validate the data, et cetera, et
2 cetera, we are two years behind. So it's a
3 look-back approach and used for different
4 reasons. So I think we just need to be clear
5 on the differences.

6 CO-CHAIR CONWAY: Sure. Patrick?

7 DR. ROMANO: No disagreements with
8 anything that has been said, just a couple of
9 clarifications. So we do have, AHRQ does
10 have, a PSI composite. And the composite
11 measure does not include this indicator. And
12 the reason for that is because it is a
13 reliability-weighted composite that is based
14 on a weighted average of rates for each of the
15 PSIs.

16 But this PSI, as has been
17 discussed, is not really estimable as a rate.
18 It is really idiosyncratic. And, therefore,
19 it wouldn't add any information value to a
20 composite, which is why it is not included in
21 the composite.

22 As far as disparities, again, we

1 are limited by the fact that we have a legal
2 requirement that we cannot report cell sizes
3 less than ten or anything that would imply a
4 cell size less than ten.

5 So, therefore, we can't estimate
6 disparities across different sociodemographic
7 groups using the HCUP data. And we apologize
8 for that limitation, but it is a legal
9 requirement.

10 And if John has any policy issues
11 related to this that he wants to address, he
12 is welcome to jump in.

13 MR. BOTT: Yes. In regard to the
14 question Patrick asked before about AHRQ's
15 continuance of a measure, so in 2012, we are
16 going to be taking a hard look at what we call
17 the measurement life cycle process. We have
18 in the past primarily focused on measure
19 development and measure maintenance and
20 measure enhancements.

21 But we need to do more to
22 acknowledge that there comes a time for

1 measures, to retire measures. And we want to
2 do more to develop solid criteria around that.

3 Although this is work yet to come,
4 I imagine the loss of NQF endorsement of a
5 measure will bear weight. And the question
6 will be how much weight, informing whether a
7 measure would be retired or not.

8 CO-CHAIR CONWAY: Jason?

9 MEMBER ADELMAN: I just want to
10 respond to what John said and what I said
11 earlier. Again, I just see sometimes I wish
12 we can endorse these measures with
13 qualifications, like this will be good for
14 public reporting and this is good for
15 value-based purchasing and this is good just
16 as a net to capture because I still think it
17 is good for the purpose of finding cases that
18 we might have otherwise missed. That's all.

19 CO-CHAIR CONWAY: Lisa won't let
20 us. Lisa?

21 MEMBER MCGIFFERT: I would
22 disagree with that. I mean, I think I was

1 arguing for that with some of the process
2 measures yesterday, that they may not be that
3 useful for the public but they're useful
4 internally for the hospital to use.

5 CO-CHAIR CONWAY: Louise?

6 MEMBER PROBST: So in our
7 community, we look at these measures and talk
8 about them with our providers. And our
9 message to the public, whether we are in the
10 press or to our own constituents, is that
11 these are not measures by which you would
12 choose a hospital. But there is comfort to
13 the public to know that there are measures out
14 there and that someone is looking at them.

15 And so what happens is because we
16 don't have any public reporting and our
17 organization's position is that there should
18 be public reporting of never events by region
19 but doesn't have to be hospital-specific but
20 there ought to be something that says to the
21 public, "Health care is risky. And sometimes
22 bad things happen. And, you know, you should

1 be careful when you go into the hospital, but
2 they don't happen that often." And so what
3 happens is we don't have anything like that.

4 And then suddenly something does
5 happen. The press finds out about it. They
6 interview the patients. They put it in the
7 paper. And then all of the hospitals look
8 really bad. But if there was just something
9 that was out there once a year that, "Oh, here
10 is the rate. And, look, it isn't very many,"
11 then people take comfort in knowing that their
12 state or some other entity is providing this
13 oversight and they don't really have to look
14 at them.

15 And so I think there is value in
16 some of that public reporting. I agree it is
17 not valuable to say this is a good or bad
18 hospital. But there is a consequence of not
19 having the public reporting.

20 CO-CHAIR CONWAY: Just as a
21 reminder, there are multiple users of NQF
22 measures. And it is the user that has to

1 evaluate whether it is a reasonable public
2 reporting measure or not. Maybe NQF should
3 clarify that, but they don't, in their
4 proceedings.

5 Okay. John, are you up or down,
6 your card?

7 MEMBER CLARKE: No.

8 CO-CHAIR CONWAY: Okay. Any other
9 comments? Anything new about these measures
10 that could add to people's thinking about
11 this? Okay. Anyone on the phone? Yes? Go
12 ahead.

13 MEMBER NAGAMINE: For Heidi. In
14 your experience, the few measures that have
15 gone to reserve status, do you -- what has
16 been the experience when they go into that
17 status? Are they still used or do people just
18 kind of ignore them once they are in that
19 status? What tends to happen?

20 MS. BOSSLEY: It's a good
21 question. Unfortunately, we don't know. The
22 Board is actually acting on the first set. It

1 is one or two measures in the next month. So
2 it will be interesting to see how others
3 continue to use it, but honestly we are not
4 sure. So this is something we are going to
5 monitor over time to see if it is at all
6 helpful to put something in this type of
7 status.

8 MEMBER NAGAMINE: Thank you.

9 CO-CHAIR CONWAY: Okay. Should we
10 move on to a vote? Jessica?

11 MEMBER CLARKE: Before we vote,
12 could we reiterate what the strategy would be
13 if we want to put it in reserve status?

14 MS. BOSSLEY: Okay. So you vote
15 based on whether the measure meets the
16 criteria. So in this instance, again, this is
17 your call on whether you want to do this or
18 not.

19 If you believe that this measure
20 doesn't meet a performance gap, 1B, then you
21 would actually vote down importance because it
22 doesn't meet all three criteria.

1 But then we would stop if that
2 happened and ask you if you want to continue
3 on to see if the measure continues to meet the
4 other three criteria because it needs to meet
5 the other three in order to be able to go
6 discuss reserve status. If that is the case,
7 then we would continue on. And then we would
8 bring you back and have you re-vote on whether
9 you think the measure applies for reserve
10 status. Does that make sense to everyone?

11 MEMBER LAWLESS: And then the last
12 question about should it be endorsed, the very
13 last question, then we say reserve, do we say
14 "Yes" or "No" to that?

15 MS. BOSSLEY: Yes. So what we
16 will do is if you take a look at this slide
17 here -- and for those on the phone, what it
18 says is "If a measure is under endorsement,
19 maintenance review, and did not pass
20 importance only due to lack of a performance
21 gap does it meet criteria to consider for
22 potential reserve status," oh, I guess the way

1 we have it written they changed it and then
2 "further evaluation and reliability and
3 validity."

4 Okay. Is it importance and then
5 this? Did we change it? Okay. So we'll do
6 it what makes more sense to that I just said.
7 So we will --

8 MEMBER LAWLESS: Can I suggest
9 that maybe before every vote, you kind of give
10 us a guide?

11 MS. BOSSLEY: I will do that.
12 Let's do that. We'll guide. I am happy to
13 guide because this is confusing. We keep
14 changing the slides. And clearly I can't keep
15 up with them.

16 CO-CHAIR CONWAY: But, Heidi, if
17 it doesn't pass importance, we ordinarily
18 wouldn't vote on keeping the measure.

19 MS. BOSSLEY: Right.

20 CO-CHAIR CONWAY: So, therefore,
21 we wouldn't --

22 MS. BOSSLEY: Right.

1 CO-CHAIR CONWAY: -- have to do
2 that. We could flip to the reserve status
3 vote, instead of that.

4 MS. BOSSLEY: Right.

5 CO-CHAIR CONWAY: Does that make
6 sense?

7 MS. BOSSLEY: So the reason why
8 you still need to demonstrate that the measure
9 continues to meet the other three criteria,
10 which is why I would like you to do
11 importance.

12 If it doesn't pass, then we'll
13 stop and say, "Do you want to continue?" Then
14 we will go to scientific acceptability,
15 usability, feasibility, but then I'm not going
16 to have you vote "Yes"/"No" until you discuss
17 the reserve status. And then we'll do an
18 overall "Yes"/"No."

19 Does that make sense to everyone?

20 MEMBER CLARKE: Heidi?

21 MS. BOSSLEY: Yes?

22 MEMBER CLARKE: Just as a kind of

1 a Robert's Rule, --

2 MS. BOSSLEY: Yes.

3 MEMBER CLARKE: -- may I suggest
4 in the future that what you do is you make the
5 known motion the reserve motion and then you
6 make the amended motion the pass motion. And
7 then once it passes the amended motion of
8 being accepted, then you could go to the main
9 motion, which is to be accepted in reserve.
10 And I think Robert's Rules would solve some of
11 your convolutions.

12 MS. BOSSLEY: Yes. We keep trying
13 to follow Robert's Rules but, for some reason,
14 keep changing it. But it is a very good idea.
15 Thank you. Yes.

16 CO-CHAIR CONWAY: Okay. Jessica,
17 take it away.

18 MS. WEBER: All right. Importance
19 to measure and report high impact, performance
20 gap and evidence? It is a "Yes"/"No"
21 question. There should be 19 responses.
22 Janet?

1 MEMBER NAGAMINE: No.

2 MS. WEBER: Gina? Gina, would you
3 like to cast your vote for importance?

4 MEMBER PUGLIESE: Yes. I vote
5 yes.

6 MS. WEBER: Six yes, 15 no.

7 CO-CHAIR CONWAY: Okay. So shall
8 we keep --

9 MS. BOSSLEY: So now did everyone
10 agree you want to continue on to scientific
11 acceptability?

12 CO-CHAIR CONWAY: Yes.

13 MS. BOSSLEY: All right. So
14 scientific acceptability, then.

15 MS. WEBER: Scientific
16 acceptability, reliability and validity. It
17 is a "Yes"/"No" question. Janet?

18 MEMBER NAGAMINE: Yes.

19 MS. WEBER: Gina?

20 MEMBER PUGLIESE: Yes.

21 MS. WEBER: Nineteen yes, two no.

22 Usability: high, moderate, low,

1 or insufficient? Janet?

2 MEMBER NAGAMINE: Moderate.

3 MS. WEBER: Gina?

4 MEMBER PUGLIESE: Moderate.

5 MS. WEBER: Five high, ten
6 moderate, six low.

7 Feasibility: high, moderate, low,
8 or insufficient? Janet?

9 MEMBER NAGAMINE: Moderate.

10 MS. WEBER: Gina? Gina, would you
11 like to cast your vote?

12 MEMBER PUGLIESE: Moderate.

13 MS. WEBER: Fourteen high, five
14 moderate, two low.

15 CO-CHAIR CONWAY: Okay. Now, a
16 rules ruling.

17 MS. BOSSLEY: Right. So now I
18 think we need to go back. Can you go back to
19 the slide where it is reserve status? So,
20 again, what you are saying here is that you
21 know it didn't pass importance but you still
22 want to consider it for reserve status.

1 So I think for the purposes of
2 this, if everyone agrees, let's just use this
3 as you're recommending this measure for
4 endorsement as a reserve status measure. Does
5 that make sense to everyone? And then you are
6 done. We will go back and fix this. "Yes" or
7 "No"?

8 Patrick, yes?

9 DR. ROMANO: Question. Can you
10 just clarify what the implications are of
11 reserve status, what it means for the world of
12 --

13 MS. BOSSLEY: Right. So the
14 measure remains endorsed. So we don't really
15 categorize endorsement other than we do have
16 now two statuses. We don't know what to call
17 them other than that. Time-limited is where
18 measure meets everything but the reliability
19 and the validity. They haven't yet provided
20 that. And this one would be it's endorsed,
21 and it has a kind of asterisk. And it says
22 "reserve status." And then we explain what

1 that means.

2 Beyond that, we make no judgments
3 of how it is used or not, but our
4 recommendation is that shouldn't be the first
5 thing you are going to do. But you should
6 continue to monitor it and report that
7 occasionally. Does that make sense?

8 CO-CHAIR CONWAY: Well, based on
9 the voting, it would be valid and reliable but
10 not important to use regularly.

11 MS. BOSSLEY: Yes, exactly.

12 CO-CHAIR CONWAY: All right.
13 Jessica?

14 MS. WEBER: Endorsement for
15 reserve status, "Yes"/"No" question. We need
16 one more response. Go ahead and cast your
17 votes again.

18 MEMBER PUGLIESE: Jessica, a
19 question. How are people voting, electronic?

20 MS. WEBER: Yes. They are voting
21 electronically.

22 MEMBER PUGLIESE: I wondered how

1 that --

2 MS. WEBER: Sorry? Could you
3 repeat that?

4 MEMBER PUGLIESE: Do you see on
5 the screen how the votes are going? Does
6 everybody get a sense of how the group is
7 voting?

8 MS. WEBER: Not until it is cast.

9 MEMBER PUGLIESE: Okay.

10 MS. WEBER: And then I am reading
11 them off for the record. Janet, would you
12 like to cast your vote?

13 MEMBER NAGAMINE: Yes.

14 MS. WEBER: Gina?

15 MEMBER PUGLIESE: This is going on
16 reserve status?

17 MS. WEBER: Yes, whether you would
18 like it to go in reserve status.

19 MEMBER NAGAMINE: Yes.

20 MS. WEBER: Nineteen yes, one no.

21 CO-CHAIR CONWAY: Okay. And that
22 should do it.

1 MS. BOSSLEY: Right. So now we
2 did this for measure 0349.

3 CO-CHAIR CONWAY: That is the
4 adult measure.

5 MS. BOSSLEY: Right.

6 CO-CHAIR CONWAY: Is there any
7 sense? Would anybody like to debate the
8 pediatric one or would your votes be the same?

9 MEMBER QUIGLEY: Sorry. This was
10 the pediatric one, wasn't it?

11 CO-CHAIR CONWAY: No. Three
12 forty-nine is adult. Yes.

13 MEMBER McGIFFERT: Yes. Are there
14 any particular issues that are different in
15 the pediatric measure that the group
16 identified?

17 DR. ROMANO: No.

18 CO-CHAIR CONWAY: The only thing I
19 heard is even more rare in pediatrics.

20 DR. ROMANO: Correct.

21 CO-CHAIR CONWAY: So I am not
22 seeing anybody wanting to separately vote in

1 additional transfusion reactions. So we'll
2 consider the votes the same and the reserve
3 status decision the same.

4 MS. WEBER: Yes.

5 CO-CHAIR CONWAY: Wonderful. Do
6 you need a break or can we forge on? Yes. So
7 we'll forge on. All right. We'll next take
8 on 0419, "Documentation of Current Medications
9 in the Medical Record."

10 This comes from CMS. And
11 Christina is the spokesperson for the
12 workgroup or Tracy. Okay. Tracy. Sorry.

13 MEMBER WANG: Sure. Great.

14 0419: DOCUMENTATION OF CURRENT MEDICATIONS
15 IN THE MEDICAL RECORD.

16 CENTERS FOR MEDICARE & MEDICAID SERVICES.

17 MEMBER WANG: So this is a CMS
18 measure. We are looking at the proportion of
19 patients that are 18 years or older and have
20 a list of current medications. And that
21 includes prescription, over-the-counter,
22 herbals, vitamins, minerals, dietary

1 supplements, et cetera. And it is documented
2 by the provider.

3 And the documentation needs to
4 include four components: drug name, dosage,
5 frequency, and route. The exclusions are when
6 the patients refuse to participate or they
7 come into through emergency situations and
8 need immediate treatment or they are
9 cognitively impaired. So those are taken out.

10 This is a process measure. The
11 data is captured using administrative claims
12 and registries. And there is concern in our
13 discussion that G codes may not be used
14 consistently to reflect what is being
15 captured.

16 So in terms of importance, this
17 measure addresses medication safety. And that
18 is in outpatient settings. And the tie-in is
19 that if there is increased knowledge of the
20 patient's medication history, it will help
21 physicians make appropriate clinical
22 decisions. And it will lead to desired

1 outcomes in reducing adverse events.

2 In terms of the body of evidence,
3 the workgroup felt that it was kind of light.
4 So perhaps the developer if they are present
5 can expound on that a little bit.

6 In terms of the scientific
7 acceptability, this measure was previously
8 endorsed with the time limit to endorsement.
9 And so the developer did follow with a field
10 test done in two different ways. And there is
11 documentation alone which resulted in a
12 moderate reliability rating, and then there is
13 documentation, perhaps the verification
14 component, which they found was somewhat low
15 reliability.

16 So the quick question is, how
17 accurate is the documentation and coding
18 interpretation? And the developer did solicit
19 input from a technical expert panel. And it
20 concluded that the certain type of testing,
21 which involves documentation plus
22 verification, was very difficult to document.

1 And so the expert panel concluded that there
2 is faith in content validity. So we wanted to
3 make sure that is acceptable.

4 In terms of usability, the measure
5 is currently being used for public reporting
6 programs and quality improvement efforts.

7 And in terms of feasibility, data
8 is captured via claims. And the expert panel
9 also recommended changing the numerator to
10 documentation only since the documentation
11 plus verification, we had a low reliability
12 score.

13 I think that is pretty much it. I
14 didn't know if the other team members had any
15 additional inputs.

16 CO-CHAIR CONWAY: Others on the
17 workgroup?

18 MEMBER WANG: Chris?

19 MEMBER MICHALEK: I just want to
20 say just the whole medication reconciliation
21 process is there are so many errors related to
22 incomplete reconciliation. So I think we all

1 felt that this was really an important
2 measure.

3 We certainly see a lot of errors,
4 certainly more so on the inpatient side
5 because they are the errors that we see
6 through ISMP and through the PACERS Program.
7 So I think we kind of collectively all agreed
8 on the importance of it.

9 Personally I did have some
10 question about the quality of the
11 reconciliation, you know, coming from claims
12 data, that whole validity piece of are they
13 really doing the reconciliation the way we
14 would like them to do it in order to be
15 effective to prevent those errors that occur.
16 And when we make recommendations at ISMP, we
17 go well beyond what is even in here.

18 We ask our scripted questions. We
19 ask about drug-eluting implantable devices.
20 And we like to see that whole piece together
21 to avoid any of those events.

22 CO-CHAIR CONWAY: Before we get

1 too deep into this, why don't we just hear
2 from the measure developer? Don, do you --
3 there were some questions the workgroup had
4 posed to you all. Maybe you can answer those.

5 DR. WILSON: Sure. This is Don
6 Wilson with the Quality Insights team.

7 I think one of the issues that I
8 know people talked about was the impact of
9 this measure. And I think we provided some
10 literature. I think the Nazarel article that
11 I think we supplied to you really talks about
12 the effect of how actually medication
13 reconciliation in the outpatient environment
14 actually causes more deaths than it does even
15 in the inpatient world.

16 And I think it has been an area,
17 like you said, where the TEP has always been
18 emphasized on the inpatient arena but not
19 necessarily on the outpatient side.

20 I think the real gap in this
21 measure is the fact that in order to pass the
22 measure, you have to really not just document

1 the medication list and say that it's current,
2 but it is a matter of having the frequency
3 route accepted, having all four of those
4 elements present, which is really where I
5 think a lot of the gap occurs.

6 If you look at some of the
7 literature, the actual -- some of the articles
8 that we supplied have rates of something like
9 20 percent being documented when you really
10 look at all 4 of those factors being present.
11 And lots of times it is really the route and
12 the frequency that fall down. So I think
13 again it was a matter of really trying to get
14 that across that you really need all four of
15 those elements.

16 I think another area that -- and I
17 know we had a discussion about this in the
18 workgroup last week, but I think another
19 element that our TEP really felt important --
20 and when you look at the literature, I think
21 it really bears it out -- is that the
22 over-the-counters and the herbals are really

1 important to be included. And they are
2 frequently left out. But I think most of the
3 literature really supports the concept that
4 they really need to be included as well.

5 So I think that is another area
6 that we really need to raise the awareness
7 that that needs to happen and where there is
8 a significant gap.

9 Other questions?

10 CO-CHAIR CONWAY: Tracy, did that
11 answer the workgroup's set of questions?
12 Thank you.

13 Let's go around the table. Jason,
14 you can start.

15 MEMBER ADELMAN: Yes. I have a
16 couple of questions for Don. I don't
17 understand this measure multiple ways. So,
18 first of all, just simply the English language
19 of the numerator/denominator.

20 The numerator is current
21 medications, including name, dosage,
22 frequency, route, and route documented by the

1 provider. So for patient with seven meds,
2 from what the English says, that would be
3 seven medications.

4 And then the denominator is all
5 patients aged 18 years and older on date of
6 patient encounter. And so as they encounter
7 ER visits, hospital visits, outpatient visits,
8 so is it all the meds documented at every
9 encounter over every hospitalization? Is that
10 what it is?

11 DR. WILSON: This measure was
12 written actually for the PQRS program. So it
13 is really taking place in the ambulatory site.
14 So if you look at the -- it also talks about
15 the fact that the denominator is defined by
16 the codes. If you just look at the
17 denominator coding set and they are
18 essentially the outpatient kind of code. So
19 it really doesn't include inpatient or even
20 ER, as I recall. So, you know, it really
21 would be an outpatient visit.

22 MEMBER ADELMAN: You know, the

1 codes are a list of numbers. I don't know
2 enough to know what those numbers are. But
3 maybe so in the denominator statement, you
4 could just make it clear that this is for
5 outpatients.

6 And even that I don't understand
7 the validity of what's the difference if
8 somebody has two meds or seven meds. If this
9 is a quality measure and a patient comes in,
10 the provider writes nothing or writes down the
11 patient meds and this patient happens to be on
12 five meds, so that doctor gets credit five
13 times because the patient happened to be on
14 five meds?

15 DR. WILSON: The way that coding
16 is written is basically that in order to pass,
17 the physician has to write that these are the
18 current meds that the patient is on. And at
19 each visit, they have to document that these
20 are the current medications that the patient
21 is on.

22 MEMBER ADELMAN: Right.

1 DR. WILSON: That is per patient
2 or per visit.

3 MEMBER ADELMAN: The language can
4 be clarified to make it more like, you know,
5 documentation that a medical history was taken
6 and completed would be much more accurate than
7 the numerator being the current meds because
8 that is what it says. I mean, you can read
9 it.

10 And then the denominator I guess
11 you are saying is every encounter. It's not
12 the patients.

13 DR. WILSON: It's all the
14 outpatient encounters, right, for every
15 encounter for that patient, right, that that
16 patient is seen during the reporting period,
17 which is --

18 MEMBER ADELMAN: And then --

19 DR. WILSON: The current
20 medications are documented. I guess I am
21 still not quite understanding your point about
22 documenting versus the current medications.

1 MEMBER ADELMAN: I read the
2 numerator, Don. If you read it again -- and
3 I don't want to keep going over it, but I just
4 think it's -- I find it to be confusing. I
5 don't know if others agree, the way it is
6 written and what you are describing.

7 CO-CHAIR CONWAY: Thank you.

8 MEMBER ADELMAN: Sure.

9 CO-CHAIR CONWAY: Lisa?

10 MEMBER McGIFFERT: So I was
11 looking at the exceptions. And it looked like
12 -- oh, where is it -- one of the exceptions
13 was people who are cognitively impaired and no
14 representative. And I understand that that is
15 hard to document, but the target population
16 are elderly people who may be in that
17 situation. Does that create some kind of an
18 issue for the measure when you are eliminating
19 maybe a bunch of the population that you are
20 trying to target.

21 MEMBER QUIGLEY: Excuse me. The
22 target population is the entire adult

1 population, 18 and older.

2 MEMBER McGIFFERT: Well, I know,
3 but the target population is elderly. And I
4 read it somewhere --

5 DR. WILSON: I mean, I think the
6 measure --

7 MEMBER McGIFFERT: -- in your
8 testing, that you don't find that there are a
9 bunch of them that are not documented because
10 they are accepted because they some kind of
11 senility or dementia or something like that?

12 DR. WILSON: But, I mean, that is
13 actually an exclusion. If the patient is
14 cognitively impaired --

15 MEMBER McGIFFERT: Right.

16 DR. WILSON: -- and they can't
17 obviously give the history, then the provider
18 can --

19 MEMBER McGIFFERT: Right.

20 DR. WILSON: -- actually list that
21 as an exclusion if they aren't able to obtain
22 the --

1 MEMBER MCGIFFERT: Yes. Yes.

2 This concerns me that that is the population
3 that probably needs this the most. That is my
4 point.

5 DR. WILSON: Right. And I guess
6 the question is, how do you get at it, then?
7 You know, it's a matter of if the patient is
8 cognitively impaired, it can't actually give
9 the information, you know, I think it's a
10 dilemma for the provider for sure.

11 But at least we have documented
12 that whenever they can, they do get that
13 information from the patient or their
14 caregiver.

15 MEMBER MCGIFFERT: And my question
16 was, in the studies, did you find that that
17 excluded a significant number of people?

18 DR. HIBAY: My name's Sharon
19 Hibay. I am from Quality Insights.

20 Our finding is so the exclusions
21 reported just slightly over one percent of all
22 the population.

1 CO-CHAIR CONWAY: Jean?

2 MEMBER de LEON: I would ask that
3 you also put something in on the timing of the
4 medications. Some of them are very
5 self-limited. And to not know when a
6 medication was started, an antibiotic, for two
7 weeks and they're on it, they stop taking it
8 because they forgot to take it or they felt
9 better, then they started up again, if
10 something is time-limited, that it is
11 documented as well, so not just the name of
12 the medication and the dosage but it's for two
13 weeks or it's for a month and it started on a
14 particular date.

15 CO-CHAIR CONWAY: And, John, we'll
16 come up this side of the table.

17 MEMBER CLARKE: I'm a surgeon. So
18 excuse me for being stupid about pushing, but
19 it seems like what we are doing here is
20 verifying medication reconciliation by looking
21 at a list of medicines that the doctor says
22 that the patient has had and the doctor's

1 signature that this is the medicines that the
2 patient is on.

3 And we're concerned. We're going
4 to ding you if he doesn't capture the
5 medicines, all the medicines, that the patient
6 has. So I wonder how you find out what
7 medicines the doctor missed by looking at the
8 medication list.

9 CO-CHAIR CONWAY: Don, can you
10 answer that?

11 DR. WILSON: Again, I would think
12 it's a matter that the point of this measure
13 is to assure that on every single visit, the
14 provider actually does at least take the time
15 to document all of the current medications
16 that the patient is on, including dose,
17 frequency, route.

18 MEMBER CLARKE: Right. But this
19 happens to me every day in practice. I have
20 a patient comes into my office. And I say,
21 "Are you on any medications?"

22 "No," to which I say, "Do you have

1 any medical problems?"

2 She says, "No."

3 I examine her. She has pitting
4 edema of the ankles, three plus. I say, "You
5 have big, swollen ankles."

6 She says, "Yes. I have high blood
7 pressure."

8 And I said, "Do you take any
9 medicines?"

10 And she says, "Yes. I take a
11 blood pressure medicine."

12 So if I didn't go back and I had
13 just written down what she said, "No
14 medications," you would never know. I would
15 never know that she was on a high blood
16 pressure pill without examining her, which is
17 an ancient Druid custom that I still practice.
18 And you would never know because you are using
19 my documentation to evaluate whether or not I
20 am picking up the medications.

21 DR. GREEN: So hi. Sorry. I am
22 Dan Green. I am a medical officer at CMS. I

1 worked with Don in Pennsylvania in developing
2 the measure.

3 As you know, we use this in a
4 pay-for-reporting program currently, which
5 will be transitioned to a pay-for-performance
6 program. I am sure as a practicing physician
7 you can imagine myself -- I am an ob/gyn by
8 training. There are numerous times that we
9 get notes from people where the medications
10 are not fully documented.

11 And you are correct in that we
12 won't be going back behind every single
13 physician or other provider to see whether or
14 not the medications were documented in an
15 accurate fashion.

16 However, we feel this is an
17 important concept. And the idea here is to
18 encourage all professionals who are in contact
19 with a patient each time to document the
20 medication. So if they are prescribing some
21 treatment, they at least have an idea that
22 there may be some contraindication, some drug

1 interaction, or some other thing that they
2 might consider when they are recommending a
3 particular treatment for a given patient.

4 I am sure those on the CSAC here
5 that are clinicians can certainly appreciate
6 and have seen personally where patients have
7 not had their medications documented. It
8 sounds like a simple thing.

9 And I am not into low bar measures
10 in general, but, unfortunately, the gap for
11 this process, as simple as it is, exists. And
12 this is one thing we are trying to encourage
13 physicians and other eligible --

14 MEMBER CLARKE: There's no doubt
15 it exists, but how do you capture the fact
16 that the doctor didn't get the medication,
17 didn't get all of the medications?

18 DR. GREEN: So that's a great
19 question, but I would suggest -- and I am not
20 saying that this is a great answer to your
21 question. I would suggest that that is true
22 basically of any of the measures that are

1 self-reported and that are not either coming
2 directly from an electronic health record.
3 And even then there could be errors in the
4 system because it is only as good as the
5 person inputting the information.

6 But, you know, all the measures
7 that we had, did you give an antibiotic before
8 you operated on a patient, that is a
9 self-reported thing. How do we know that the
10 antibiotic, in fact, was given? We only know
11 by the doctor --

12 MEMBER CLARKE: Yes, but at least
13 in that case, the doctor wasn't -- maybe I'm
14 being more pay care, but you went to ding me
15 if I didn't put on my record that the patient
16 was on an antihypertensive.

17 You look at my record. My record
18 does not show that the patient is on
19 antihypertensive. How do you ding me?

20 DR. GREEN: We would "ding you,"
21 basically how you report the measure, same way
22 we would ding you in the penicillin thing. If

1 you told us you reported penicillin, we can't
2 possibly nor I don't think any quality
3 program, be it CMS, be it any program, go
4 behind and say, "You know what? Did Dr.
5 Clarke really prescribe the antibiotic for
6 this particular patient?" If a doctor says
7 that he or she document the medications in the
8 record to the best of his or her ability --
9 and, again, it's --

10 MEMBER CLARKE: Let me try to
11 rephrase this. How do you know that i.e., I
12 asked the question "Are you on an
13 antihypertensive?" and the patient said, "No"
14 or that I never asked the question?

15 DR. GREEN: What we would know by
16 you telling us that you documented the
17 medications in the record is that you asked
18 the patient for all the medications he or she
19 was on. That's what we would know.

20 CO-CHAIR CONWAY: Yes. John, let
21 me try and help. And I want to go back to
22 Jason's question and get this clarified. Don,

1 could you? Maybe people here aren't familiar
2 with G codes. Could we just go through the
3 mechanics here? Is this a single G code
4 checkbox where the doctor said, "I created a
5 medication list" or is it more complicated
6 than that?

7 DR. WILSON: If you look at the --
8 I don't know if you guys have the measure
9 specs or not, but there are three G codes for
10 this measure as it is currently configured.
11 So basically -- and the way it is done through
12 the claims reporting for PQRS is the physician
13 actually has to append one of these G codes to
14 their claim submission.

15 CO-CHAIR CONWAY: Which page are
16 you on?

17 MS. BOSSLEY: It's on page 6 of
18 the form.

19 CO-CHAIR CONWAY: Okay.

20 MS. BOSSLEY: And in the .pdf,
21 it's page 49 if you look at the workgroup.

22 DR. WILSON: So if the physician

1 did indeed create a list of current
2 medications for that visit, then they would
3 report G-8427. And the definition of that G
4 code says, "List of current medications,
5 including prescription, over-the-counter,
6 herbals, vitamins supplements, or documented
7 by the provider, including drug name, dosage,
8 frequency, and route."

9 So, again, it's a matter of the
10 measure itself -- and I understand where you
11 are going with this. It's like how do you
12 really know that that is the accurate list or
13 that -- but I think the point of the measure
14 is, you know, right now doctors when you look
15 at -- and other providers, like I said, in the
16 couple of studies we have, only like 20
17 percent of the time did they even ask or
18 document that they had checked the current
19 list. So we have to get them to start trying
20 to verify that they at least asked and tried
21 to document this is the current list, as I
22 understand it, you know, for this visit.

1 I think that is a whole different
2 set of issues, you know, around the current.
3 And, really, what can you really hold the
4 provider to at that moment in the world once
5 hopefully we get the electronic medical
6 records and have health information exchange,
7 et cetera. That is obviously the big benefit
8 that that is going to provide, you know, the
9 provider can get that information, but right
10 now, that is one of the major problems with
11 our current fragmented health care system.
12 Lots of times the patient is your only source
13 of information. So yeah, exactly.

14 So, I mean, I think that that is
15 case in point for why we need better health
16 information technology. But for at least for
17 now, I think if we can at least just
18 consistently get providers to say that every
19 time they see a patient they are document, as
20 I understand it, this is the current meds,
21 including over-the-counters, et cetera, that
22 the patient is on. And I am taking that into

1 account as I am creating my treatment plan.

2 CO-CHAIR CONWAY: Okay. Let's
3 continue on up the table. Is Patrician next?

4 MEMBER QUIGLEY: Thank you, Dr.
5 Conway. Was that Janet or --

6 CO-CHAIR CONWAY: Janet, we'll get
7 to the phone in a minute.

8 MEMBER QUIGLEY: Thank you, Dr.
9 Conway.

10 I would just like to share that I
11 was one of the members of this workgroup. And
12 my scores aren't up there, but I did enter
13 them into the database. But I was one of the
14 people that had multiple difficulties with
15 this quality indicator.

16 And part of my difficulty is that
17 it did include everything in terms of
18 medications. It was even the over-the-counter
19 meds and the herbals and the vitamins. And we
20 had this discussion on our workgroup. And I
21 talked about it with a couple of the
22 physicians that I work with. And I am a

1 prescribing provider. To be able to include
2 all of this as medications was one of the
3 issues that we had. And was it really
4 realistic?

5 But what I learned in the
6 workgroup discussion and having our measure
7 stewards on our call is that for this to pass,
8 it has to be the current list of meds. And
9 you have to make sure that you have addressed
10 the name, the dose, the frequency, and the
11 route. And, even if you can't get that, every
12 time you see a patient when they come into
13 your clinic or in the ambulatory area is you
14 have to write that the patient doesn't know.

15 So, for example, they're on a
16 dietary supplement and they don't even
17 remember the frequency that they are taking
18 it. You have to be able to write that to be
19 able to pass. This is what I understood on
20 the conference call.

21 So I have issues with this as, you
22 know, if this is really valid and reliable and

1 this could truly be an indicator to be able to
2 indicate medication safety in that regard.

3 CO-CHAIR CONWAY: Okay. Thank
4 you.

5 And Vallire?

6 MEMBER HOOPER: I think I am
7 getting more confused as the questions go
8 around. I am confused as to if this is
9 self-reported by the provider, "Yes, I did the
10 reconciliation" or "No, I did not."

11 CO-CHAIR CONWAY: Yes, it is.

12 MEMBER HOOPER: Okay. And in that
13 case, what is the current compliance level
14 because this is a maintenance set? And do you
15 do any checks where we go back and see? This
16 seems right now to be a very easy checklist,
17 "Yes, I did it" or "No, I did not." It's kind
18 of like the education measure yesterday, "Yes,
19 I did it" or "No, I did not."

20 When you talk about pre-op
21 antibiotics in a hospital, there are
22 electronic components that you can pull from

1 the chart to document that it was prescribed
2 and it was given.

3 So I am just a little bit confused
4 as to how we actually know this was truly done
5 and all of the elements were truly accounted
6 for.

7 MEMBER QUIGLEY: Dr. Conway, my
8 understanding is that for this to pass, all of
9 the elements of the medication have to have
10 been reviewed. For this to pass and the
11 numerator, it had to include the dose of
12 frequent --

13 MEMBER HOOPER: So how do the --

14 MEMBER QUIGLEY: Right. It's not
15 just a simple "Yes" or "No" for medication --

16 DR. WILSON: I can maybe provide
17 some clarity with that. Again, it is a matter
18 of, as it is currently being operationalized
19 in the PQRS system, it is a self-reported
20 measure.

21 But, as with all measures in the
22 PQRS program, physicians are always aware that

1 they could be audited. And when we do our
2 testing -- and we can talk about the testing
3 -- that is literally what we do when we pull
4 the charts is we want to see documentation.

5 If the provider reported that G
6 code that they indeed did it, then we
7 requested a series of records randomly pulled
8 across the country and assess how often there
9 is documentation in the medical record that
10 supports that they indeed did do it if they
11 reported that code.

12 MEMBER QUIGLEY: What are the
13 findings?

14 DR. WILSON: What was that?

15 MEMBER QUIGLEY: What are the
16 findings?

17 DR. WILSON: The findings were the
18 reliability. If we just looked at at
19 documentation alone, the statistics -- it was
20 about 78 percent of the time where we really
21 felt that there was documentation to support
22 it that they had done it.

1 So it was felt to be reliable and
2 that providers were reliably reporting, you
3 know, accurately whether they -- in other
4 words, there was documentation in the medical
5 record to support the fact that they had done
6 it if they reported that they had.

7 MEMBER THRAEN: The ones --

8 MS. BOSSLEY: Iona?

9 MEMBER THRAEN: The ones that were
10 reported --

11 MS. BOSSLEY: Iona?

12 MEMBER PUGLIESE: Can I make a
13 comment?

14 CO-CHAIR CONWAY: Yes. We're
15 going to do Carol, Charlotte, and Janet.

16 MEMBER PUGLIESE: And Gina.

17 CO-CHAIR CONWAY: Okay. And Gina.

18 MEMBER THRAEN: The ones that
19 they're reporting that they did not do it,
20 what was the finding for that?

21 DR. WILSON: The ones who reported
22 they did not do it? First off, that was a

1 fairly small number because, again, I think
2 the thing that you have to understand is the
3 way this program is currently set up is
4 voluntary reporting.

5 So it is unlikely in all honesty
6 that a provider is going to report this
7 measure if they didn't really do it, you know,
8 what I mean, if they are not complying because
9 it is voluntary reporting.

10 But the intent, though, is
11 eventually it won't be that way, you know,
12 that these measures will evolve into this
13 point where this will be into a
14 pay-for-performance kind of an initiative,
15 where it won't matter and it may become
16 mandatory.

17 But for right now the data you
18 have -- and I think you always have to
19 remember that in all the data that when we get
20 down into the testing data are looking at some
21 of the prevalence kinds of how it was reported
22 that this is really sort of a -- it's a biased

1 sample because you are really only looking at
2 physicians who elected to voluntarily report
3 this measure. So I don't know if I answered
4 your question.

5 MEMBER THRAEN: Okay. So just so
6 I understand, of those that agreed to report,
7 78 percent compliance with the documentation,
8 agreement between "I did this" and there is
9 documentation in the record to support it.

10 You don't have a sense of who
11 chose not to report. So you don't know how
12 big it is. You know, is this like
13 representing one percent, 2 percent, 30
14 percent, 100 percent of your physicians? So
15 you don't have any sense of that, right?

16 DR. WILSON: I don't think we have
17 a number as far as who chose not to report the
18 measure because, again, in the PQRS Program,
19 if you understand the way it works, physician
20 can pick three measures out of the total cadre
21 of 200 measures that they want to report on.
22 And they can get a performance incentive or an

1 incentive just based on actually reporting
2 because, again, the whole impact right now for
3 the PQRS Program is just to get physicians in
4 the mode of starting to report data, you know,
5 with the idea that it is going to transition
6 further down the road.

7 CO-CHAIR CONWAY: Okay. Now, I
8 know there is a lot of enthusiasm over it, but
9 let's proceed in order. We'll go up the left
10 side of the table, to the phone, and then down
11 the right side. So Carol is next.

12 MEMBER KEMPER: Okay. Thank you.

13 Just to preface, I would say I
14 think this is a really important process. And
15 it's one that we have struggled with. And I
16 think someone mentioned thereabout that it is
17 deceptively simple. And I would agree with
18 that. I mean, we have struggled with this
19 process on an inpatient and ambulatory side
20 within our organization.

21 But I think that what is really
22 important to kind of echo what Jason said. I

1 still am not completely clear on the measure.
2 And so I think that needs to be refined.

3 I'm still unclear if the code is
4 each visit. So each visit do I assign that
5 code or do I assign that code for each
6 medication because it looks here almost as if
7 you would assign it for each medication so I
8 could see that all of those components were
9 completed.

10 So that I think just needs to be
11 more clearly written because I think you are
12 going to get varying results if you keep it
13 this way.

14 CO-CHAIR CONWAY: It's each visit.
15 Physicians here probably are familiar with G
16 codes. It's each visit you need to check
17 certain boxes.

18 Charlotte?

19 MEMBER ALEXANDER: In just
20 response to that, maybe even adding something
21 like "a list" at the preface would clarify it.

22 I have been using this measure for

1 a while. And I have got several observations.
2 Lisa, when you were concerned about the
3 elderly and that that was the one that is the
4 most important, it takes a huge amount of time
5 in my office, but if we can find the pharmacy
6 that they used, we can call the pharmacy.
7 Their list of meds doesn't pick up everything
8 if they have used more than one pharmacy.

9 It is an effort. And I have to
10 say that this reporting mechanism has given
11 validity to my office staff more than my just
12 asking them to do that. Now that we have to
13 report it, I get more buy-in. It helps me a
14 great deal because I tend to pick up a little
15 bit better when people are on an anticoagulant
16 therapy, which for me as a therapist or a
17 surgeon is an important thing.

18 I fall into the same problems that
19 John does in that people don't tell me what
20 medicine they are on. If they are a diabetic,
21 they just assume I know they are on insulin.
22 They won't tell me they are on insulin. And

1 so you do have to do some querying to fill it
2 out.

3 The challenge in my mind is how we
4 pick up whether we are really reconciling. If
5 I have someone come in that is on two
6 anti-inflammatories, I am very comfortable
7 saying you can't take these two at the same
8 time and trying to reconcile that. I am not
9 comfortable when they are coming in in on
10 three or four blood pressure medicines or
11 heart medicines saying, "You are on too much
12 medicine."

13 And I think the goal in the long
14 run is that we are giving safer care and that
15 we are really reconciling the meds. And so I
16 don't know how we start progressing to go to
17 that point. It may be the list is the start,
18 that we are actually just looking at it, and
19 that we can hopefully move forward toward
20 better care.

21 CO-CHAIR CONWAY: Okay. Thank
22 you.

1 Janet?

2 MEMBER NAGAMINE: Thank you. So I
3 just want to echo what was just said about the
4 list being the start. There is nothing that
5 says that this list is going to be accurate.
6 And there are different levels of effort.

7 So, that said, I completely agree
8 that we should set the expectation that we
9 should have an accurate meds list on the
10 outpatient side.

11 I also, though, wanted
12 clarification about the measure
13 specifications. Does this apply to the
14 primary care physician or any physician? So
15 if you get referred to GI or a subspecialist,
16 is it the same expectation for the
17 subspecialist that views it maybe once or
18 twice or does this apply only to the primary
19 care physician?

20 CO-CHAIR CONWAY: Don?

21 DR. WILSON: It applies to any
22 physician. So, again, if you would look at

1 the codes in the back -- and I understand if
2 most of you are like me, you don't really have
3 these things memorized like some people do
4 that are coders, but it would be anybody that
5 bills those codes.

6 And so the E&M codes that are
7 listed are the same E&M codes that a primary
8 care physician bills as specialists also bills
9 those codes as well because, again, when you
10 really look at the literature, I think it is
11 very much emphasized that every provider that
12 sees a patient really should have a current
13 list of medications.

14 MEMBER NAGAMINE: In theory, I
15 completely agree with you. I am an internist.
16 And this is one of my pet peeves. I deal with
17 this every day. It is either an incomplete
18 list or the wrong dose or someone is admitted
19 to the hospital because one guy gave him
20 Metoprolol, another gave Atenolol and, gee,
21 they're bradycardic now --

22 DR. WILSON: Right.

1 MEMBER NAGAMINE: -- or they have
2 Lasix and hydrochlorothiazide and they're now
3 in renal failure.

4 So I just don't know how to
5 operationalize this measure in a way that is
6 realistic, but, for example, if someone comes
7 into their primary care physician for a rash
8 and you have given hydrocortisone or some
9 cream, do you really need to spend the time to
10 go over their ten meds, you know, because I
11 know how long that takes.

12 I do think it is important in
13 certain situations to, critically important
14 to, have that list, but I don't know that in
15 everyday outpatient practice that this would
16 be realistic for an internist whose patients
17 are very old and on -- that's just my
18 hesitation there.

19 CO-CHAIR CONWAY: Okay. Anything
20 else?

21 DR. GREEN: Hi, Janet. May I, Dr.
22 Conway, make a comment?

1 CO-CHAIR CONWAY: Sure.

2 DR. GREEN: Hi, Janet. This is
3 Dan Green. I think you bring up a great
4 point. I mean, obviously, you know, with
5 internists, their time is being squeezed more
6 and more. I would suggest, though, that as
7 e-prescribing is further adopted, you know,
8 one of the components, even, in the measure
9 that you all have endorsed is the ability for
10 the eRx program to actually query the pharmacy
11 benefit manager, which would, in turn -- the
12 payer basically, which would, in turn, be able
13 to help provide a list of medications that the
14 person is on.

15 I would suggest, I mean,
16 hydrocortisone, probably not that big a deal,
17 but for many other medications that internists
18 would prescribe, you know, after a short
19 visit, like somebody perhaps on an antibiotic
20 or whatever coming in for an upper respiratory
21 infection, obviously the medications would be
22 important because of the potential drug

1 interactions that could be associated with
2 that.

3 So I think this will work itself
4 out in terms of being able to get a more
5 accurate list, like Charlotte was talking
6 about and Dr. Clarke was also mentioning, but
7 I also think that as the eRx is further
8 adopted. So I can appreciate your comment,
9 though

10 CO-CHAIR CONWAY: On that point,
11 let me just try to clarify something. This
12 doesn't ensure med reconciliation. This just
13 states that you maintained a list, correct,
14 Don?

15 DR. WILSON: That's correct. Can
16 I just say one other quick thing before we
17 move ahead? We just realized it. I think one
18 of the reasons why there may be some confusion
19 is there is a set of instructions that are
20 listed in the measure specs that are out on
21 the PQRS side that providers see when they
22 report this measure. And apparently that's

1 not on the NQF form.

2 If I can just quickly read,
3 basically it says, "This measure is to be
4 reported at each visit occurring during the
5 reporting period for patients seen during the
6 reporting period." And it is intended to
7 determine whether or not documentation of
8 current medication lists occurred for all
9 patients age 18 years and older.

10 And it goes on to say, "This
11 measure may be reported by eligible
12 professionals, who perform the quality actions
13 described in the measure based on the services
14 provided in the denominator coding."

15 So I think, again, maybe that was
16 why there was some confusion about the fact
17 that it's reported every time.

18 And, again, to go back to your
19 question about whether you report the G code
20 for every medication, again, if you would look
21 at the -- and maybe we need to -- because if
22 was confusing to you, then perhaps it is

1 confusing to others.

2 But if you would look at the G
3 code, it basically says you report the G code
4 on each visit if a list of current medications
5 were documented by the provider. So the
6 assumption is in order to be able to report
7 the measure, the G code, you have to have the
8 complete list there and all the four elements
9 for each drug or over the counter is actually
10 listed as well.

11 So you have to be compliant with
12 all of that in order to report, and you just
13 report one code. But, again, if you feel that
14 there is some confusion --

15 CO-CHAIR CONWAY: Okay. Gina?

16 MEMBER PUGLIESE: Oh, yes. I
17 don't really have anything to add. I think it
18 is an important measure as one of the
19 important safety measures, even though we
20 justify and make sure that it's accurate and
21 whatnot, that they're using to collect it, I
22 think that it's important to keep. And I

1 think that the -- I think that we can at least
2 find out what some of the issues are.

3 CO-CHAIR CONWAY: Okay. Thank
4 you.

5 Turn to the right.

6 MEMBER LAWLESS: Okay. A couple
7 of things. The emotionality created by this
8 measure is just short of the emotionality
9 that's going to be created when you have a
10 handoff measure.

11 (Laughter.)

12 MEMBER LAWLESS: So I am just
13 preparing you ahead of time. Is there a
14 category called "Strategic Measure. Don't
15 worry about it. Please work on progress.
16 Don't worry about perfection" category that
17 you can put in place?

18 This has been an area of my
19 research interest. We just published a lot of
20 the pediatric results on this. So I can tell
21 you that from a system standpoint, we have it
22 in a fully electronic system. We compensate

1 for our providers for doing medication
2 reconciliation.

3 We have ER, outpatient, inpatient,
4 the whole nine, the whole system that way, any
5 prescribing rates up in the 79 percent range.
6 Okay? So we report 95 percent.

7 The accuracy I'm telling you, that
8 when we go back and look, somebody does med
9 rec. They try. When you then go back and you
10 make calls to families and say, "Bring your
11 medicines in now," 50 percent of the time the
12 families get it right. So we ask them to
13 bring their medicines in because we don't
14 trust you. So we now tell the providers,
15 "Just list your medicines. Don't worry about
16 dose, dosage, and everything else unless you
17 actually have the medicines in place.

18 So now if you take that, so take
19 your 90 percent rate, cut it in half because
20 the families don't get it right, and then you
21 take that and you look at the sig statements,
22 which is the written part of the statement,

1 which is not granular, there is about a 12
2 percent inherent error in that.

3 So now I am about 37 percent
4 accurate in terms of a medication list. And
5 that's even with the electronic systems. But
6 it is an unbelievably important issue.

7 So I would say you have got to
8 start somewhere with it and do it. And that
9 is why I say strategic measure, what do you
10 really want to accomplish at first? Maybe it
11 is getting duplicative medicines, which you
12 can get from claims data. You are on the
13 thiazide, and you are on the this. You know,
14 do you really want to be on both these
15 medicines because they interact with each
16 other?

17 It almost I guess strategic focus,
18 if we are going to start this first and then
19 this one and this one and/or put out a call
20 for proposals to people and say, "Who has got
21 it right? Where in this country are they
22 doing this correctly?" because otherwise what

1 you are doing, you are throwing darts at a
2 problem which is crucial, but you are
3 contributing to it.

4 You are saying to people, "You do"
5 this, this, this, this. Nobody is comfortable
6 with it. But is there any place you can point
7 to in the country that is actually doing it
8 right?"

9 Right now this is a measure that
10 is unbelievably important, and it is really
11 the heart. But it is just not telling you a
12 story.

13 MS. BOSSLEY: Just hit the mute.
14 It's a mute button there. Dr. Green?

15 DR. GREEN: Sorry. I'm only an
16 ob/gyn. If I were like ID or something, I
17 would have figured it out right away.

18 I think your points are very
19 well-taken. To my knowledge, I don't know of
20 any place in the country that has got it
21 perfect. I would think that Kaiser is
22 probably as close to perfect as you can get

1 because it's a closed system, but even Kaiser
2 has patients that are taking botanicals.

3 And I can tell you, especially as
4 an ob/gyn, you know, with some of their herbal
5 supplements and things like that or the
6 compounded pharmacies where people go, you
7 know, because of the preeminent gynecologist,
8 Dr. Suzanne Somers, who advocates these
9 bioidentical hormones -- excuse me. I'm
10 sorry. Did that actually come out on the
11 mike? But, putting that aside --

12 PARTICIPANT: But she looks good.

13 DR. GREEN: She does look very
14 good. She looks great. But, in any case, you
15 have patients that are taking these kinds of
16 things -- and you are not going to capture
17 that, obviously, even from a system such as
18 Kaiser's.

19 But I think your initial point was
20 probably the most important point. And that
21 is we have got to start somewhere. You have
22 too many health care providers that are not

1 even making an attempt to document the
2 patients' medications. And until that is
3 done, you know, even if -- let's say you're
4 using your numbers. Let's say it's even 20
5 percent, less than the 37 percent you said.

6 If there's one out of five
7 medications that the patient is on, that's
8 still better than zero out of five because if
9 that particular medication is going to
10 interact with the other medication that I am
11 going to prescribe, okay. I happen to have
12 gotten lucky, but I've gotten somewhere. But
13 if I haven't even asked, you know, the horse
14 is out of the barn. And if the patient has a
15 drug interaction, then, you know, we can be
16 discussing the untoward effects for the
17 patient in the population.

18 MEMBER LAWLESS: See, that's why
19 I'm saying maybe the suggestion would be to
20 have someone outline the whole process. You
21 know, the idealized process is this, the whole
22 soup to nuts through it. And then you say

1 component pieces of it, and you say, "We're
2 working on this piece, this piece that fits
3 into the organized hole" because what it
4 looked like is we have thrown out med rec out
5 there as a -- which is good. And then people
6 are interpreting it or people are finding now
7 the holes, but we just have to --

8 DR. GREEN: You know, I think we
9 would all, especially you guys here, agree
10 that quality reporting and measures are
11 important, obviously, like with PQRS. And I'm
12 not saying that that is the be all and the end
13 all because we know that it is not. But it
14 was a start and to get doctors in the habit of
15 reporting quality measures.

16 Is it perfect? No. Do we pay
17 them on performance at this point? No. We
18 pay them simply for reporting. So it was a
19 start to get doctors to change behavior in
20 terms of, hey, now I've got to send some
21 information in.

22 It seems like some of these

1 measures are easy, but, again, it's a start
2 and the same thing I would argue with the
3 medication reconciliation. Can there be
4 improvements to the measure? I hope that
5 there are improvements.

6 Again, even if we get to the PBM
7 thing, the pharmacy benefit manager I was
8 talking about with the e-prescribing, that is
9 still not going to give us 100 percent
10 because, as you know, patients use these
11 herbals and botanicals and, you know, the
12 health food store and all this kind of stuff.
13 And some of them are embarrassed to tell their
14 traditional medical person that they are
15 actually using them.

16 So we may never get to 100
17 percent. But by virtue of not being able to
18 get to 100 percent doesn't mean we shouldn't
19 start somewhere and make an effort.

20 So thank you for that opportunity
21 to speak.

22 CO-CHAIR CONWAY: Jason?

1 MEMBER ADELMAN: Just I'm an
2 inpatient provider. I don't see outpatients.
3 I haven't used G codes. I just want to make
4 sure I understand this.

5 You are saying that when a
6 provider sees a patient as a outpatient, they
7 fill out a code to generate a bill. And there
8 is a G code, where they are attesting to the
9 fact that they took a current list of
10 medications and that is what this is
11 capturing.

12 So if Dr. Clarke sees a patient in
13 his office, as part of generating a bill, even
14 though he might not have gotten the exact --
15 because the patient will attest to the fact
16 that he got a current list.

17 DR. WILSON: Yes.

18 MEMBER ADELMAN: And, you know,
19 the Joint Commission had a med rec rule. And
20 then it disappeared for two years, went on
21 hold. And then it came back. And they added
22 language like, you know, "We made a reasonable

1 effort because we realize it is impossible."

2 But I guess that language isn't in
3 the code itself. It doesn't say, "We made a
4 reasonable effort to get a complete list." It
5 just says I've got a -- so you have no choice
6 to either say you did it or you didn't do it,
7 even though the truth is you made a reasonable
8 effort. You didn't call the patient's
9 pharmacy and check or the patient's daughter
10 and check. But I have that right. Okay.

11 And so because of that, then, this
12 is those attestations because I was going to
13 say yesterday we looked at a DVT prophylaxis
14 measure. And it just said DVT prophylaxis was
15 done or documentation why it wasn't, but it
16 didn't say the accurate DVT prophylaxis, just
17 that it was done. And the way you described
18 it was that we captured some med list. We are
19 not so concerned about the accuracy. That's
20 a first step in a process.

21 And so I would say change the
22 language to -- we just captured a list, not

1 the actual list, but because you are relying
2 on that the physician attested to the fact in
3 their bill that it was an accurate list, that
4 is why we are going with this.

5 I understand I think more than I
6 did before.

7 DR. WILSON: I think understand
8 what you are saying. And I wasn't here
9 yesterday for the DVT prophylaxis piece, but
10 I am sure you have probably looked at all of
11 the DVT measures. And, as you know, that is
12 the first measure sort of in a set.

13 The first thing is, did you do it
14 or not? But then there are subsequent
15 measures in the hospital reporting program,
16 for instance, that looks at, did you do the
17 right one, and did you do it in a timely way,
18 and that sort of thing. So it is kind of like
19 a group of measures.

20 And I would anticipate that
21 eventually, especially as we get more into
22 electronic health records, et cetera, we will

1 be able to have more sophisticated measures in
2 the outpatient world. And I am sure it will
3 come out through meaningful use. You know,
4 there is going to be better med rec done
5 through the EMRs.

6 MEMBER ADELMAN: I have a better
7 understanding of what the intention is. I
8 still think the language can be cleaned up a
9 little bit to make it more understandable.

10 DR. WILSON: Okay.

11 CO-CHAIR CONWAY: Mary?

12 MEMBER SIEGGREEN: I just wanted
13 to comment on how important I think this is.
14 I work in an academic medical center. And
15 before we had med reconciliation, we had
16 residents who would discharge the patients on
17 all the meds that we put them on in our
18 hospital. And our hospital formulary carries
19 different medications from what they were on
20 before. And they also put at the bottom,
21 "Resume all home meds."

22 So when the patient got to us in

1 the office, it was like you would look at the
2 medications. If you did look at the
3 medication list, you would get chest pain
4 right there.

5 I think, even if we can begin
6 something like this so you're looking at this
7 duplication, it is a huge safety effort and a
8 change. And I think it is really critical for
9 those patients, whether or not you are the
10 prescriber of these medications. But in our
11 practice, we prescribe things like pain
12 medication and antibiotics a lot.

13 So it is really important to know
14 what all the patient is on and also
15 anticoagulants but also all those other things
16 that you might have in combination with it.

17 CO-CHAIR CONWAY: Jean?

18 MEMBER de LEON: I just wanted to
19 point out there is a very big indirect benefit
20 just by having asked to make a list, whether
21 I have got the list right or not. I see a lot
22 of geriatric. I probably don't have it

1 exactly right.

2 But in some ways, I am probably
3 more correct than the pharmacy because I have
4 asked the patient. So now they are going to
5 tell me, "Well, yeah. But I don't really take
6 it like that" or "I don't take this one at
7 all" or "I only take this once a week" or "I
8 only take this one when I notice I have
9 swelling." So I get a much more accurate
10 picture of what the patient is doing.

11 And because I asked, now they are
12 actually being a little more forthright about
13 what they are taking or how they are taking it
14 because they feel that it is going to impact
15 my evaluation that day.

16 So there is a huge indirect
17 benefit to just asking for the list, whether
18 it is correct or not.

19 CO-CHAIR CONWAY: For the next
20 loop around, maybe we could focus some of
21 those new questions or clarifications that I
22 will cover.

1 John?

2 MEMBER CLARKE: Thank you.

3 I agree that I think this is an
4 important concept, particularly the herbals,
5 but I have concerns because it seems to be a
6 crude measure of a poorly done process.

7 And so the point of the National
8 Quality Forum is to come up with quality
9 measures. And I think that quality measures
10 could be interpreted two ways: measures of
11 quality and quality measures of quality. And
12 I wonder if we are not just premature in
13 tackling this problem with a crude measure of
14 a poorly done process.

15 And it might be better to defer
16 this kind of reconciliation until we can, in
17 fact, correctly measure true reconciliation
18 with deferring this until after we have the
19 kind of prescribing that would allow us to do
20 this properly, rather than the way it is being
21 proposed right now.

22 CO-CHAIR CONWAY: Okay. Thanks.

1 Tracy?

2 MEMBER WANG: I have a question
3 regarding that mode or criteria. So if I
4 understand this correctly, it is a way of
5 looking -- the numerator the way it is
6 written, it is looking for both documentation
7 plus verification. But your field testing
8 results show that the reliability is only
9 about 22 percent. Am I interpreting
10 correctly?

11 And so it also seems like when you
12 consulted the technical expert panel, the
13 recommendation seems to be moving to a
14 different numerator code. So when we are
15 voting and dosing this metric, are we voting
16 with the previous for the way it is written
17 currently or are we moving into the new
18 recommendation made by the Committee?

19 CO-CHAIR CONWAY: Don?

20 DR. WILSON: The original measure
21 did say documentation and verification, that
22 the meds have been actually verified by the

1 provider, not just the fact that he had
2 documented a current list.

3 As you correctly point out, when
4 we did our testing on the measure and actually
5 requested 500 or so charts and got them in and
6 looked at it, it was the providers who
7 reported that they were compliant with the
8 measure.

9 The consistency, as we have talked
10 about already with the documentation piece
11 that they had that indeed the current
12 medications were documented was high. The
13 part that was not reliable was that the
14 abstracters who went and tried to verify this
15 couldn't really meet the criteria of saying
16 that the provider had gone an extra step in
17 saying these were verified or with the
18 patient.

19 And when we went back to the TEP
20 panel, they really felt that that was inherent
21 in the measure, that if you actually obtained
22 a list from the patient or their caregiver

1 during their visit, that that verification
2 piece was really an inherent part of that.
3 And, therefore, we didn't need to actually
4 have that be sort of a separate piece that
5 needed to be documented.

6 So with our last iteration of the
7 measure, we actually took the verification
8 statement out and just basically say now that
9 the current medications have to be documented
10 at the time of the visit.

11 Does that answer your question,
12 Tracy?

13 CO-CHAIR CONWAY: Okay. Any other
14 questions that people need to clarify this
15 measure? I'm sorry? What? Yes?

16 DR. HIBAY: Again Sharon Hibay. I
17 would just like to make a couple of comments
18 on some information that was shared.

19 There was a question about
20 potentially deferring this measure this time.
21 And I just would like to put out my thoughts
22 on that that when you look at this, we have

1 talked about this medication reconciliation
2 process. And Dr. Wilson and Dr. Green have
3 also spoken about the magnitude of the work
4 that is done in medication reconciliation.
5 Again, medication documentation is just one
6 step in that whole process.

7 One of the articles that we
8 provided for impact, et cetera, talks about
9 the different possible breakdowns or failure
10 points in the entire medication reconciliation
11 process: physician/provider-related health
12 system, practice/process-related,
13 pharmacy-related, patient-related. So this
14 one has the opportunity to kind of go after
15 that patient/provider link and do some
16 positive work there.

17 But to defer this measure until
18 another time provides an opportunity for
19 missed patient safety, missed improvement,
20 missed communication between patient and
21 provider to be able to take a look at
22 recognizing the safety issue and trying to

1 move these initiatives forward.

2 CO-CHAIR CONWAY: Thank you.

3 Gina or Janet, do you have any
4 final questions?

5 MEMBER PUGLIESE: No.

6 CO-CHAIR CONWAY: Then, Jason, one
7 --

8 MEMBER ADELMAN: You know, if we
9 are about to vote, if the numerator and
10 denominator stand as is and that is what we
11 are voting on, I still think it is very
12 confusing. However, if the numerator said
13 something like, you know, it is the
14 attestations by the providers that a current
15 med list was on, I might vote differently
16 because the numerator is not current
17 medications. That is what it says. But what
18 was described was an attestation. And even
19 the denominator, it's not all patients, you
20 know, blah blah blah. It is encounters.

21 And so before we vote, if the
22 developers agreed that the language would be

1 changed to reflect what it actually said, it
2 would affect the way I voted.

3 CO-CHAIR CONWAY: Don, is that
4 something --

5 DR. GREEN: I'm green. I'm good.
6 There's a little pun there, actually.

7 So, look, no. The intent of the
8 measure is for these services, did you query
9 your patient about what medications is he or
10 she on? That is it, nothing more, nothing
11 less.

12 We are not looking for the doctors
13 to sign, you know, their chart in blood or
14 whatever. We realize that you are only as
15 good as the information you get, which is true
16 of anything that you do in your office.

17 Forget medications. You know, you
18 can only rely on what the patient is telling
19 you. You know, we all know and understand
20 that. I don't mean just we as CMS. You guys
21 all understand that as well. So that is the
22 intent.

1 And I can speak from a CMS
2 perspective. We have no problem changing the
3 instructions, the way the measure is written
4 to capture that intent if there is confusion
5 on your part. So we would be happy to work
6 with whoever the content person was at NQF
7 that helped to steward this through.

8 I'm sorry. I'm coming through a
9 little bit -- coming in a little bit late.
10 But to come up with a language that captures
11 exactly what I just said. And if you are
12 comfortable voting on that concept, then I
13 would hope that you would vote for it.

14 So does that answer your question,
15 sir?

16 CO-CHAIR CONWAY: Iona?

17 MEMBER THRAEN: I'm just going to
18 speak in favor of what Jason just said because
19 this is used for public reporting. So it's
20 attestation is what this code is. It is an
21 attestation code is what you are actually
22 capturing.

1 And so I think it is important
2 that the language reflect the reality of what
3 you are doing.

4 CO-CHAIR CONWAY: Okay. Any
5 additional questions?

6 DR. WILSON: If I could just make
7 one comment? I think that is fine. I am sure
8 we can work out the wording for that. But we
9 just have to be careful that we don't get it
10 such that the physician has to in his --
11 because this is kind of where we ran into the
12 issue with the verification piece is, you
13 know, the physician may document these to the
14 current medications, but if we are going to
15 actually require them in order to be able to
16 verify that I attest that these are the -- as
17 long as it is inherent that if they report to
18 code, they literally are testing. That is
19 kind of how this evolved because of the fact
20 that you can't find that in a medical record.

21 And the other thing that our TEPs
22 pointed out, for instance, when we go from

1 electronic into EMRs, you know, there is not
2 going to be a checkbox that says, "I attest
3 that these are the current records." You are
4 going to assume if they do the meds, that that
5 is implying that they are the current
6 medications.

7 MEMBER THRAEN: So, then, given
8 what you just said, does that mean, then, the
9 definitions for the numerators and all the
10 pieces that are in this proposal in the
11 document today changes as soon as electronic
12 medical records get in this.

13 DR. WILSON: I think it doesn't
14 the way it is currently written. That is one
15 of the reasons why we took that verification
16 piece out because the TEP was concerned that
17 as you go to EMRs, there won't be an easy way
18 to document that in an EMR. It would require
19 actually another structured element of a
20 checkbox. They would have to click and
21 without an additional step in the workflow or
22 provider to document that.

1 And, again, we felt that it was
2 inherent, that it was understood that if a
3 provider actually collects that information
4 during the visit, that they are attesting that
5 that is the current list.

6 But I think that we can say that
7 if it makes you feel more comfortable in the
8 documentation of the G code, we can say that
9 a provider is attesting by submitting the G
10 code that that is the current list.

11 DR. GREEN: Or something like
12 "documents to the best of his or her ability"
13 or something like that.

14 MEMBER ADELMAN: I'm sorry.
15 Perhaps instead of voting now, we are going to
16 meet again. You have the opportunity to
17 change the language to reflect more what you
18 mean because I don't think what is written
19 matches what you have said. And so you are
20 given the opportunity to tweak it. And then
21 we'll vote on it next time. I don't know if
22 that is an option.

1 MS. BOSSLEY: Well, if you keep
2 pushing things to phase two, we are going to
3 have to make your meeting in phase two like
4 three-four days.

5 (Laughter.)

6 MS. BOSSLEY: So one thing we can
7 do is I think you should vote now, even on the
8 -- it's up to you all, but you could vote now
9 on how the measure is. We could give them an
10 opportunity to come back with some revised
11 language.

12 We have the one measure that you
13 deferred yesterday that we are hoping to be
14 able to bring back to you in the next few
15 weeks. We can have that, any changes,
16 reconsidered by you at that point if you would
17 like to do it that way.

18 And so you can either vote today
19 or not. But I would prefer not to defer all
20 the way to phase two, but we can defer for a
21 couple of weeks if you would like.

22 CO-CHAIR CONWAY: Steve?

1 MEMBER LAWLESS: Actually, for you
2 guys, if you go down the hallway to the people
3 taking care of meaningful use, they actually
4 word meaningful use with the electronic format
5 exactly as Jason is mentioning it.

6 So in year one when you are
7 getting your reimbursements for meaningful use
8 or you are qualifying, you actually attest
9 that you are doing meaningful use. And there
10 is an electronic format just a check. It's
11 not by G code.

12 So I think you can very easily
13 reconcile by using this language what they are
14 using for meaningful use. So when people
15 transition to the EMRs, it's not a big deal.
16 And they do the same thing.

17 CO-CHAIR CONWAY: Okay.

18 DR. GREEN: I'm familiar with what
19 you are saying. There are processes set up
20 currently as an attestation. They will most
21 likely be migrating eventually from a strictly
22 attestation.

1 We are trying to make this as
2 painless on the docs as possible. I get that
3 the G codes are hardly anything but painless,
4 but the idea in the future is to try to move
5 away from that so it is a seamless process.

6 I mean, all of you are clinicians
7 in here. I mean, I can honestly say in my 17
8 years of practice I never once documented a
9 medical record and only put one medication or
10 the one that I cared about.

11 You know, if we are taking the
12 medications, we are taking all of the
13 medications as best we can that the patient
14 will give us or the family gives us of a
15 little list that they bring in.

16 So, you know, no one is looking
17 from a CMS perspective. And I realize you
18 don't just endorse measures for CMS. I get
19 that. But no one is looking to come back and
20 check behind the provider "Oh, you missed one.
21 You know, you lied to us. We are fining you
22 \$10,000 and sending you to jail for 6 months."

1 I mean, obviously that is crazy and that is
2 silly. We are looking for the providers' best
3 effort.

4 Jason, I'm sorry. I don't know
5 your last name. So I will have to call you by
6 Jason.

7 MEMBER ADELMAN: Call me Jason.

8 DR. GREEN: Okay. Thank you. You
9 can call me Dan.

10 (Laughter.)

11 DR. GREEN: We will, you know,
12 change the language so that it is more
13 reflective of the concerns that we heard
14 because you understand, I hope, what our
15 intention is.

16 We want people to try to document
17 the medications as accurately as we can. And
18 that is what we are trying to encourage.

19 CO-CHAIR CONWAY: Go ahead.

20 MEMBER THRAEN: I'm sorry. But I
21 understand the intent today. And I absolutely
22 agree with it, but the intent today changes

1 tomorrow. CMS has just issued a set of
2 provider preventable conditions and which they
3 are not paying facilities on.

4 So this moves from an intent to
5 change behavior to a financial remuneration or
6 lack of payment in the future. So I think
7 that we have to stay true to making sure that
8 the definitions reflect the reality, labeling
9 reflects the reality, and that if we are going
10 to support the measure today, that when it is
11 used differently in three or four years down
12 the road, that we are comfortable with what we
13 did today.

14 CO-CHAIR CONWAY: Okay. Maybe I
15 will take a Chair prerogative. I would
16 suggest we go ahead and vote on this. It is
17 not clear to me that it will even reach the
18 threshold of importance. Therefore, language
19 becomes a moot point. If we get beyond
20 importance and we begin to fail on scientific
21 grounds, we could debate whether CMS could
22 recover that.

1 So if that sounds okay, we will
2 move on to voting. Jessica?

3 MS. WEBER: All right. Importance
4 to measure and report. Are all three
5 subcriteria met: high-impact, performance
6 gap, evidence? It is a "Yes"/"No" question.
7 We need one more vote. Oh, there.

8 Janet?

9 MEMBER NAGAMINE: Yes.

10 MS. WEBER: Gina?

11 MEMBER PUGLIESE: Yes.

12 CO-CHAIR CONWAY: Okay.

13 MS. WEBER: Nineteen yes, two no.

14 CO-CHAIR CONWAY: Good.

15 MS. WEBER: Scientific

16 acceptability of measure properties:

17 reliability and validity. It is a "Yes"/"No"
18 question.

19 DR. PHELAN: Excuse me. Janet?

20 MEMBER NAGAMINE: Yes?

21 DR. PHELAN: It's Dr. Phelan. You
22 know, I don't have the agenda in front of me.

1 When is the endotracheal tube confirmation
2 metric going to be evaluated?

3 MS. BOSSLEY: Michael, it's Heidi.
4 You are next. Just give us a couple of more
5 minutes.

6 DR. PHELAN: Okay. I'm sorry.

7 MS. BOSSLEY: That's fine.

8 DR. PHELAN: I am getting paged.
9 So I am going to have to walk away from the
10 phone a little bit. Then I am going to come
11 back. So I'm going to have you on mute for a
12 moment.

13 CO-CHAIR CONWAY: That will be
14 okay. We are going to have a break after
15 this. So it will be a little bit.

16 MS. BOSSLEY: You will be good.

17 DR. PHELAN: Oh, it will be a
18 little bit? Should I call back in?

19 CO-CHAIR CONWAY: Fifteen minutes.

20 DR. PHELAN: I will call back in
21 in 15 minutes. Thanks

22 CO-CHAIR CONWAY: Okay.

1 MS. WEBER: All right. Janet,
2 would you like to cast your vote for
3 scientific acceptability?

4 MEMBER NAGAMINE: Well, this one,
5 reliability and validity, it's different for
6 me. I am not sure in this.

7 CO-CHAIR CONWAY: It has to pass
8 both.

9 MEMBER NAGAMINE: Okay. Then it
10 would be a no.

11 MS. WEBER: Okay. Gina?

12 MEMBER PUGLIESE: Yes.

13 MS. WEBER: All right. Eleven
14 yes, ten no.

15 CO-CHAIR CONWAY: So should we ask
16 if we --

17 MS. BOSSLEY: I think I am even
18 possibly confused on whether everyone voted
19 based on the measure as it is currently before
20 you or what was discussed as potential
21 changes. And it sounds like everybody did it
22 differently.

1 MEMBER THRAEN: I voted on what is
2 in front of us because, even though there are
3 lots of promises to changed language, they
4 have to take it through a process. No?

5 DR. GREEN: We are going to change
6 it. You have my word. We will change it.

7 MEMBER THRAEN: I want to see it
8 in writing. I'm sorry. I want it in writing.

9 DR. GREEN: We will change the
10 language based on capturing the intent of the
11 -- obviously it was including all of you, but
12 the one that --

13 MEMBER McGIFFERT: Can we vote and
14 then rescind our vote if it doesn't get
15 changed in a way that we feel is acceptable?

16 CO-CHAIR CONWAY: We're very, very
17 tight here on scientific credibility. So, you
18 know, we can table this. Heidi won't be
19 happy, but we can table this.

20 The problem with the changes, I
21 heard a whole lot of requests. And it's not
22 clear to me how that is going to shake out.

1 So it may be best if we table this and bring
2 it back at our next meeting.

3 MS. BOSSLEY: So what we can do is
4 even not wait until the next meeting. I think
5 they can make the changes fairly quickly, it
6 sounds like.

7 Again, you have got the other
8 measure that you deferred that I think we are
9 going to be able to bring back to you on a
10 conference call within the next month it
11 sounds like.

12 Let's see if we can bring this
13 measure back and then have you vote on it
14 after you see the changes that they have made.
15 Is that acceptable to everyone?

16 CO-CHAIR CONWAY: Anyone disagree
17 with that?

18 (No response.)

19 CO-CHAIR CONWAY: Okay. Let's do
20 it that way.

21 Okay. Let's take a break. I
22 think you just earned it.

1 (Whereupon, the foregoing matter
2 went off the record at 11:01 a.m. and resumed
3 at 11:18 a.m.)

4 0501: CONFIRMATION OF ENDOTRACHEAL TUBE
5 PLACEMENT. CLEVELAND CLINIC.

6 CO-CHAIR CONWAY: Well, why don't
7 we start with measure 501, confirming
8 endotracheal tube placement. The measure
9 developer from Cleveland Clinic is not on the
10 phone yet, but Louise could begin by giving us
11 a summary of the workgroup's assessment.

12 MEMBER PROBST: So I'm happy to
13 walk through the measure. It was not
14 available at the time of our workgroup. So
15 our workgroup has not actually discussed it
16 and I don't believe measured it.

17 But, with that, I think you all
18 have a copy of it. And it is a maintenance
19 measure. Its measure owner is the Cleveland
20 Clinic, as was mentioned. And we are really
21 measuring here confirmation of ET to placement
22 following emergency room or pre-hospital

1 placement of an ET tube.

2 And let's see. So the numerator
3 is the number of emergency department patients
4 with an ET tube placed or assessed with an
5 endotracheal tube already in place who had
6 their ET tube confirmed, position confirmed.

7 The denominator is the total
8 number of endotracheal tubes evaluated,
9 including those patients who had ET tubes
10 placed in ER and those that arrived with them,
11 so the total number of patients. The
12 denominator is the total number of the
13 patients who are in the ER with an ET tube
14 because they got it there or got it
15 previously. And the numerator is those that
16 have documentation placement of the ET tube
17 was assessed.

18 In terms of importance, there is
19 quite a bit of documentation about the need to
20 have a properly placed ET tube in terms of
21 oxygenation. And I think there was a study
22 that suggested that about 5.5 percent of

1 patients with an ET tube have it inadvertently
2 placed.

3 And there have been some studies
4 that look at how often there is documentation
5 of proper placement. I think one study showed
6 that 18 percent of the time there was no
7 documentation at all, 26 percent of the time
8 it was just documented that placement was
9 checked by auscultation or listening to the
10 lungs, which was not deemed to be adequate.

11 There seemed to be a lot of
12 discussion about gaps in terms of registries
13 to really track patients and ET tubes, but
14 probably the registry that would be the most
15 useful is the one that looks at in-hospital
16 cardiac arrest. And in that situation, there
17 is information about ET tube placement.

18 But the biggest concern about the
19 gap seems to be that people aren't familiar
20 with the best practices and the most sensitive
21 measures for assessing ET tubes. And so
22 they're really looking to see that not only

1 that it's documented but the way in which it
2 is documented.

3 Let's see where we're at.

4 DR. PHELAN: I'm back on the
5 phone.

6 CO-CHAIR CONWAY: Okay. Michael,
7 just hang on a minute. We're beginning your
8 measure.

9 DR. PHELAN: Sure.

10 MEMBER PROBST: Okay. Let's see.
11 And so the best practice is to use a tool that
12 looks at CO2 coming out of the tube or test
13 that. I've actually never seen that. I
14 actually left nursing when they still did
15 chest X-rays. So I'd love to come see it.
16 And, of course, with bedside oxygenation and
17 things.

18 So, but, what most impressed me
19 about the literature was the huge opportunity
20 here just if you're measuring to educate
21 people about what the proper techniques are.

22 There was some question in terms

1 of its validity and reliability that just
2 documenting the two -- that you have done an
3 assessment doesn't necessarily mean that it is
4 in the right place or that it doesn't move
5 from time to time.

6 And so, you know, it wasn't a
7 correlation there, but there are strong
8 correlations that when the tube is in the
9 wrong place, morbidity and mortality are
10 higher. And so it seems like an important
11 measure.

12 With that, I'll turn it over to
13 the measure developer.

14 CO-CHAIR CONWAY: Okay. Michael?
15 Michael?

16 DR. PHELAN: Yes, sir? Yes, sir?

17 CO-CHAIR CONWAY: We just heard a
18 summary from our lead panel assessor. Do you
19 have anything to add about this measure?

20 DR. PHELAN: I believe there was
21 some concern about the validity --

22 CO-CHAIR CONWAY: Okay.

1 DR. PHELAN: -- and reliability.

2 CO-CHAIR CONWAY: And how has that
3 been tested?

4 DR. PHELAN: It really hasn't.
5 And one of the things that -- I mean, it's
6 like any chart-reviewed abstracted measure.
7 The National Registry of CPR, now called the
8 -- you know, get with the guidelines
9 resuscitation -- does reliability and validity
10 testing of the whole abstracted chart on
11 someone who has an in-hospital cardiac arrest.

12 And the way that they do their
13 study is you become a participating member
14 through a fee. They teach you how to do the
15 abstraction. And then they do intermittent,
16 periodic reabstractions. They will just
17 randomly select charts to review and make sure
18 that they are capturing what they are supposed
19 to be capturing.

20 And one of the things I said, this
21 is kind of like the validity and reliability
22 testing that you would do for -- I think I

1 sent someone this article on parachutes for
2 gravitational challenges.

3 CO-CHAIR CONWAY: All right.
4 Okay. Are there questions from the panel
5 members? Steve?

6 MEMBER LAWLESS: Yes. It seems to
7 me this is a measure of what is a best
8 practice. I'm not sure about translating it
9 into a reportable quality measure per se. I
10 mean, I just absolutely agree this is the best
11 practice. You should be doing this. It
12 happened.

13 As a reportable measure, though,
14 I'm not really sure where it fits in as a
15 reportable measure.

16 CO-CHAIR CONWAY: And Vallire?

17 MEMBER HOOPER: I agree it is an
18 important measure in that we still get many
19 incidents where the placement of the ET tube
20 is not confirmed and we have subsequently very
21 poor outcomes.

22 This measure, although the

1 evidence in the discussion sections, talks
2 about the appropriate method for confirming ET
3 tube placement, which is end tidal CO2. But,
4 yet, in the numerator, it just states
5 placement confirmed.

6 And there are still a lot of
7 people in this world that think bilateral
8 breath sounds or what they perceive as
9 bilateral breath sounds are
10 placement-confirmed or that, heaven forbid,
11 they should wait for the chest X-ray, you
12 know.

13 So to retain this measure, I would
14 like to see that we are actually ascertaining
15 that best practice is being done. So I would
16 like the measure to reflect confirmation with
17 end tidal CO2.

18 Additionally, I am curious as to
19 if there are other measures that evaluate this
20 process in-house, as opposed to just the ED,
21 because we have the same episodes and poor
22 outcomes in emergency intubations in-house as

1 well as in the ED.

2 So I am curious as to if there are
3 other measures that also look at that. And if
4 not, I would recommend expanding this measure
5 to outside of the ER.

6 CO-CHAIR CONWAY: Okay. Heidi, do
7 we have other measures?

8 MS. BOSSLEY: No. This is the
9 only measure we have endorsed looking at this.

10 CO-CHAIR CONWAY: Carol and then
11 John.

12 MEMBER KEMPER: I agree with
13 Vallire. One of the things that I think is
14 needed is just to confirm, have a more clear
15 definition of what secondary confirmation
16 includes because it looked like that was
17 pretty open.

18 The other thing is there was a lot
19 of discussion about the physicians'
20 documentation and looking at physician
21 documentation that this had occurred. I
22 wondered if that was the only documentation

1 that would be looked at in the measure because
2 I know, for example, in my institution, it is
3 usually the respiratory therapist who is
4 documenting this.

5 And, of course, it is documented
6 in a variety of places. So it can be
7 challenging as it always is, I think when you
8 are trying to do a chart review, but I think
9 to get at the data, the measure would have to
10 include that it would have more documentation
11 forces than just the physician.

12 DR. PHELAN: May I speak?

13 CO-CHAIR CONWAY: Sure, Mike.

14 DR. PHELAN: The reason it was
15 left intentionally vague is there will be
16 situations where end tidal CO2 won't be
17 present in cardiac arrest situations,
18 prolonged cardiac arrests. And yes, as a
19 matter of fact, I think it just says
20 confirmation. And it doesn't label which
21 specific practitioner is required to do that.

22 We deliberately left that vague

1 because in an arrest situation, oftentimes the
2 nurse will be contemporaneously documenting.
3 The physician and maybe respiratory therapy
4 will do their documentation at some later
5 point. So we left that answer vague that it
6 wasn't physician documentation, just any
7 documentation in the medical record.

8 CO-CHAIR CONWAY: Thank you.

9 And John?

10 MEMBER CLARKE: I think a point
11 that shouldn't be lost here is the potential
12 for using this to document and report E tube
13 placement from the field.

14 My guess is that this is actually
15 the only place you are going to be able to
16 capture how well the EMTs are doing when they
17 put in tubes in the field because you need
18 that in-house confirmation for that. So I
19 think it shouldn't be lost that this is a way
20 of monitoring a pre-hospital performance.

21 CO-CHAIR CONWAY: Vallire?

22 MEMBER HOOPER: And I understand

1 that since a prolonged cardiorespiratory
2 arrest, that the end tidal CO2 may not be
3 exactly appropriate but if we're not going to
4 recommend best practice, then why have the --

5 DR. PHELAN: You know, American
6 College of Emergency Physicians has come out
7 with a practice guideline. And I think I have
8 provided the link for you. It goes over some
9 of the situations and issues involved, which
10 is saying every single time you have to have
11 this because there are situations where it may
12 not -- not many but some.

13 And if you just say, "If you don't
14 have an end tidal CO2, you fail to measure,"
15 it might not be appropriate because if you use
16 something called an esophageal detector device
17 or a relaryngoscopy, where you re-look and you
18 see the tube actually going through the cords,
19 that is considered satisfactory, especially in
20 situations where you may not be able to get an
21 end tidal CO2 because there's no CO2 getting
22 to the lungs.

1 Massive pulmonary emboli is one
2 situation. Your tube will be in place, but
3 you won't get a positive end tidal CO2 in that
4 situation. In prolonged cardiac arrest, where
5 there is no movement of blood through the
6 system anymore, either it's all clotted off or
7 it's not moving, you won't get an end tidal
8 CO2 there. And, of course, there are
9 situations where end tidal CO2 will be
10 positive, but it could actually mean you are
11 still in the stomach.

12 So there are best practice
13 recommendations, but there are tiny caveats to
14 each of them. So if you said, "We want 100
15 percent confirmation of end tidal CO2," it may
16 be problematic from that perspective.

17 MEMBER HOOPER: Could you include,
18 then, some exclusionary criteria related to
19 those situations? I mean, it just seems to me
20 leaving it wide open is really opening it up
21 to measuring, to getting a high score for
22 non-evidence-based practice and for --

1 DR. PHELAN: Correct. And I think
2 it may have to go through different editions
3 of it. You know, first give us documentation.
4 And I think Joint Commission has worked on an
5 in-hospital cardiac arrest package of metrics
6 that they are looking at. And one of them is
7 documentation of endotracheal tube placement
8 for cardiac arrest patients.

9 So I think they're working on it
10 and waiting for the appropriate time to
11 release it, but they haven't released it. But
12 they had asked me to participate in some phone
13 conversations and sending them some literature
14 regarding it.

15 So I think it is one of these
16 things that it may take a little bit of a
17 process, you know, baby steps. "Oh, look,
18 everyone is 100 percent." Well, when have we
19 asked for appropriate documentation, which
20 would be the three, you know, either end tidal
21 CO2; EDD, which is the esophageal detector
22 device, or re-look as an adequate means of

1 confirming endotracheal tube placement.

2 And some of them involve a cost.

3 The end tidal CO2 monitor, which watches, you
4 know, end tidal CO2 over time, is very
5 expensive or the quick easy cap is a \$15 piece
6 of equipment that is on most code carts in the
7 hospital and in the emergency department.

8 MEMBER HOOPER: So why not --

9 DR. PHELAN: But getting at -- go
10 ahead.

11 MEMBER HOOPER: I was going to
12 say, so why not expand the measure to include
13 those three steps now?

14 DR. PHELAN: We could. I would be
15 fine with that.

16 MEMBER HOOPER: I would recommend
17 that. Thank you.

18 DR. PHELAN: Okay.

19 CO-CHAIR CONWAY: Susan?

20 MEMBER MOFFATT-BRUCE: Yes. Thank
21 you.

22 I think that looking at what the

1 numerator is, looking at the number of ED
2 patients, as a thoracic surgeon, we are often
3 asked to fix the situation when those
4 endotracheal tubes don't end up in the right
5 place. Actually, the biggest opportunity out
6 there is in code patients.

7 DR. PHELAN: You're right.

8 MEMBER MOFFATT-BRUCE: So to be
9 exclusive of your Code Blues, where we have
10 practitioners placing endotracheal tubes that
11 often don't do it, I think would be much more
12 of an opportunity for improvement. And so I
13 would ask that.

14 And then I would echo using al
15 algorithm approach that in the event that you
16 can't detect the end CO2 because of
17 cardiopulmonary arrest that's prolonged, then
18 going to the appropriate next steps, which are
19 well-established in the literature around
20 emergency medicine and Code Blue resuscitation
21 I think is most appropriate. So I thank you
22 for that.

1 CO-CHAIR CONWAY: Steve?

2 MEMBER LAWLESS: Yes. I second
3 what Val was saying, also in terms of it's the
4 process. It's the endotracheal tube. It's
5 the intubation. So it's confirmation of
6 wherever the intubation is, not just the ER.
7 It could be in the field or wherever else.
8 It's the confirmatory steps.

9 So as long as you take a
10 confirmatory, rather than just listening to
11 the breath sounds, there is something you are
12 documenting. We did this yesterday.

13 There is a logarithm or something
14 that you are using to document beyond just one
15 facet that is there. It is a big problem.
16 But it is a big problem also in inpatient
17 movements.

18 So, actually, when you are moving
19 a patient from the ICU to the OR or whatever
20 else --

21 DR. PHELAN: Correct.

22 MEMBER LAWLESS: -- they do this.

1 And so I think it is with patient movement or
2 initial any intubation, there is a primary and
3 a secondary confirmation of some sort. So I
4 think it is a good start, but it could be
5 expanded.

6 CO-CHAIR CONWAY: Okay. Michael?

7 DR. PHELAN: Yes, sir?

8 CO-CHAIR CONWAY: There is some
9 enthusiasm for perfecting this measure. It
10 sounds like it's a couple of different ways.
11 One is to include three steps that Vallire has
12 pointed out.

13 The other is looking at the sites
14 of care. NQF is trying to take its measures
15 across the continuum of care. I guess this
16 could stand as an ER measure, but if you're
17 interested, you may want to expand this to
18 other locations in the hospital and even
19 potentially pre-hospital care.

20 DR. PHELAN: You know, the only
21 concern --

22 CO-CHAIR CONWAY: Do you have

1 interest and ability to do this?

2 DR. PHELAN: I don't have ability.
3 The only concern about expanding it to outside
4 the hospital is, all of a sudden, you have to
5 say, "Well, does the OR get included? Does
6 the PACU get included?"; although they confirm
7 100 percent of their tube placement.

8 That is something that was in my
9 mind. And I'm like "How far do we want to go
10 with this? And do we want to go with baby
11 steps first, see if we can get the EDs on
12 board on it.

13 And then by the time the Joint
14 Commission's cardiac arrest metrics get that
15 put out there, then, all of a sudden, we have
16 an opportunity to -- what do they call that?
17 -- marry the two.

18 CO-CHAIR CONWAY: Harmonize.

19 DR. PHELAN: Harmonize. Yes. So
20 right now there is no opportunity to
21 harmonize.

22 Sorry. My mind is working on a

1 couple of different things here.

2 So I am thinking from my
3 perspective stick to the ED. And adding the
4 caveat to the measure that it must be done by
5 according to the American College of Emergency
6 Physicians, practice guidelines would not be
7 difficult. The question is, how would you
8 turn that over to a hospital and say, "Review
9 all of your records and make sure any
10 intubated patient or any patient who arrived
11 intubated met these three guidelines. And if
12 they don't, it's a fail"?

13 CO-CHAIR CONWAY: Very good. So
14 the scope remains focused on the ED. That
15 answers that question.

16 And then, Vallire, you want to
17 have a follow-up?

18 MEMBER HOOPER: I was just going
19 to say I would not be opposed to starting with
20 the ED as long as we consider expanding to
21 other areas as soon as possible.

22 CO-CHAIR CONWAY: Okay. Susan,

1 are you still up? All right. So the measure
2 is as written is the answer, I think.

3 Any other questions or discussion
4 on this? Sorry.

5 MEMBER HOOPER: Are we voting on
6 the measure as written or are we going to vote
7 on the measure with the added algorithm as we
8 discussed, where if it's not confirmed by the
9 end tidal CO2 cap, then you do -- if not
10 confirmed by A, then you go to B and then you
11 go to C?

12 CO-CHAIR CONWAY: Michael, can you
13 recast this in that manner?

14 DR. PHELAN: Yes. And I will send
15 you something. How soon do you need it?

16 CO-CHAIR CONWAY: And then, Heidi,
17 how do we handle that?

18 MS. BOSSLEY: We can work with
19 Michael over the next couple of weeks and see
20 if we can do anything. But I still have a
21 question I guess to the Committee of whether
22 the measure now or even with the changes will

1 continue to meet the scientific acceptability
2 criteria and especially if we make the changes
3 and add in the algorithm. I'm not sure that
4 we have any testing information on that.

5 Michael, I guess one of the
6 questions I have is, you have stated that
7 there is a group out there that is abstracting
8 data now. And one question would be, can you
9 get that data from them so that we can bring
10 this back to the Committee with some
11 reliability and validity testing?

12 DR. PHELAN: Let me call, get with
13 the Guideline Committee, and see about
14 specific to that element alone, I am not sure.
15 But specific to the overall get with the
16 guideline criteria, I can see.

17 MS. BOSSLEY: Okay. Well, and so
18 maybe it makes sense to table/defer the
19 measure and we'll see whether it's defer it
20 for the next month or so or if it's something
21 that we would bring -- we'll work with Michael
22 and figure out because I think the other --

1 DR. PHELAN: Can I give you
2 another option?

3 MS. BOSSLEY: Sure.

4 DR. PHELAN: Approve the measure
5 going forward with the caveat if it's
6 satisfactory to the group, then it can
7 continue on.

8 MS. BOSSLEY: Again, that is for
9 the Committee to ultimately decide, --

10 DR. PHELAN: Sure.

11 MS. BOSSLEY: -- although we
12 essentially indicated before it needs to pass
13 the criteria. And I am not sure that you have
14 provided enough information for them to say
15 that it passes the criteria. And I am seeing
16 some nodding in the room.

17 MEMBER LAWLESS: Yes. I would
18 just say I would rather not -- I mean, we vote
19 on it and whatever else. If it doesn't pass,
20 you know, it needs more work if it's the
21 criteria the reliability is not there yet. It
22 doesn't mean that it is not going to continue

1 to go on without it.

2 DR. PHELAN: Okay.

3 MEMBER LAWLESS: It's not ready
4 for prime time.

5 DR. PHELAN: Okay. The only
6 problem is I don't think that they have --
7 what was the heading of this measure? It got
8 put in the category of approved but --

9 MS. BOSSLEY: So yes. I think I
10 did mention this to the Committee.

11 DR. PHELAN: Right.

12 MS. BOSSLEY: This measure was one
13 of the time-limited measures that we brought
14 into maintenance --

15 DR. PHELAN: Right.

16 MS. BOSSLEY: -- that had met all
17 of the criteria on its first review but had
18 not provided reliability and validity testing
19 yet. And so, as you can tell, Michael is
20 still identifying that data to be able to
21 bring it to you.

22 So we're in that unusual spot of

1 can he be able to bring that to you quickly
2 enough so that you can evaluate it or the
3 question will be, is this a measure that you
4 all think he needs to continue to move forward
5 and bring back at another point?

6 MEMBER THRAEN: What's the time
7 limit?

8 MS. BOSSLEY: So the time limit
9 there, we're lucky. We have two options. So
10 we can work with Michael and see if he can
11 bring something back in the next I would say
12 month. We need to consider it because you do
13 have a few remaining things you need to do on
14 a conference call. If not, if he can get it
15 to us by the time of your next meeting for
16 phase two, we can move the measures back.

17 If he cannot -- and Michael will
18 have more conversations about this offline.
19 If he can't, then I think your choice will be
20 to vote on the measure as it stands before you
21 and then move forward. And that could be I
22 would assume removing endorsement.

1 CO-CHAIR CONWAY: Which of those
2 would you like to pursue, Michael?

3 DR. PHELAN: I would like to
4 continue the metric as an approved metric
5 pending the revision to the definition, adding
6 that it should be according to ACEP practice
7 guideline recommendations and then b) pending
8 some validity and reliability testing from the
9 abstraction process in the national or get
10 with the guidelines resuscitation, if that is
11 sufficient, approve the measure.

12 And the question I have is, how do
13 I pose the question to the people that get
14 with the guideline resuscitation to make it
15 sufficient for you to be satisfied with their
16 answer to get to the --

17 MS. BOSSLEY: So, Michael, yes.
18 This is Heidi. We will work with you offline
19 --

20 DR. PHELAN: Perfect.

21 MS. BOSSLEY: -- and make sure you
22 have everything that you need to be able to go

1 to them. We're happy to be on the call as
2 well. So we'll --

3 DR. PHELAN: That would be nice.
4 Yes.

5 MS. BOSSLEY: Yes. We'll figure
6 that out. That is not a problem. I guess the
7 question to the Committee is, would you prefer
8 to vote on this now or would you like to wait
9 and have us come back to you with more
10 information? Defer?

11 DR. PHELAN: It sounds like if we
12 vote on it now, it would get turned down.

13 MS. BOSSLEY: Right. So they are
14 all agreeing to defer.

15 DR. PHELAN: So option B is if
16 it's got another month of life into it, let's
17 give it another month of life. Let's
18 reconfirm that endotracheal tube placement.
19 I think I am seeing a positive end tidal CO2
20 here.

21 (Laughter.)

22 MS. BOSSLEY: You're deferred.

1 We'll touch base with you next week.

2 DR. PHELAN: Awesome, Heidi.

3 Thank you. Everyone have a nice holiday and
4 a good New Year.

5 CO-CHAIR CONWAY: Thank you.

6 DR. PHELAN: Bye bye. You bet.

7 MEMBER THRAEN: Okay. So I
8 inadvertently went to NQF's website to look at
9 measures. There is a -- this relates back to
10 the last conversation and NCQA 0019
11 medication, documentation of medication lists
12 in outpatient records, measure that was
13 approved in 2009.

14 So when we revisit the CMS
15 measure, could someone look to see about
16 harmonization related to that one?

17 MS. BOSSLEY: I had mentioned that
18 to Pam and to Bill as well. What we will do
19 is when we bring back the revised measure from
20 quality insight from CMS, we will also give
21 you kind of the list of all the other measures
22 that are related to medication reconciliation

1 and documentation of medication, et cetera, so
2 you know what is endorsed, what that covers,
3 and everything else. And then we can address
4 the harmonization as well, yes.

5 CO-CHAIR CONWAY: For people on
6 the phone, we are going to take a lunch break.
7 But it is going to be a working lunch. So we
8 will be back to work here in about 15 or 20
9 minutes. Okay, Janet and Gina?

10 MEMBER NAGAMINE: Sounds good.
11 Thanks.

12 MEMBER PUGLIESE: Also thank you.

13 CO-CHAIR CONWAY: Okay.

14 (Whereupon, the foregoing matter
15 went off the record at 11:44 a.m. and resumed
16 at 12:08 p.m.)

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1 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 (12:08 p.m.)

3 CO-CHAIR CIPRIANO: Lisa, are you
4 ready for measure 0346, iatrogenic
5 pneumothorax rate? That is you, right?

6 MEMBER McGIFFERT: Do you want to
7 get started or do you want to wait a few
8 minutes for people to come back?

9 CO-CHAIR CIPRIANO: I think we
10 have got our Committee members on the phone.

11 MEMBER McGIFFERT: Okay.

12 CO-CHAIR CIPRIANO: So I think I
13 would like to get started.

14 MEMBER McGIFFERT: Okay.

15 0346: IATROGENIC PNEUMOTHORAX RATE (PSI 6).

16 0348: IATROGENIC PNEUMOTHORAX RATE (PDI 5).

17 AGENCY FOR HEALTHCARE RESEARCH AND QUALITY.

18 MEMBER McGIFFERT: And Carol and I
19 are going to do this in tandem because she's
20 got the pediatric measure also. And I am
21 going to have to get it up. Just a second.

22 CO-CHAIR CIPRIANO: All right. So

1 you are suggesting that our conversation will
2 cover 346 and 348?

3 MEMBER McGIFFERT: Yes.

4 CO-CHAIR CIPRIANO: So if you
5 would just tag team and let us know what
6 specific --

7 MEMBER McGIFFERT: Yes.

8 CO-CHAIR CIPRIANO: That would be
9 great.

10 MEMBER McGIFFERT: Do you want me
11 to kind of start or do you want to --

12 CO-CHAIR CIPRIANO: Hang on one
13 second. I think Patrick would like to make
14 introductory comments.

15 MEMBER McGIFFERT: Okay. Did you
16 say hang on?

17 DR. ROMANO: Sorry.

18 CO-CHAIR CIPRIANO: Can we defer
19 to Patrick first?

20 MEMBER McGIFFERT: Yes.

21 DR. ROMANO: A couple of
22 preparatory comments. So we are back in the

1 realm now of events that are mishaps related
2 to, we hope mishaps related to, procedures,
3 but they're not extremely rare. In this case,
4 they are more common events. However, they
5 are not always preventable events. And so we
6 are now back in the realm where we have a
7 risk-adjusted rate that is based on a
8 numerator and a denominator. And it is based
9 on patient characteristics in the risk
10 adjustment mode.

11 A lot of the action with these
12 measures and a lot of the concern focuses on
13 the exclusion criteria because the intent is
14 to exclude large groups of patients for whom
15 the event could be an expected consequence of
16 the procedure and less preventable. In some
17 cases, the exclusions may be drawn overly
18 wide. In other cases, they may be too narrow.

19 We do have some additional
20 information and analyses that we have done
21 based on the workgroup discussion as well as
22 some additional validation information. We

1 are happy to put that into the forms. It is
2 up to the Committee, of course.

3 We can discuss that in this
4 context and I can present that information
5 verbally or we can defer discussion until
6 everybody has a chance to review it on paper.
7 But we have done some additional analyses to
8 address the comments that were raised in the
9 workgroups.

10 CO-CHAIR CIPRIANO: Okay. Maybe
11 as the leads come to those areas, they will
12 ask for additional input. Okay. Did you say
13 Carol was going to go first or are you?

14 MEMBER MCGIFFERT: Well, I was
15 just going to say that was the biggest concern
16 in the workgroup, which I vocalized and a lot
17 of people countered. There are pages and
18 pages and pages of exceptions.

19 And I understand that this is an
20 expected outcome in many procedures. And so
21 there was a lot of discussion about that.

22 So I think we may want to hear

1 about the exceptions ahead of time. What do
2 you think, Carol?

3 MEMBER KEMPER: Well, I think kind
4 of, as Patrick has said, the exceptions, the
5 exclusions that are in the pediatric measure
6 -- and this is iatrogenic pneumothorax. So
7 it's the percentage of discharges among cases
8 that meet those inclusion and exclusion
9 criteria, where iatrogenic pneumothorax is in
10 the secondary diagnosis field.

11 The exclusion criteria are
12 primarily related to patients that have had
13 chest trauma, so again could have a
14 pneumothorax associated with that, also
15 thoracic surgery or cardiac surgery, so some
16 of those kinds of surgeries where there would
17 be some disruption and potentially expected to
18 have a pneumothorax.

19 MEMBER MCGIFFERT: I was thinking
20 exceptions were exclusions. Are exceptions
21 something else?

22 MEMBER KEMPER: I was speaking of

1 exclusions.

2 MEMBER McGIFFERT: Yes,
3 exclusions. That's what I was. I wonder if
4 Patrick was talking about exclusions. Okay.
5 Okay. Good.

6 I guess the other -- and I
7 understand that that is the situation. And
8 the question that I asked is, is there a
9 measure or should we try to solicit a measure
10 that would measure all of those exclusions
11 where it is expected to happen? And does the
12 right response happen when it is expected to
13 happen?

14 And I don't know. Maybe some of
15 you know of other measures, but to me when you
16 have so many that are, so many situations
17 where this is "expected to happen," a quality
18 measure, a good quality measure, would be so
19 how does the surgeon respond or how does the
20 team respond when it does happen as an
21 assessment of quality?

22 So I think, Patrick, if you can

1 talk to us about those exclusions or the
2 analysis, further analysis, that you did or do
3 you want to wait until after everybody
4 discusses it?

5 CO-CHAIR CIPRIANO: No. We can go
6 ahead. The only thing I would say in response
7 to what you just presented is that that seems
8 to me almost like a different measure.

9 MEMBER McGIFFERT: It is, but it
10 just came up because this is staring us in the
11 face. That's it.

12 CO-CHAIR CIPRIANO: Right. And I
13 think as we work through these measures, it is
14 very -- again, we are always tempted to say we
15 need more, we want more, we want to see the
16 actual management.

17 And, you know, obviously I want
18 Patrick to speak to the exceptions, but it may
19 be that for now we will need to address this
20 measure with the limited scope that it has.

21 Carol?

22 MEMBER KEMPER: I wonder if we

1 could just -- we could even just like provide
2 the summary and then come back to some of
3 those kinds of questions, I think.

4 So, you know, we have talked a
5 little bit about what the exceptions are.
6 Again, just like all the other AHRQ PDIs and
7 PSIs, it's pulled from administrative data.
8 So certainly pulling it seems to be reliable
9 and have some consistency there.

10 From the pediatric side, the rate
11 seems to be about .2 I'm going to say from
12 what I'm seeing in the literature per 1,000
13 discharges. And the study that a lot of us
14 have been talking about as we have discussed
15 the PDIs, which is that Scanlon article,
16 mentions for this particular measure that over
17 that 2003 to 2005 data pull from 72 hospitals,
18 I think it was, they had 646 cases. And of
19 those, 11 percent were present on admission.
20 Now, again, the present on admission code
21 wasn't in place at that time and is now.

22 Sixty percent were not considered

1 preventable because they were expected during
2 procedures that the software had not flagged
3 for exclusions. And they were things like
4 tracheal reconstruction, although -- and
5 Patrick can talk about this more, but there
6 have been refinements to the algorithm I think
7 since this article was written so that some of
8 those may not be an issue currently.

9 And then 30 percent were
10 associated with central line placement and
11 were considered preventable. So, I mean,
12 those are the ones that I think we are really
13 trying to capture and are concerned about.

14 The positive predictive value --
15 again, this is data that is a bit dated
16 because changes have been made since that time
17 -- was a high of 64 percent positive
18 predictive value. And the low was reported as
19 29. The reason they had that spread there on
20 the positive predictive value is they included
21 and excluded those that were considered
22 uncertain preventability.

1 So the low included the uncertain
2 and the high -- or I'm sorry. I switched
3 that. The low excluded them and the high
4 included them, I believe.

5 So I think there have been
6 additional changes to the measure since even
7 that data were evaluated. Again, I think,
8 like we have talked about before, there is a
9 lot of value in case finding. I think with
10 this measure, the question on comparison still
11 comes up. And some of that is related to the
12 discussion that we had yesterday about low
13 volumes.

14 And it is really hard to detect a
15 difference, a hospital that is really worse
16 because of the low volumes but can be a
17 valuable measure, certainly for these
18 situations where we're finding that it is
19 related to a central line placement.

20 MEMBER MCGIFFERT: And on the
21 adult side, two studies were cited that
22 estimated the positive predictive value of

1 79.6 and 83.9. So that seemed pretty high to
2 me.

3 MEMBER THRAEN: Why the difference
4 between pediatric and adult? Do you know?

5 MEMBER KEMPER: As far as?

6 MEMBER McGIFFERT: The predictive
7 value?

8 MEMBER KEMPER: Positive
9 predictive value?

10 MEMBER McGIFFERT: I don't know.

11 MEMBER KEMPER: Well, and, again,
12 remember that I don't what all the codes are
13 that are included in the adult measure, but,
14 you know, as was cited in this particular
15 article, there were some that those values
16 that I gave you did not include some codes
17 that I think have now been added. So I am not
18 sure if maybe they would be closer now. I
19 don't know. Patrick might be able to speak to
20 that.

21 MEMBER McGIFFERT: And this
22 measure has been out for a while and has been

1 used pretty extensively, it looks like, you
2 know, in various settings. And I am trying to
3 --

4 MEMBER NAGAMINE: Iona?

5 MEMBER McGIFFERT: It allows users
6 to risk-adjust the rates. And let's see.

7 MEMBER NAGAMINE: Iona, I was on
8 the TAP when this was discussed. And I
9 believe in the pediatric population, it is
10 very different, particularly with preemies.
11 So it was very weight-dependent how often this
12 happened and to whom.

13 MEMBER KEMPER: And this
14 particular measure that we're looking at, PDI
15 5, excludes neonates.

16 MEMBER NAGAMINE: Oh, okay. Okay.

17 MEMBER KEMPER: There's a separate
18 measure for neonates.

19 MEMBER NAGAMINE: Got it.

20 CO-CHAIR CIPRIANO: Okay. Are we
21 ready to hear from Patrick again, then? Okay.
22 Please go ahead.

1 DR. ROMANO: Okay. So yes. It's
2 correct that we have gotten some information
3 from the authors of these studies, both the
4 adult and pediatric studies, that has allowed
5 us to augment the list of exclusionary
6 procedures. Unfortunately, I can't tell you
7 right off the top of my head exactly which
8 procedure was added in which year and which
9 version.

10 But the current list of procedures
11 does reflect some incremental changes with
12 each annual update. So I am going to read
13 some numbers to you, which you may not be able
14 to follow, but we will certainly give them to
15 you in writing. But it will give you a sense
16 of the impact of these different exclusions.

17 So this is for the adult
18 indicator. Based on one year of national data
19 from the nationwide inpatient sample, 5,139
20 events were flagged by PSI 6, 5,139.

21 Three hundred and twenty-six --
22 now I am going to talk about the exclusions,

1 but these exclusions are potentially
2 overlapping. So I am going to give you
3 numbers for each exclusion independently, not
4 marginally. Okay? So the marginal impact of
5 any one exclusion would be less than what I am
6 describing.

7 But the chest trauma exclusion
8 basically eliminates 326 cases. So those are
9 patients who came in with some form of chest
10 trauma. And for those patients, we have some
11 concern that the pneumothorax was actually
12 present on admission and was not reported
13 accurately as being present on admission.

14 Some of those patients may not
15 have a pneumothorax apparent on their initial
16 chest X-ray and then after some period of
17 observation in the hospital, they develop a
18 pneumothorax but it's really related to the
19 chest trauma that brought them into the
20 hospital in the first place. So that's 326.

21 We have 4,945 events excluded
22 related to pleural effusions. And the reason

1 for that is because pleural effusions are, of
2 course, often treated with chest tubes or with
3 a diagnostic thoracentesis. And particularly
4 the chest tube usually involves some air
5 getting into the pleural space. It may be a
6 small amount of air depending on how sharply
7 the radiologist reviews the X-ray. It may or
8 may not be documented. But we anticipate that
9 this would be a natural consequence of chest
10 tube placement for drainage of pleural
11 effusion.

12 Nineteen cases excluded because of
13 pregnancy or childbirth. That's a universal
14 exclusion because there is a separate set of
15 codes and it's complex coding issues.

16 Thoracic surgery, 7,535 events
17 excluded. Those are patients where there is
18 some opening of the pleural space in the
19 course of the procedure. And so it is
20 expected there that air will get into the
21 pleural space and may be apparent on a
22 postoperative X-ray.

1 Two thousand, ninety-two cases
2 excluded in the course of lung or pleural
3 biopsies. Now, in those cases, the
4 pneumothorax may be preventable, but these are
5 patients who often have large lesions.
6 They're often getting percutaneous biopsies,
7 often by interventional radiologists,
8 sometimes by surgeons.

9 But these procedures, depending on
10 the placement, there is a known risk of
11 pneumothorax. And it is part of the embedded
12 risk of the procedure; in other words, that
13 the physicians decide to pursue this route to
14 achieving a diagnosis because it is better and
15 safer than an alternative route, recognizing
16 that it involves a risk of pneumothorax.

17 Then there are 3,379 exclusions
18 related to cardiac surgery. Again, that
19 usually involves entry through the mediastinum
20 or through the pleural space or both, where
21 there is a known risk of pneumothorax.

22 And, finally, 124 cases due to

1 diaphragmatic surgery, where, again, there may
2 be diaphragmatic surgery, where air may enter
3 the pleural space as a direct consequence of
4 the procedure.

5 So that gives you a spectrum.
6 Certainly the number of cases captured is much
7 smaller than the number of cases excluded, but
8 we think that there is a rational basis for
9 these exclusions.

10 But it has been an incremental
11 process over the years. The exclusion list
12 has evolved. And it will continue to evolve.
13 So we are certainly open to suggestions about
14 how to narrow it or expand it.

15 MEMBER MCGIFFERT: I think on page
16 25 is where there is a reference to based on
17 analysis, that you have made recommendations
18 to revise the exclusions. And it looks like
19 only one, exclusion 1, is recommended to be
20 dropped or were you referring to something
21 after this paper was written or am I looking
22 at the wrong place?

1 DR. ROMANO: Well, let me make
2 sure I am looking at the right place. You are
3 only page 25 --

4 MEMBER McGIFFERT: At the bottom.
5 And it says --

6 DR. ROMANO: -- of the PSI 6
7 document?

8 MEMBER McGIFFERT: -- "Results."
9 And it says, "Based on the analysis."

10 DR. ROMANO: Oh, yes. So this is
11 what I have given you verbally. I am sorry
12 about reading numbers aloud, but that is an
13 oral representation of the numbers behind this
14 analysis that is described here.

15 The specific recommendations here
16 are draft recommendations from the analytic
17 team. And so they haven't really gone through
18 the internal process of review by a clinical
19 panel. But yes, the essential argument here
20 is that almost all of these exclusions would
21 be retained except possibly for the first one,
22 which is the chest trauma exclusion.

1 And the reason for that basically
2 was in the analysis, when we actually drilled
3 in and looked at when patients got chest tubes
4 and so forth, it appeared that in most of the
5 cases, the chest tubes were placed late in the
6 hospital stay, suggesting that these were
7 patients who actually didn't have pneumothorax
8 at admission and had a central venous catheter
9 placement and then may have had the
10 complication as a result of that.

11 CO-CHAIR CIPRIANO: Okay. Open it
12 up to discussion. John, is your card up?

13 MEMBER CLARKE: I think my card is
14 up. I want to talk, but I think it would be
15 more appropriate if Susan talked first since
16 she's a thoracic surgeon.

17 MEMBER MOFFATT-BRUCE: So I think
18 that on page 1, we did a service to
19 understanding what the exclusions are when you
20 simply summarize it by including the exclusion
21 of chest drama; surgery, whether or not it's
22 cardiac or thoracic; and then having

1 underlying thoracic pathologies.

2 And then when we open it up to
3 page 8, that is basically a reflection of how
4 difficult it is, our coding is, currently
5 around -- this is basically a list of every
6 thoracic or cardiac procedure that we do. And
7 that's unfortunate. We have 12 ribs because
8 it lists out by number of rib fractures. It
9 lists whether or not I go in thoroscopically
10 or through a thoracotomy. And God forbid I do
11 it robotically. And so that really is what
12 that is a reflection of within our specialty.
13 So you can imagine what --

14 (Off mic comment.)

15 MEMBER MOFFATT-BRUCE: Yes,
16 absolutely. Yes, you know, in the STS
17 database right now is just expanded from four
18 pages to seven-page collection tool because of
19 this complexity. So I apologize for that on
20 behalf of our society.

21 You did a very good job, Patrick,
22 of summarizing that, awesome, very nice.

1 CO-CHAIR CIPRIANO: Okay. John
2 and then Jason?

3 MEMBER CLARKE: I concur with
4 Susan. I think the list of exclusions,
5 although extensive, is imminently reasonable
6 because when you cut into the pleuralist
7 cavity or cut into the lung or the tracheal
8 tree --

9 CO-CHAIR CIPRIANO: Gently
10 dissect.

11 MEMBER CLARKE: Well, yes.
12 Cardiac surgeons say, "Gently dissect." I'm
13 a trauma surgeon. We just cut.

14 (Laughter.)

15 MEMBER CLARKE: And I think it is
16 a perfectly reasonable list because those
17 things will produce air leaks inevitably or at
18 least you assume they would produce air leaks.

19 With regard to the pneumothorax, I
20 don't object to some nuances on the delayed
21 presentation of pneumothorax. People who come
22 in without an apparent pneumothorax except on

1 CT sometimes do show up with a pneumothorax,
2 although it is unusual.

3 And in terms of putting central
4 lines in those patients, we actually put the
5 central line in on the side of the trauma,
6 rather than run the risk of giving them the
7 pneumothorax on both sides: one from the
8 trauma and one from the central line. We only
9 provide the risk on the area that is at risk
10 anyway.

11 I do want to make sure -- and I
12 hope that's evident -- that when you talk
13 about a thoracic procedure, that you are not
14 talking about a subclavian line and no one is
15 misinterpreting that as a thoracic procedure
16 because that is obviously -- thyroid trauma
17 from respirators and central lines would
18 really be things that we are trying to
19 capture. I think this does a reasonable job
20 doing that.

21 CO-CHAIR CIPRIANO: Thank you.

22 Jason?

1 MEMBER ADELMAN: Just, Patrick,
2 forgive me. I am going to make a general
3 statement about all of these measures. Right
4 now we are talking about the positive
5 predictive values are a little bit better. I
6 just have a problem with all of the -- I think
7 that this work is great and it is important
8 and it has its role.

9 And we discussed earlier that it
10 is just great for helping to find cases where
11 we can learn a ton. But once you get into
12 moving into publicly reported data as some way
13 that it is a measure that either a provider
14 can judge us or it can be a value-based
15 purchasing measure, where, actually, our
16 compensation could be judged by it, then like
17 the statistical rigor should really be there.

18 And so, for example, like we don't
19 know the sensitivity specificity. I don't
20 know that we could because it is so hard to
21 find false negatives, but I am thinking back
22 to the blood transfusion discussions.

1 Like I know of wrong patients
2 getting blood. I have a feeling that there is
3 a huge number that is being missed. And we
4 could even get some idea of what the
5 sensitivity specificity is, maybe by comparing
6 the data from the PSI with the data from some
7 of the other reporting systems that John
8 mentioned are really very good.

9 But the point is I am a huge fan
10 of the PSIs for the purpose of learning about
11 errors and making it better. Just I feel
12 like, you know, even if the positive
13 predictive value is 80 percent, what is the
14 sensitivity specificity and negative
15 predictive value? You can't even answer it.

16 And it surprises me sometimes. I
17 feel like AHRQ hasn't put enough into funding
18 research around this. A lot of the studies
19 that we talked about have n's of like 120
20 charts were reviewed, like they couldn't --
21 you know, they're the ones that are begging
22 for money. They control the money. It's

1 their PSIs. More studies can be done. Better
2 studies could be done. And I am just nervous
3 about making a blanket statement, all of these
4 as publicly reported data for those reasons.

5 Thank you. Sorry.

6 CO-CHAIR CIPRIANO: Okay. Rich?

7 MEMBER WHITE: Do you tell us why
8 the positive predictive value is so much
9 higher in adults than kids?

10 DR. ROMANO: I think that the
11 major reason for that is because there are
12 different procedures that are sometimes done
13 in children, which contribute to the risk.
14 And some of those procedures were not in the
15 original exclusion list. And so they were
16 added subsequently.

17 And one of the examples that is
18 specifically cited I believe in Scanlon's
19 paper is some tracheal procedures, tracheal
20 reconstructive procedures, which are
21 procedures related to congenital anomalies of
22 the trachea in general.

1 To address your question, I'll
2 defer to John. I think that certainly we are
3 happy to do additional validation work. And
4 I think AHRQ is currently reassessing its
5 priorities for validation work going forward.
6 So I ask John to make some comment on that.

7 MR. BOTT: Yes. So I apologize if
8 I missed the very front end of this
9 conversation. I got back about 12:10. And it
10 sounds like we were already en route in
11 discussing these measures.

12 Actually, Patrick and company just
13 provided a paper, which I think is at the very
14 beginning of this, of validation methods used
15 up to this time. And so we're reviewing that
16 at the time, some statisticians at AHRQ and et
17 cetera, as one of the steps.

18 But I had mentioned before that
19 one of our big priorities in 2012 will be
20 reassessing what we're calling here at AHRQ
21 the measure life cycle process.

22 And as a part of that, we're going

1 to be looking at criteria by which we'll be
2 used to evaluate measures for retirement.

3 But another part of that will be
4 revisiting the measure validation process. We
5 think some good work has been done to date
6 from that validation pilot that we have been
7 doing for several years but want to stress
8 that that was a pilot phase.

9 And we have learned a lot from
10 that phase, but we do need to go back and
11 systematically think about how do we with a
12 high degree of rigor go about periodically the
13 validation process, repeating it periodically
14 and developing criteria by which even when we
15 do establish a process, when would measures
16 come out of the sequence to be for validation
17 outside of that, say, when codes change
18 substantially or when our methodology changes
19 substantially, it needs to be done even more
20 frequently than planned.

21 So it is a high priority to
22 develop that, a validation process going

1 forward for all RQIs. And so that is the
2 first step in moving this from pilot to what
3 we perceive will be a more rigorous process
4 going forward.

5 DR. ROMANO: What John alluded to
6 at the beginning of his comments was that we
7 have proposed and pilot-tested a methodology
8 for assessing sensitivity of these relatively
9 uncommon events, basically using a sampling
10 method that would oversample cases where we
11 had reasons to suspect that the event
12 happened, but it wasn't reported.

13 For example, we can sample cases
14 that had a chest tube inserted after 24 hours
15 into the hospital stay and see whether some of
16 those chest tube insertions were related to a
17 pneumothorax. And that potentially gives us
18 the power to estimate sensitivity; whereas, we
19 couldn't if we were just doing a random sample
20 of all hospitalizations. It would be
21 hopelessly inefficient.

22 So we pilot-tested that method.

1 It actually seems to have worked reasonably
2 well. We did find some false negatives for
3 this indicator. And we hope to extend that
4 now to a larger sample, a larger group of
5 hospitals. And obviously I defer to the
6 Committee about the fact that we obviously
7 don't have those data yet.

8 CO-CHAIR CIPRIANO: Okay. We have
9 Bill and Charlotte and then Pat.

10 CO-CHAIR CONWAY: Patrick, that
11 was a nice rundown of the frequency of those
12 exclusions. Do you have information? What
13 are we measuring with this now? What's left?

14 DR. ROMANO: Right. So what we're
15 measuring, I think, is best described -- and
16 I'm sorry that the references weren't included
17 in the submission, but there's a paper by
18 Sadeghi and colleagues, including me, from the
19 non-VA hospitals and then a paper by Kafirani
20 and colleagues from the VA hospitals. And
21 those are the two sources of the positive
22 predictive values that Lisa mentioned and so

1 what those two studies show.

2 So from the Sadeghi study,
3 basically 200 cases that were reviewed. And
4 of those 200 cases, basically 69 of them had
5 a central venous catheter as the cause of the
6 event. Nine had a trans-thoracic needle
7 aspiration or biopsy. Fifty-six had other
8 invasive procedures, most commonly pacemaker
9 lead placements or defibrillator placements.
10 And then five were barotrauma related to
11 mechanical ventilation. One was related to
12 cardiopulmonary resuscitation. And 16, we
13 couldn't figure it out. That was based on
14 chart review.

15 CO-CHAIR CONWAY: The nine that
16 were trans-thoracic biopsies, I thought that
17 was on the exclusion list.

18 DR. ROMANO: Right. Well --

19 CO-CHAIR CONWAY: Did they just --

20 DR. ROMANO: -- unfortunately, our
21 concern is that that type of procedure is
22 often done at the bedside, especially when it

1 is an aspiration, rather than a biopsy, which
2 means that it is under-reported.

3 So, therefore, we don't rely on
4 that procedure code as the basis for the
5 exclusion. Instead, we rely on the diagnoses,
6 like pleural effusion, that would trigger that
7 procedure.

8 So it is possible that we could
9 revisit. So that if those procedures are, in
10 fact, coded, then we could add that to the
11 exclusion list. But currently they are not.

12 CO-CHAIR CIPRIANO: Thank you.

13 Charlotte?

14 MEMBER ALEXANDER: My question
15 sort of tails in on what Bill was saying. If
16 what we are really looking at is iatrogenic
17 pneumothorax after a central line insertion,
18 for example, why don't we title the measure
19 that, instead of having a blanket measure with
20 so very many exclusions?

21 CO-CHAIR CIPRIANO: Bill, did you
22 want to give an opinion on that? I'm sorry.

1 Patrick?

2 DR. ROMANO: I can tell you that
3 the reason that we haven't done that is
4 because previous -- and this is older
5 literature now. So this is literature that
6 goes back 15 to 20 years -- showed that
7 bedside central venous catheter placements are
8 under-coded substantially. Only about 50
9 percent of them were actually coded.

10 So, for that reason, we were
11 concerned that if we limited the denominator
12 to those cases, we would be missing a lot of
13 the patients who are actually at risk.

14 Now, that may have changed. And
15 that is quite possibly something that we
16 should reevaluate because to the extent that
17 those procedures are now being done under more
18 controlled situation with concurrent nursing
19 involvement -- when I was in training, you
20 know, we used to do this without a nurse
21 anywhere in sight. But now, of course, it is
22 a very different -- surprise, surprise. So

1 now it is a very different situation. And the
2 nurses make sure that we document things
3 correctly. And so this may need to be
4 reevaluated.

5 CO-CHAIR CIPRIANO: Okay. I think
6 we have Pat next.

7 MEMBER QUIGLEY: Thank you, Dr.
8 Cipriano.

9 My question was related to in
10 reviewing both of them, the evidence was very
11 clear and presented I thought clearly for the
12 adult one and graded, but the evidence and the
13 literature to support the pediatric one was
14 not and actually wasn't included, but, yet, it
15 was entered by AHRQ as being moderate.

16 So I just wanted to just make sure
17 that there was evidence to support the
18 pediatric one. If someone maybe could speak
19 to that?

20 DR. ROMANO: There was a little
21 bit of a rush when we submitted the forms.
22 And I apologize for that. But some of the

1 material that should have gotten into both
2 forms did not. So I apologize.

3 CO-CHAIR CIPRIANO: Okay. Iona
4 and then John?

5 MEMBER THRAEN: I can't find it
6 now, but back to the same kind of question.
7 In the pediatric version, there is a statement
8 that between 2000 and 2007, there has been an
9 actual decrease in the incidence of the
10 condition that we are talking about. So that
11 then raises the question similar to what we
12 were talking about before about the
13 performance gap in the room for improvement.

14 CO-CHAIR CIPRIANO: John?

15 MEMBER CLARKE: Like Charlotte, I
16 struggled with whether this should be an
17 inclusive or exclusive set of criteria, but
18 the thought occurred to me that there are so
19 many new technologies, particularly minimum
20 invasive technologies, coming down the pike
21 that I think to make it just an inclusive
22 criteria might be to miss potential future

1 problems. And so I would actually support
2 Patrick's concept of exclusion criteria.

3 I think the exclusion criteria,
4 unfortunately, will be a long list. But you
5 know what? When you are trying to have a
6 really accurate measurement, this kind of
7 fine-tuning always occurs.

8 CO-CHAIR CIPRIANO: Okay. So if
9 you guys will put your tents down over here if
10 you're not asking a question? Having a little
11 post-lunch fatigue.

12 (Laughter.)

13 CO-CHAIR CIPRIANO: Okay. So we
14 heard a lot of discussion and explanation
15 about the inclusive measure with very specific
16 exclusion criteria with data. We have heard
17 a little bit more background in terms of
18 additional studies that speak to the evidence
19 and validity of the information.

20 Are there any other questions or
21 comments, either for Patrick or from Patrick
22 or anyone else on your team, at this point?

1 DR. ROMANO: Just to respond to
2 one question. So the reduction in the
3 prevalence was from 2.134 to 1.329, so roughly
4 a one-third reduction. So I think we would
5 argue that we certainly made progress, but
6 we're not at the six sigma level.

7 CO-CHAIR CIPRIANO: Okay. And
8 then I think this probably is a good example
9 that as we are seeing additional technology,
10 we are seeing improvements that at the next
11 measure maintenance assuming it is approved
12 now, that we may, in fact, be seeing a very,
13 very small gap, which would be great.

14 Question was, was it true for both
15 pediatric and adult?

16 DR. ROMANO: Yes, but the numbers
17 on the adult side are more consistent, more
18 reliable.

19 CO-CHAIR CIPRIANO: Okay. Are
20 there any comments or questions from those on
21 the phone?

22 OPERATOR: Just a reminder it is

1 *1 if you have a question today.

2 (No response.)

3 OPERATOR: No.

4 CO-CHAIR CIPRIANO: Okay. Are we
5 ready to vote?

6 (No response.)

7 CO-CHAIR CIPRIANO: All right.

8 And what I would suggest is that we are voting
9 on both measures consistently unless someone
10 would like to deal with them separately. Is
11 there consensus that our votes will count for
12 both measures? I see lots of heads nodding.
13 Okay. All right.

14 Jessica, if you will lead us
15 through that, please?

16 MS. WEBER: All right. Importance
17 to measure and report. Are all three
18 subcriteria met: high-impact, performance
19 gap, evidence, "Yes"/"No" question? And if
20 you could just cast your vote again? I think
21 we need one. Oh, there it is.

22 Janet?

1 MEMBER NAGAMINE: Yes.

2 MS. WEBER: Gina?

3 MEMBER PUGLIESE: Yes.

4 MS. WEBER: Eighteen yes, one no.

5 Scientific acceptability of
6 measure properties: reliability and validity.

7 It is a "Yes"/"No" question. Janet?

8 MEMBER NAGAMINE: Yes.

9 MS. WEBER: Gina?

10 MEMBER PUGLIESE: Yes.

11 MS. WEBER: Seventeen yes, two no.

12 Usability: high, moderate, low,
13 insufficient? Janet?

14 MEMBER NAGAMINE: Mod.

15 MS. WEBER: Gina?

16 MEMBER PUGLIESE: Moderate.

17 MS. WEBER: Six high, 12 moderate,
18 1 low.

19 Feasibility: High, moderate, low,
20 insufficient? Janet?

21 MEMBER NAGAMINE: Moderate.

22 MS. WEBER: Gina?

1 MEMBER PUGLIESE: High.

2 MS. WEBER: Nine high, nine
3 moderate, one low.

4 Overall suitability for
5 endorsement. Does the measure meet all the
6 NQF criteria for endorsement? Janet?

7 MEMBER NAGAMINE: Yes.

8 MS. WEBER: Gina?

9 MEMBER PUGLIESE: Yes.

10 MS. WEBER: Eighteen yes, one no.

11 CO-CHAIR CIPRIANO: Okay. Thank
12 you very much. And, again, thank you, Patrick
13 and colleagues, for that discussion.

14 DR. ROMANO: And if I could just
15 ask if NQF staff would be willing to reopen
16 the forms, we would be happy to enter some
17 more full information in response to the
18 questions.

19 CO-CHAIR CIPRIANO: Great. Thank
20 you very much.

21 Okay. We are ready to move to the
22 next two measures on pain assessment. And,

1 Operator, if you would make sure that we have
2 open phone lines for Deborah Deitz, Eugene
3 Nuccio, and David Hittle?

4 OPERATOR: Yes, I can do that.

5 CO-CHAIR CIPRIANO: Okay. Thank
6 you very much.

7 And Jim? Where did Jim go? Oh,
8 he's left. Sorry. All right.

9 0523: PAIN ASSESSMENT CONDUCTED.

10 0524: PAIN INTERVENTIONS IMPLEMENTED

11 DURING SHORT TERM EPISODES OF CARE.

12 CENTERS FOR MEDICARE & MEDICAID SERVICES.

13 CO-CHAIR CIPRIANO: So 0523 is
14 pain assessment, and it is specific for home
15 health. Is there anyone else in the group
16 that would like to describe this measure?
17 This is a process measure.

18 MEMBER de LEON: If you would
19 like, I can just at least summarize because --

20 CO-CHAIR CIPRIANO: Sure, Jean.

21 That would be great.

22 MEMBER de LEON: -- it kind of

1 goes into the next one.

2 CO-CHAIR CIPRIANO: Okay. Great.

3 MEMBER de LEON: It is a process
4 measure. It is looking at strictly the home
5 health setting and the assessment of pain on
6 the initiation of a home health episode of
7 care, not each visit but the episode of care.
8 And the numerator is those patients who were
9 accepted into the home health agency. The
10 denominator is all of the patients basically.

11 Our discussion on this had to do
12 with trying to pair this with the following
13 indicator or the following measure and what
14 else was out there in the home health.

15 There is very little literature
16 that is targeted at home health patients. And
17 the majority of the evidence is on education,
18 but there is no evidence -- and this will
19 follow in the measure after this, the
20 intervention. There is no evidence that says
21 that doing an assessment changed the quality
22 of care for the patient. But we all would

1 reason that if you didn't asses, how were you
2 going to start to initiate an appropriate
3 treatment?

4 But the evidence doesn't link an
5 assessment to an actual outcome. This is a
6 process measure, same thing for the treatment.

7 Is it okay if I discuss the next
8 one a little bit as I go?

9 CO-CHAIR CIPRIANO: I think it
10 might be beneficial for the group, especially
11 if we want to have some discussion about
12 pairing the measures. Thank you.

13 MEMBER de LEON: The same thing
14 was very true of the intervention, the fact
15 that you make unintervention, didn't talk
16 about the quality of the intervention, that it
17 had anything to do with your pain but that you
18 did something and it was in the orders, is not
19 linked with the outcome. And there is no
20 evidence to support that.

21 But common sense tells us that
22 pain is affecting a lot of our patients in a

1 home health setting. It is not being
2 addressed well from the literature, but we
3 don't have the evidence that tells us exactly
4 what we need to do to effect that outcome.

5 But reason tells us you need to
6 assess it. Then you need to come up with a
7 treatment plan. And then you need to initiate
8 the treatment plan.

9 But what we would come to in the
10 discussion group is -- and then you need to
11 measure whether that treatment plan was
12 appropriate. And that is what the measure is
13 missing.

14 So we have a couple of pieces but
15 not the actual piece that most of us felt
16 would make the difference, which is measuring
17 what the intervention was and whether that was
18 appropriate and whether the pain scores go
19 down or the patient's perception of their
20 function improved or something like that.
21 These measures don't cover that. Simply did
22 you assess it? And did you do anything?

1 CO-CHAIR CIPRIANO: Okay. Thank
2 you.

3 Is it okay with the Committee
4 members if we asked the measure developer to
5 speak to these next -- okay. Deborah, Eugene,
6 or David, whoever is going to take the lead,
7 if you would like to describe the measure and
8 give us any additional background, please?

9 MS. DEITZ: This is Deborah.
10 These two measures are part of our pain suite
11 for home health measurement, which consists of
12 four measures. One is, did you do an
13 assessment? Was it addressed in the care
14 plan? And then was that care plan
15 implemented?

16 There is also the fourth outcome
17 measure. Did the patient experience a
18 reduction in the amount of pain that would
19 interfere with their movement?

20 So we do have all four of those
21 measures. We presented those four measures to
22 NQF several years ago. And these, the outcome

1 measure is endorsed. And the pain assessment
2 and the pain implementation were endorsed.

3 Some of the issues around
4 adequately assessing whether or not the
5 patient received the care that they need for
6 their pain are influenced by their bio how we
7 collect information in for these home health
8 measures, which is strictly through the OASIS
9 data assessment. So we are a bit limited in
10 what we can measure based on what the OASIS
11 collects.

12 If you have any other questions, I
13 will be happy to respond to them.

14 MEMBER de LEON: Okay. So if I
15 understand you correctly, you are saying there
16 are some outcome measures that NQF has already
17 endorsed that get at --

18 MS. DEITZ: There is an outcome
19 measure for a patient, yes.

20 MEMBER de LEON: -- that get at
21 the concerns of whether a home health visit
22 where they ask about pain actually resulted in

1 addressing that pain?

2 MS. DEITZ: Yes.

3 CO-CHAIR CIPRIANO: Or is it the
4 actual treatment intervention, not looking at
5 the upstream activities, but once there was an
6 intervention, was it effective?

7 MS. DEITZ: The measure, the
8 outcome measure, does not tie the was the
9 intervention effective. It doesn't tie the
10 intervention and the outcome. It merely asks
11 whether there was an improvement between when
12 the patient began home care and when the
13 quality episode ended at the end of care.

14 CO-CHAIR CIPRIANO: Okay. Let's
15 go ahead and take other questions from the
16 group. Vallire?

17 MEMBER HOOPER: I have several
18 questions. My first question, just for point
19 of clarification, because home health is not
20 my area, is my understanding was an episode of
21 care was not each visit.

22 MEMBER de LEON: The

1 certification. It's a certification period.

2 So it's depending on assessment that --

3 MEMBER HOOPER: So we are not
4 evaluating pain assessment with each visit,
5 nor are we evaluating pain intervention with
6 each visit. So an episode of care could be
7 weeks, months.

8 MEMBER de LEON: But you would be
9 excluded if you said you didn't have pain on
10 the first assessment.

11 MEMBER HOOPER: And then there
12 wouldn't be a reassessment.

13 MEMBER de LEON: Because if you
14 have pain on the next assessment or the next
15 visit, we're not counting that.

16 MEMBER HOOPER: Okay. Secondly, I
17 am very concerned with 0524. And, again, I am
18 going to preface this statement with I am not
19 a home health care nurse. But I am concerned
20 with the terminology of physician plan of care
21 and that from a nursing perspective, someone
22 implies a medical model to pain management,

1 which may not be the case, but even though
2 there may not be a lot of data about
3 assessment and management of pain in the home
4 health care setting, there is a huge amount of
5 data assessment and management of acute pain
6 and chronic pain. And all of that data points
7 to a multimodal approach to pain management.

8 So I am a little bit concerned
9 about what the implications of physician plan
10 of care or --

11 MEMBER de LEON: The physician
12 signs a plan of care for each of the home
13 health patients. And it can be -- when I
14 signed a plan of care, 9 times out of 10, 80
15 percent of what is there has nothing to do
16 with me because I am a wound care specialist.
17 And I started them on home care for their
18 wound.

19 But the internist has 12 meds
20 going on. They may have infectious disease
21 that has added a couple of things going on.
22 And then it's compiled by the home health

1 agency. It's printed up as a physician plan
2 of care. Some physician has to sign that plan
3 of care.

4 MEMBER HOOPER: Okay. That is
5 helpful.

6 MEMBER de LEON: So it is not as
7 though somebody is over there just going,
8 "Well, let me think about this carefully." It
9 doesn't happen that way.

10 MEMBER HOOPER: And a third area
11 of concern is -- and I would be curious to see
12 the outcome measure, the measure related to
13 outcomes because I am not seeing anywhere the
14 recommendation for the establishment of a
15 comfort function goal, which is very strongly
16 supported in the evidence, whether it is acute
17 pain or chronic pain, that we need to be
18 assessing the patient's pain, working with the
19 patient using a patient-centered approach to
20 establish a comfort function goal, and then
21 working with the patient and their significant
22 others to create a treatment plan to meet that

1 comfort function goal.

2 And I am curious as to if the
3 comfort function goal is addressed in any of
4 these measures because I am not seeing it in
5 these two.

6 CO-CHAIR CIPRIANO: Deborah, would
7 you like to comment?

8 MS. DEITZ: No. I mean, yes, I
9 will comment that, no, we have not developed,
10 nor are we currently collecting any
11 information about the establishment of a
12 comfort function goal. That would be
13 something that we would be interested in
14 looking at for future development. But that
15 has not been something that has been done
16 today.

17 CO-CHAIR CIPRIANO: So I think, to
18 summarize, Vallire, there is no comfort
19 measure here. It does say electronic clinical
20 data are the source for this.

21 But it does tie back to only
22 interventions included in the signed plan of

1 care. So there may be additional measures
2 that are provided by the home health nurse,
3 with or without a formal comfort measure plan,
4 that they would not be picked up.

5 MEMBER HOOPER: And am I also
6 understanding that this is not exploring
7 assessment and intervention with each
8 individual visit? It is --

9 MEMBER de LEON: That is correct.

10 MEMBER HOOPER: -- exploring it
11 just -- there is no dictation about how many
12 times this is addressed over the episode of
13 care, which is quite different from what the
14 performance measures around acute care -- this
15 is very, very short of the mark if you look at
16 the requirements for the management of pain in
17 the assessment and reassessment of pain in the
18 acute care setting. This is very, very short
19 of the mark.

20 CO-CHAIR CIPRIANO: Right. And,
21 again, is very different.

22 Okay. We have Carol, Lisa, and

1 Iona.

2 MEMBER KEMPER: Some of my
3 comments are similar. Just I am concerned if
4 we are only picking up those physician orders
5 and just there are a lot of interventions that
6 I think home health nurses are doing that I
7 just think I want you to be able to capture
8 those. And so I think limiting it to the
9 physician order is concerning.

10 The other thing is -- and Vallire
11 sort of alluded to this -- that there are
12 measures out there. And I know home care is
13 very different. I have practiced in a home
14 care setting. And I know there are unique
15 issues there.

16 However, you know, some of the
17 measures, like the NDNQI measure associated
18 with pain, which has an assessment
19 intervention, reassessment, if there was a way
20 to tailor that and have all of those
21 components into one measure, I just think that
22 would add a lot more valuable information.

1 CO-CHAIR CIPRIANO: Lisa?

2 MEMBER McGIFFERT: I would just
3 say this is a process measure and that we
4 should move away from process measures and
5 especially one that has as many flaws as this
6 one seems to have. And I would be very
7 interested in seeing the details of the
8 outcome measures that are out there before we
9 vote or --

10 MS. BOSSLEY: I can point the one
11 outcome measure that they have been
12 referencing. I can tell you what that is. So
13 the title is "Improvement in Pain Interfering
14 With Activity." And the description is
15 "Percentage of patients who have less pain
16 when moving around and the way it is
17 captured." Just a second.

18 So let me start with the
19 denominator first. This is the same
20 developer. It's home health. It's using the
21 same data source and everything. It's all
22 home health episodes. And, Deborah, tell me

1 if it has been updated. I think it is an
2 update now.

3 But all home health episodes
4 except where either of the following
5 conditions applies. And that's where at the
6 start or resumption of care, assessment is
7 zero, indicating there is no pain. They are
8 excluded. And then the patient did not have
9 a discharge assessment.

10 So this is looking at from the
11 time of when they are admitted to when they
12 are discharged within that home health
13 episode.

14 And the numerator is the number of
15 home health episodes where the value recorded
16 in OASIS is numerically less than the value
17 recorded at the start. So, again, I am
18 looking at the difference in the scale.

19 MEMBER MCGIFFERT: Can I ask, so
20 the pain is less than when it started?

21 MS. BOSSLEY: Yes.

22 MEMBER MCGIFFERT: Okay.

1 MS. BOSSLEY: Yes. That's it.

2 MEMBER HOOPER: No comfort
3 function goal in that measure.

4 MS. BOSSLEY: No unless --
5 Deborah, I am assuming it has not been updated
6 to include that. Right?

7 MEMBER HOOPER: Thank you.

8 MS. DEITZ: No, it has not.

9 MEMBER HOOPER: Okay.

10 MS. DEITZ: I would like to just
11 comment on this issue about the
12 physician-ordered plan of care. I just want
13 people to understand that this is not
14 restricted to a typical -- I mean, it includes
15 non-pharmacological and other interventions.

16 The reason that we stated that it
17 had to be included in the physician plan of
18 care is because that is the plan of care that
19 the clinician uses when they are treating the
20 patient. And if it is not in that plan of
21 care, there is no assurance that it will be
22 consistently understood that that is the plan

1 of care.

2 In other words, it is not like
3 there is a physician plan of care. And then
4 there is also the other plan of care. That is
5 the plan of care that is documented for what
6 the agency is going to be doing for that
7 patient. So that's why. But it frequently
8 includes all kinds of other measures beyond
9 pharmacological.

10 MEMBER THRAEN: Excuse me. I
11 think the challenge with these two is that
12 they are using the OASIS tool. The OASIS for
13 CMS is the primary assessment tool. It is a
14 quasi billing, quasi clinical tool, kind of
15 falls in between those two ends of the
16 continuum. And they are using the data from
17 OASIS in order to capture some measure of this
18 issue.

19 So it is really a problem of the
20 OASIS assessment tool and the kind of data
21 that it is capturing. So in order to make
22 changes to do a better job at getting at the

1 answer that you are asking for, the OASIS
2 assessment tool in and of itself would have to
3 be changed in order to capture different kinds
4 of data.

5 Currently OASIS is probably the
6 only thing that is available in the home
7 health world in any kind of standardized
8 fashion to capture what is going on at all.

9 I have not heard much conversation
10 about the clinical information systems in home
11 health. There probably are some. But I know
12 that its meaningful use is starting at the
13 hospital level. And in about probably 10-15
14 years, it will eventually probably get into
15 the home health world. But as it stands right
16 now, OASIS is it.

17 So if you want any kind of
18 surveillance in that world, you have to use
19 the OASIS tool as the mechanism.

20 CO-CHAIR CIPRIANO: Pat and then
21 Carol.

22 MEMBER QUIGLEY: Thank you, Dr.

1 Cipriano.

2 My comments and my concerns are
3 related to the assessment indicator. And that
4 is because the literature review to support
5 this indicator to me did not even reflect the
6 standard of practice. And it is really quite
7 dated.

8 I would look for a synthesized
9 literature review in relationship to pain
10 management. The article that was reviewed to
11 indicate that nurses had issues with knowledge
12 and a knowledge gap and pain assessment is
13 over ten years old, and it is one study. And
14 the nursing profession for two decades has
15 been really building science related to
16 nurses' role and leadership in pain assessment
17 and management.

18 And I know in the Department of
19 Veteran's Affairs, pain assessment is our
20 fifth vital sign, as it is in many places.
21 And it is across the entire continuum of care,
22 be it in hospice or home care or ambulatory

1 care or even in assessing our homeless
2 veterans. You know, we still ask patients
3 about pain upon every encounter. It's not
4 just upon admission.

5 So I was really very concerned
6 that, you know, a quality indicator should not
7 just be based on the state of the science but
8 should be able to help us advance our practice
9 to a higher level and move that gap, move the
10 standard of practice forward. So I was very
11 concerned about this indicator.

12 And, Madam Chair, those are my
13 comments.

14 CO-CHAIR CIPRIANO: And, Pat, did
15 you have any similar concerns about the
16 evidence in the second measure: the
17 intervention measure?

18 MEMBER QUIGLEY: Yes, I did.
19 Thank you.

20 CO-CHAIR CIPRIANO: Carol?

21 MEMBER NAGAMINE: This is Janet.
22 My hand is up when you are ready.

1 CO-CHAIR CIPRIANO: Okay. Janet,
2 go ahead.

3 MEMBER NAGAMINE: Just to tag onto
4 the question of evidence and impact, it seems
5 like the gap or the problem is focused on
6 nursing assessment in home health of pain,
7 rather than a patient-centered gap of what is
8 the incidence of lack of pain management in
9 this population?

10 I'm looking for evidence that
11 there is a gap from the patient perspective.
12 And I didn't see that. And so I just throw
13 that out there that I am not seeing that
14 impact.

15 CO-CHAIR CIPRIANO: Okay. Carol?

16 MEMBER KEMPER: Just a comment
17 again about the OASIS data. And I think, you
18 know, if OASIS is limited in what it is
19 providing, I would hope that there is some
20 other mechanism to get that information. I
21 know it is easier to get it out of OASIS
22 because, you know, I have electronic data

1 pull.

2 But it would be more meaningful to
3 look at some other data source if OASIS isn't
4 providing us the detail that we need.

5 CO-CHAIR CIPRIANO: Iona, is your
6 card up again?

7 MEMBER THRAEN: Oh, I'm sorry.

8 CO-CHAIR CIPRIANO: Okay. That's
9 all right. Vallire?

10 MEMBER HOOPER: I guess my
11 question would be -- and this may be a little
12 bit early, but given the concerns that we have
13 around the quality of these quality measures
14 and what they are actually getting at, I feel
15 very strongly that there should be quality
16 measures in the home health setting regarding
17 pain, as there should be across all settings.

18 But it's like Patricia said. Pain
19 should be the fifth vital sign. It should be
20 assessed at every visit.

21 We need quality measures, but
22 these are of poor quality. And I don't know

1 that they're telling us anything that would be
2 helpful to improve patient outcome.

3 CO-CHAIR CIPRIANO: Deborah, would
4 you like to respond to that? And then also in
5 general terms, if you would speak to us about
6 the fact that if this measure were not
7 continued for endorsement, I mean, these are
8 reported activities that you are going to look
9 at as part of the home health evaluation
10 system. So what would be the impact of having
11 the measure not endorsed?

12 MS. DEITZ: Well, I just want to
13 say that, you know, in the first paragraph of
14 the document that we provided to you, that we
15 say that pain, both acute and chronic, has
16 been identified as areas requiring frequent
17 assessment and follow-up. So we are aware
18 that these have been identified as pain
19 assessments requiring standards of care, you
20 know, as applicable in all the health care
21 settings.

22 We are, as has been stated,

1 restricted by what OASIS collects. And in my
2 experience, which -- I have recently been
3 going out to home health agencies. We have
4 received a lot of feedback that this has
5 really changed the way that they are dealing
6 with pain assessment because it requires them
7 to use a standardized, validated pain
8 assessment and to use it consistently. And
9 agencies have changed their behavior to
10 address that.

11 So I think it has been very
12 useful. And our concern is that if we take
13 away a measure like this that agencies really
14 are paying attention to, that they will be
15 backsliding. There will be kind of the
16 message that, actually, we are not really
17 considering this important anymore because
18 agencies do very much pay attention to "Oh,
19 this is what is important because this is what
20 CMS is measuring. And this is what is being
21 reported on us."

22 So that is our concern about re

1 moving a measure before we have a better -- I
2 mean, we are very interested in improving the
3 measures, particularly if we can access some
4 kind of data that we could use for those
5 measures, but we would be concerned about
6 removing the measures without a new and
7 improved measure to replace them.

8 CO-CHAIR CIPRIANO: Okay. Thank
9 you.

10 Bill?

11 CO-CHAIR CONWAY: I have a
12 question and a statement for the record. The
13 question is, Deb, do you have home care CAHPS?
14 And if so, aren't there questions related to
15 pain on that?

16 MS. DEITZ: No. I was thinking
17 about that when you were talking about other
18 sources of data. And I have to say I am sorry
19 I am not particularly familiar with CAHPS.

20 But perhaps I don't know, David,
21 if you would want to, David Hittle, if you
22 would want to comment on CAHPS if you have

1 more familiarity with what is being collected
2 in a CAHPS?

3 DR. HITTLE: Am I on?

4 CO-CHAIR CIPRIANO: Yes.

5 DR. HITTLE: Yes. Okay.

6 CO-CHAIR CIPRIANO: Yes.

7 DR. HITTLE: Actually, I'm not
8 that familiar with the specifics of all the
9 different items in the scoring of the home
10 care CAHPS. I can certainly probably find
11 that out in a few minutes.

12 DR. NUCCIO: This is Gene Nuccio.

13 We do have CAHPS, a CAHPS
14 instrument. It is new. The home health
15 provider group of HHS began being required to
16 have that instrument in October of this year.
17 So the data are rather limited. Regarding the
18 specific items, I can't recall if pain is one
19 of the items on there and how it would be
20 assessed, but we can certainly find that out.

21 CO-CHAIR CONWAY: Okay. Thanks.

22 The statement for the record --

1 Heidi has already heard this, but now she can
2 formally record it. When panels are asked to
3 look at questions like this that appear
4 fragmented, it is helpful if we see this in
5 the context of what is going on.

6 Most people here aren't home care
7 providers. And we don't see the whole
8 picture. OASIS has a whole array of process
9 measures home care nurses have to report. And
10 I would just learn we have an outcome measure
11 in the CAHPS instrument that tells us what the
12 patient thinks of the adequacy of their
13 comfort care.

14 So, rather than viewing each of
15 these things in isolation, it helps if we see
16 them in a broader context.

17 CO-CHAIR CIPRIANO: And I guess do
18 we happen to know, Heidi, when the outcome
19 measure that was described that you pulled up
20 is due for maintenance?

21 MS. BOSSLEY: I looked at the
22 endorsement date. That was endorsed in 2009,

1 which is why it wasn't pulled over because it
2 had not yet reached the 3-year mark, same with
3 the home health CAHPS. That's also endorsed.

4 So those should be looked at in
5 the next safety cycle or, actually, no. I
6 take that back. The home health CAHPS will be
7 looked at next year because we have a patient
8 experience and engagement project underway
9 then. And then the next one will actually
10 come back to the next safety group. So that
11 would be 2013.

12 DR. NUCCIO: This is Gene Nuccio.

13 Sorry. Actually, the assessment
14 of pain interfering with activity outcome
15 measure has been around since 1999. And it
16 was approved later on by NQF in its work. So
17 the process measure is actually a very recent
18 set of items for OASIS.

19 CO-CHAIR CIPRIANO: Okay. I'm
20 going to suggest we go back and specifically
21 look at these two items in order.

22 Vallire, is your tent up or down?

1 Okay. Well, why don't you go ahead?

2 MEMBER HOOPER: Well, and this is
3 actually a comment related to the first
4 measure. I appreciate that the fact that
5 these two measures are currently NQF-endorsed
6 likely have improved the process of pain
7 assessment and management or at least increase
8 the awareness in the home health care setting.
9 And I would hate to see that backslide.

10 I certainly would be supportive of
11 -- the pain assessment measure does not cause
12 me so much concern. I would like to see, if
13 possible, that that would be required for
14 every visit, as opposed to an episode of care.
15 So I would be in support of that.

16 The pain intervention measure, I
17 am not so sure that that is really telling us
18 anything, but I do appreciate the need to have
19 something out there.

20 CO-CHAIR CIPRIANO: Okay. Bill?

21 CO-CHAIR CONWAY: When we have the
22 opportunity to measure an outcome if there is

1 a CAHPS instrument -- and Heidi can read the
2 question in a minute. I mean, we do have an
3 instrument. I just hate to see providers
4 having to go through mindless checkboxes that
5 I did something if we have the ability to
6 measure the outcome.

7 So why doesn't CMS clean up the
8 CAHPS question, hear what the patient has to
9 say about pain management, and let the poor
10 home care provider not go through these extra
11 checkboxes?

12 You might want to read the
13 question, which isn't exactly adequate today,
14 but that could be fixed.

15 MS. BOSSLEY: Right. So I just
16 pulled up the most current version of the home
17 health CAHPS. And the only question that I
18 could identify that dealt with pain is in the
19 last two months of care, did you and a home
20 health provider from this agency talk about
21 pain? And it's "Yes"/"No."

22 CO-CHAIR CIPRIANO: Gene, is that

1 the measure that you were referring to?

2 DR. NUCCIO: That's the item on
3 the CAHPS. Referring to the item on the
4 instrument is more detailed regarding the
5 frequency of pain interfering with their
6 activity. So it asks if the patient has had
7 pain that does not -- has pain, but it does
8 not interfere with activity or movement, pain
9 on a daily basis or less often than daily,
10 daily basis but not constant or all the time.

11 MS. DEITZ: You're talking about
12 the OASIS measure?

13 DR. NUCCIO: Right. That's the
14 OASIS measure, yes. Yes. The item on the
15 CAHPS instrument is fairly minimal.

16 CO-CHAIR CIPRIANO: Okay. Let's
17 take another comment. Pat?

18 MEMBER QUIGLEY: Thank you, Madam
19 Chair. And I appreciate being able to provide
20 one more comment.

21 My comment was I am concerned that
22 still both of the indicators to me really are

1 standards of practice. You know, this is what
2 was expected of a nurse in home care or any
3 practice setting as well as interventions that
4 should be interdisciplinary.

5 So I don't know how in 2009
6 something that is considered a standard of
7 practice became a patient safety indicator
8 when it should be a standard of practice. So
9 I had a little disconnect with that.

10 I would certainly understand if it
11 was false, but for something that is really
12 considered to be a standard of practice, you
13 know, in every arena, you know, this is what
14 should be expected in patient care.

15 And the Agency for Health Care
16 Research and Quality has had guidelines for
17 pain management since the 1980s. They were
18 expert opinion. There's standards of practice
19 and care for home health nurses from the
20 American Nurses Association, I am sure, that
21 addresses that this is a standard of practice.
22 So to me this is just not congruent with our

1 workgroup.

2 CO-CHAIR CIPRIANO: Thank you.

3 Jean?

4 MEMBER de LEON: And I would echo
5 that it is confusing when you look at these
6 because pain is such a major problem. And it
7 is probably under-treated. It doesn't mean
8 that it is not important, the measure or what
9 it is looking to to push the provider to do an
10 assessment, do an intervention is important.

11 But it is not necessarily a
12 measure of quality care. It should be
13 standard or best practice. And if you have
14 the detail of the OASIS in the outcomes, then
15 the measure should all be based upon those
16 questions, not about just checking to see if
17 we asked.

18 CO-CHAIR CIPRIANO: Okay. Gina or
19 Janet, do either of you have any comments or
20 questions at this point?

21 MEMBER PUGLIESE: No.

22 CO-CHAIR CIPRIANO: Deborah or

1 Gene, do you have anything else that you would
2 like to add?

3 DR. NUCCIO: No.

4 MS. DEITZ: No.

5 CO-CHAIR CIPRIANO: Okay. What I
6 would like to do, then, is go back to 0523,
7 which is the measure of pain assessment being
8 conducted at a single episode, not per visit.
9 But, actually, let me ask a question of
10 Deborah, then.

11 Is it feasible that this could be
12 revised to be an assessment at every visit?
13 And what would the issues be with that kind of
14 change? I mean, is that something --

15 MS. DEITZ: Yes. That is a good
16 question. I would ask the Committee to think
17 about what that would entail in terms of
18 burden for the agency. And I think that is
19 why it was not originally designed that way
20 because what we would do is we would say the
21 way that the OASIS collects information, it
22 would say at the end, was this patient

1 assessed for pain at each visit?

2 And then in order to be able to
3 adequately answer that, the person who was
4 doing the discharge assessments would have to
5 go back and look at every patient visit that
6 occurred during an episode of care, which
7 could be longer than a year under the visits.
8 So that is why it is not collected that way.

9 CO-CHAIR CIPRIANO: Iona?

10 MEMBER THRAEN: I know in the MDS,
11 there is a schedule of how often the
12 assessment process has to take place. Is
13 there a similar schedule for the OASIS?

14 DR. NUCCIO: Yes, there is.

15 MS. DEITZ: Yes.

16 MEMBER THRAEN: Could you
17 articulate that schedule?

18 MS. DEITZ: The OASIS assessment
19 information is collected at least every 60
20 days. There is no requirement for --

21 DR. NUCCIO: Actually, which is
22 actually more often than the MDS.

1 MEMBER THRAEN: Okay. So going
2 back to the question of episode versus visit,
3 if a patient is under home health care for
4 more than 60 days, you would have 2 or 3 time
5 intervals where this data would be available,
6 correct?

7 And I don't know what the average
8 length of stay is for home health. So I don't
9 even know if that is even feasible, but my
10 point is if you are making assessment every 60
11 days and the patient is with home health for
12 120 days, you have 2 assessment time periods,
13 getting --

14 DR. NUCCIO: The average length of
15 stay is actually less than six days. So for
16 most of the episodes, we have a start of care
17 and a discharge or a transfer to inpatient
18 care. And that is all we have.

19 MS. DEITZ: For the majority of
20 home health.

21 DR. NUCCIO: For the majority.
22 There's a substantial tail. You know, there

1 is a long tail.

2 MS. DEITZ: When the measure was
3 initially proposed, we did, in fact, have --
4 we looked at the last episode of -- for burden
5 purposes, we said, "Okay. We'll go back and
6 look at the last episode and tell us, you
7 know, since the last OASIS, did you assess the
8 pain?"

9 Oh, I'm sorry. This is the pain
10 assessment. I am misspeaking. I am thinking
11 about the implementation. So that is
12 different. I'm sorry.

13 So yes. There could be for
14 patients who are in longer than 60 days. We
15 could assess it every 60 -- we could ask about
16 was it assessed every 60 days --

17 MEMBER THRAEN: But that's going
18 to --

19 MS. DEITZ: -- resistance to that
20 because of burden issues.

21 MEMBER THRAEN: But that has got
22 to be rare, right? That is a rare event.

1 Those are the rare cases.

2 DR. NUCCIO: Well, they're a
3 minority. I wouldn't say they're so rare, you
4 know, a small enough number as to be
5 considered really rare, but they are a
6 minority.

7 CO-CHAIR CIPRIANO: Okay. Well, I
8 think we are ready to vote on measure 0523,
9 which is that the pain assessment was
10 conducted at the start of home health episode.
11 Any additional comments or questions before we
12 vote?

13 (No response.)

14 CO-CHAIR CIPRIANO: Okay. And I
15 think we need to vote based on what we have
16 here, not any proposed revisions. Okay.
17 Jessica?

18 MS. WEBER: All right. Are all
19 three subcriteria met for importance to
20 measure and report: high impact, performance
21 gap, evidence? It's a "Yes"/"No" question.
22 I think we should have one more vote. Janet?

1 MEMBER NAGAMINE: No.

2 MS. WEBER: Gina?

3 MEMBER PUGLIESE: Yes.

4 MS. WEBER: Eight yes, 11 no.

5 CO-CHAIR CIPRIANO: Okay. So that
6 renders this measure rejected. Okay. So it
7 will not be recommended for endorsement again,
8 for maintenance.

9 Okay. So let's go to measure
10 0524, which is pain interventions implemented
11 during short-term episodes of care. So this
12 is episodes during which pain interventions
13 were included in the plan of care and
14 implemented.

15 Any additional questions or
16 comments?

17 (No response.)

18 CO-CHAIR CIPRIANO: All right. So
19 are you ready for voting? Okay. Jessica?

20 MS. WEBER: Importance to measure
21 and report. Are all three subcriteria met:
22 High impact, performance gap, evidence? It is

1 a "Yes"/"No" question. There should be one
2 more vote. Janet?

3 MEMBER NAGAMINE: No.

4 MS. WEBER: Gina?

5 MEMBER PUGLIESE: No.

6 MS. WEBER: Seven yes, 12 no.

7 CO-CHAIR CIPRIANO: All right. So
8 this measure will also not be recommended for
9 measure maintenance.

10 Okay. Well, we thank Deborah,
11 Gene, and David on the telephone, appreciate
12 your participation. I suspect there is some
13 disappointment, but I hope you can appreciate
14 the concern. I think probably one of the key
15 aspects is, does this really fall into a
16 patient safety measure versus is it in synch
17 with current practice as well as the advances
18 in the evidence over the last decade? Okay.

19 MS. DEITZ: We appreciate your
20 consideration.

21 CO-CHAIR CIPRIANO: Thank you very
22 much.

1 1729: POLYTHERAPY WITH ORAL ANTIPSYCHOTICS.

2 CENTERS FOR MEDICARE & MEDICAID SERVICES.

3 CO-CHAIR CIPRIANO: Okay. So I
4 think we are at 1729, our last measure for the
5 day. Is that right? Christina?

6 MEMBER MICHALEK: This measure is
7 polytherapy with oral antipsychotics. It is
8 actually a new measure. What we know about
9 polytherapy is that monotherapy with oral
10 antipsychotics has demonstrated efficacy, but
11 20 to 35 percent of the patients will fail or
12 have an incomplete response to monotherapy.
13 And polytherapy has not been consistently
14 proven to be either safe or effective in those
15 people that fail monotherapy, but, despite
16 that fact, there are a lot of patients out
17 there that are on more than one oral
18 antipsychotic.

19 In those patients that fail
20 monotherapy, there is really only one proven
21 alternative. And that is clozapine. And
22 those studies were done in patients who have

1 resistant schizophrenia, although these drugs
2 are used across other diagnoses as well.

3 And we do know that with
4 clozapine, it does have side effects. It
5 requires frequent white blood cell and ANC
6 monitoring every two weeks. There are some
7 patients who have been on it longer. That can
8 be extended out.

9 And some physicians will try
10 polytherapy for incomplete responses, although
11 there's really not a lot of data out there to
12 support that.

13 There are two other measures,
14 approved NQF measures, out there from Joint
15 Commission, related to this. One is about
16 decreasing polytherapy to monotherapy at
17 discharge from a health care facility. And
18 the other one relates to documenting
19 justification of polytherapy for one of three
20 reasons: either a history of three or four
21 failed monotherapy trials, cross-titration
22 with a goal of eventually getting to

1 monotherapy or that the patient is on
2 polytherapy and one of the agents is
3 clozapine.

4 MEMBER THRAEN: Are those
5 antipsychotic-related measures or polytherapy
6 in general?

7 MEMBER MICHALEK: Yes,
8 antipsychotics.

9 MEMBER THRAEN: Thank you.

10 MEMBER MICHALEK: As far as the
11 impact, this does affect a large number of
12 patients. And it utilizes a large amount of
13 resources, dollars. Overuse of medications is
14 an NPP priority under safety. Then, like I
15 said, there are those other NQF measures as
16 well.

17 The staff that reviewed this
18 measure did note that it really seemed to be
19 more of a resource one. And I'll comment on
20 that a little bit further into my discussion.

21 As far as a performance gap, it
22 appears from the stats that we were given that

1 overuse is evident. It looks like of the
2 patients that are on more than one, only a
3 small percentage were on clozapine. And there
4 are a lot of patients on more than one.

5 Unfortunately, really, the
6 information that we have really just addresses
7 the resources and not necessarily the quality.
8 Although there is a lot of data out there to
9 talk about poor quality when you use more than
10 one, the measure really seemed to focus more
11 on resources.

12 There are not a lot of randomized
13 clinical trials that have examined efficacy of
14 switching from polytherapy to monotherapy.
15 There was one that showed that when you have
16 polytherapy, it was associated with more
17 weight gain than monotherapy. I mean, that is
18 a minor adverse effect, I guess, depending.

19 There is really no empiric support
20 for having more than one. There was a meta
21 analysis done. It showed that polytherapy was
22 slightly more effective than monotherapy when

1 clozapine was used, again pushing back to the
2 second agents: clozapine. It also showed
3 that polytherapy was associated with a higher
4 risk of non-serious side effects.

5 I mean, if you look through a lot
6 of the guidelines that are out there, I mean,
7 they really do suggest taking one agent,
8 pushing that dose to the maximum allowable for
9 that patient before switching to another.

10 There is really nothing out there that says
11 outside of clozapine to combine two.

12 And although it seems that the
13 goal is really to avoid polytherapy, there is
14 really just not a lot of evidence to support
15 it.

16 In our discussion -- I'm sorry. I
17 should also say they did have an expert panel.
18 And 83 percent of them strongly agreed or
19 agreed that this data as collected based on
20 the measure would be interpretable so as far
21 as looking at the usability of the data.

22 The things that came up in our

1 discussion were, should we be looking at
2 polytherapy as compared to looking at finding
3 the lowest dose that is effective for the
4 patient with the least amount of adverse
5 effects? And we also had discussion around
6 the fact that this seemed to be very dollars
7 and cents-driven as not necessarily
8 quality-driven. I guess you could make maybe
9 perhaps the leap that it could be quality.

10 Also, the age groups are 18 and
11 above. A lot of the data that is here to
12 support not using polytherapy is in the
13 elderly.

14 And I think that summarizes
15 everything. If any of my other team mates
16 want to add anything that I might have missed,
17 please do so.

18 CO-CHAIR CIPRIANO: Okay. Well, I
19 don't see any tents up. So if our measure
20 developers would like to comment? And if you
21 would tell us your names first, please?

22 Thanks.

1 DR. CAMPBELL: Okay. My name is
2 Kyle Campbell. I am a pharmacist and project
3 director at FMQAI. I have with me Dr. Soeren
4 Mattke from RAND, who is a physician; and Dr.
5 Almut Winterstein from the University of
6 Florida.

7 Just a few things to respond to
8 the comments. One is that the point of it
9 being a resource use versus a quality issue,
10 I apologize the way the form indicated we did
11 tend to emphasize more of the resource
12 utilization aspect of that, but there are a
13 number of observational studies that have
14 quantified both metabolic syndrome and adverse
15 cardiovascular events associated with
16 polytherapy as well as greater rate of
17 non-serious side effects, like you pointed
18 out.

19 And one of the things that I think
20 is important to consider in this particular
21 patient population is that adherence to this
22 particular class of drugs is essential. And

1 any of these side effects that occur, although
2 there are no studies to support this
3 inference, are likely to reduce adherence to
4 the regimen in this population if they had a
5 side effect profile.

6 The other thing is with regard to
7 the evidence and the age criteria, the meta
8 analysis actually was for patients that were
9 -- just one second -- 16 to 65. And that
10 included 19 RCTs.

11 The existing NQF-endorsed measure
12 is inclusive of all ages and has submeasures
13 for pediatrics as well as those 18 and over.
14 Our particular measure is, as you said, 18 and
15 over and is inclusive of all ages above 18.

16 DR. MATTKE: I also wanted to
17 clarify. So if the clinical decision-making
18 -- and I have to paraphrase my psychiatrist
19 colleague Machana Horowitz here, who explained
20 that to me because I'm just a lowly
21 cardiologist, so more an electrician and a
22 plumber than somebody who actually understands

1 this.

2 The antipsychotics all have a
3 fairly similar way of affecting the brain, but
4 they all have a slightly different side effect
5 profile. So what she says is if you combine
6 more than one drug, you actually do not gain
7 effectiveness of treatment but you gain the
8 possibility of adding a second side effect
9 profile to the profile that you already have.
10 And this has been borne out in several
11 studies, 19 randomized trials, that adding a
12 second antipsychotic with the exception of
13 clozapine to an existing regimen that doesn't
14 work, is clinically not effective.

15 And so, therefore, the guidelines
16 do not support that practice but recommend
17 that if the current regimen is maxed out, you
18 switch to a different drug, rather than trying
19 to add a second drug to the existing drug.

20 And we think this is a key quality
21 issue in a vulnerable population and,
22 therefore, a safety issue. We take the cost

1 reduction of avoiding adding a relatively
2 ineffective or a proven ineffective treatment
3 to an existing treatment, sort of as a side
4 effect of implementing such a measure, but
5 insist that this is really a key safety
6 measure, not a resource use measure.

7 CO-CHAIR CIPRIANO: Okay. Bill
8 and then Iona and Pat.

9 CO-CHAIR CONWAY: Could the
10 measure developers or somebody on the
11 workgroup help out by elaborating on what
12 those side effects are?

13 The write-up here is very vague in
14 general. So it is hard to assess the safety
15 issue here. The utilization issue and the
16 cost issue I completely understand, but this
17 is a safety panel. So give us a little more
18 detail.

19 DR. CAMPBELL: Okay. So the
20 observational studies that are out there
21 suggested an increased risk for metabolic
22 syndrome and diabetes and higher

1 cardiovascular mortality in this population.

2 And the increased risk of non-serious side
3 effects were extrapyramidal symptoms, sexual
4 dysfunction, and sedation.

5 CO-CHAIR CONWAY: I understand. I
6 can read that, but, I mean, does that happen
7 a half a percent of the time, 20 percent of
8 the time, what?

9 DR. CAMPBELL: I don't have -- I
10 would have to get back to you on the relative
11 percentages of those particular side effects.
12 I don't have that with me.

13 CO-CHAIR CIPRIANO: Iona?

14 MEMBER THRAEN: First, a point of
15 clarification. In the conversation a moment
16 ago, you referenced another NQF-endorsed
17 measure. Is that different than this CMS
18 measure that is before us?

19 DR. CAMPBELL: Yes. The existing
20 endorsed measure is for inpatient care. And
21 this measure would be for ambulatory care
22 using Part D data.

1 MEMBER THRAEN: All right. That's
2 the clarification. Thank you.

3 CO-CHAIR CIPRIANO: Pat?

4 MEMBER QUIGLEY: Thank you, Madam
5 Chair. Madam Chair, I was actually asked by
6 people that I work with because we run falls
7 clinics and we see patients for falling. And
8 our geriatricians oftentimes will make
9 recommendations to modify psychiatric
10 medications to reduce fall risks. But the
11 question that they had asked is, you know, the
12 geriatrician would not make those
13 modifications but would ask the psychiatrist,
14 make those recommendations to the
15 psychiatrist.

16 So is this population really the
17 patients who have a known mental health
18 disorder and are being treated by psychiatry.
19 I mean, is it a very specific patient
20 population that we are targeting here? And I
21 did not know the answer to that.

22 Who would be the one prescribing

1 this that we would be really targeting for
2 their safe medication prescribing practices?

3 DR. CAMPBELL: So the answer to
4 that question is it would be all patients who
5 receive antipsychotics. It wouldn't just be
6 patients that were prescribed antipsychotics
7 by psychiatry. So the entire --

8 MEMBER NAGAMINE: And that would
9 be in and outpatient?

10 DR. CAMPBELL: That would be in an
11 outpatient setting. That's correct.

12 MEMBER NAGAMINE: Outpatient only?

13 DR. CAMPBELL: Outpatient only.

14 MEMBER QUIGLEY: So these were
15 patients that have a mental health disorder?

16 DR. CAMPBELL: Yes or potentially
17 off-label use of antipsychotics as well would
18 be included in this patient population.

19 CO-CHAIR CIPRIANO: Okay. Iona?

20 MEMBER THRAEN: I'm a little bit
21 familiar with this, not specific to the adult
22 population but specific to foster care

1 children, same kinds of issues. But the
2 problem has been in the Medicaid population
3 that the patient may start out initially with
4 a psychiatry consult of some sort but that the
5 management of the patient usually falls into
6 the hands of a family medicine physician or
7 advanced practitioner and that oftentimes the
8 psychiatry because of the reimbursement issues
9 remains only in a consultant role and that the
10 management of the patient really takes place
11 at the primary care level.

12 And so you often see primary care
13 practitioners not fully understanding the use,
14 utilization of these kinds of drugs and may be
15 incrementally adding drugs over the course of
16 time. So it is a problem because of the
17 reimbursement problem associated with
18 specialty care.

19 CO-CHAIR CIPRIANO: Susan?

20 MEMBER MOFFATT-BRUCE: Just for a
21 point of clarification. So this would include
22 the patients that are coming to the ED as

1 well? It would be captured in the ambulatory
2 cohort?

3 DR. CAMPBELL: Yes. So patients
4 in ambulatory care that were filling their
5 prescriptions through Medicare Part D would be
6 included in this population, so measures
7 calculation on the Part D claims data.

8 MEMBER MOFFATT-BRUCE: If they go
9 to the emergency room, this would be captured?

10 DR. CAMPBELL: If they were a
11 Medicare Part D patient, yes.

12 MEMBER MOFFATT-BRUCE: Okay.
13 Because I do think that this is a very
14 important measure in that we just don't have
15 enough psychiatrists for all of these
16 psychiatric patients. I mean, we are turning
17 them away after being in the emergency room
18 for 72 hours because we just can't get them
19 into our institution.

20 So I would be in favor of really
21 encouraging you to meet the expectations of
22 the group because I do think that we need to

1 have metrics out there around how we treat
2 this very under-served patient population.
3 And so I congratulate you on facilitating
4 this. And I would encourage the meeting of
5 our expectations.

6 DR. CAMPBELL: Thank you.

7 CO-CHAIR CIPRIANO: Thanks.

8 Jason?

9 MEMBER ADELMAN: There was a
10 mention from one of the developers -- I'm
11 sorry. I didn't catch your name. I think it
12 was the cardiologist -- that there was I think
13 you said 17 randomized controlled trials that
14 showed that polypharmacy does not work. Is
15 that right? Because I didn't see.

16 I guess I have seen a lot of
17 measures where a profound evidence-based
18 practice like giving aspirin to somebody with
19 a heart attack becomes a measure. But taking
20 away a physician's right to maybe do something
21 a little bit outside of label is like a step
22 beyond what I typically see.

1 A patient that is really resistant
2 and somebody wants to try an extra -- even
3 though there has been -- but 17 randomized
4 controlled trials would be pretty strong
5 evidence. I just didn't see that. I saw a
6 place that mentioned two and another one that
7 mentioned three, but I didn't see it. So I
8 would think the evidence would have to be
9 really overwhelming before you could tell a
10 provider that you can't try to add an extra
11 drug.

12 And I understand that there was
13 the risk-benefits and the side effects were
14 sexual dysfunction. It wasn't like major
15 mortality or life-threatening kinds of side
16 effects are mentioned, more morbidity kind of
17 stuff.

18 So I just wanted to scrutinize the
19 evidence a little bit more. And I didn't
20 really see 17.

21 MEMBER NAGAMINE: Bill, my hand is
22 up.

1 DR. MATTKE: It's a meta analysis
2 of 19 trials that have compared the
3 effectiveness of combination therapy. And
4 that meta analysis showed that already the
5 combination with clozapine has superior
6 effectiveness to any monotherapy. That is the
7 meta analysis by Correll.

8 So it is possible that in exotic
9 cases where everything else fails, the
10 polytherapy may be justified. I can't speak
11 to that. I think it is more likely that what
12 our colleague just mentioned, that this is
13 done in primary care and primary care
14 approaches this like hypertension treatment.
15 If the ACE inhibitor doesn't do it, let's add
16 a beta blocker. Let's add the diuretic.

17 This is not effective, at least
18 from what we know today. And the guidelines
19 are very clear about this not being an
20 effective practice.

21 It is also not the case that there
22 are only known serious side effects. I mean,

1 there is weight gain, but there is also
2 increased risk of metabolic syndrome and
3 evidence for increased cardiovascular
4 mortality under polytherapy. So it's not like
5 a dramatic short-term effect, but you will see
6 longer, higher long-term mortality out of
7 combination therapy, again with no positive
8 evidence of this practice being effective.

9 CO-CHAIR CIPRIANO: I have one
10 clarifying question. Then we'll go to Chris.

11 Where is the language that says
12 this is specific for outpatient? And is that
13 on further explanation somewhere in terms of
14 a numerator/denominator.

15 I don't see that, but I may just
16 be missing it. I see others are saying they
17 don't see it either.

18 DR. CAMPBELL: I'm not sure where
19 it is in the form, but by nature, the Part D
20 data are outpatient claims data. And in this
21 particular case, we're attributing the care to
22 the unit of analysis of a Part D plan or a

1 physician group. Obviously physician group
2 would be outpatient care.

3 There are, I will say, just to
4 clarify, patients that would be in long-term
5 care facilities that would be included into
6 this population when their Part D benefit
7 would be covering their medication use in an
8 LTC. So I do want to clarify that.

9 CO-CHAIR CIPRIANO: And I guess
10 just general clarification, though. The
11 measure would not be limited to Medicare
12 beneficiaries. So if others wanted to use the
13 measure, it would seem that we would need to
14 --

15 DR. CAMPBELL: Absolutely.

16 CO-CHAIR CIPRIANO: -- make clear
17 that it was for outpatient?

18 DR. CAMPBELL: Correct.

19 CO-CHAIR CIPRIANO: Okay. Chris?
20 And then, Janet, you will be next.

21 MEMBER MICHALEK: The other point
22 that we had some question about in your -- you

1 had said in here about having difficulty to
2 determine at the physician level -- now I lost
3 -- here it is -- by physician group that the
4 data wasn't I guess in your testing, that data
5 wasn't reliable at the physician group level.
6 And if you could just speak to that at all?

7 And what are you going to use?
8 Are you going to just hold the data that way?
9 And how are you going to -- it talked about
10 maybe at least using 30 patients. Is that
11 going to make a reliable result?

12 DR. CAMPBELL: Sure. Let me speak
13 to that. What we said in the submission form,
14 that we had the ability to make limited
15 statistical inferences for those physician
16 groups with at least 30 patients because when
17 we compared quintiles, we weren't able to see
18 -- we had an overlap of our confidence
19 intervals in order to achieve the denominator
20 threshold in which 90 percent of the physician
21 groups had a reality score greater than or
22 equal to .7 was 137.

1 So when we operationalize this, we
2 would do so with the larger physician groups
3 and should it go to the physician quality
4 reporting system.

5 CO-CHAIR CIPRIANO: Janet next.

6 MEMBER NAGAMINE: The difficulty I
7 have with this measure is it's unclear to me
8 exactly what entity and the population we are
9 dealing with because antipsychotics could be
10 applied to so many different situations.

11 And I am inpatient-based as a
12 hospitalist, but I could certainly see at a
13 long-term care facility the range of things
14 that you would be seeing in especially the
15 elderly population.

16 Is it delirium? Is it
17 hallucinations? Is it psychotic depression or
18 bipolar episode, in which case sometimes you
19 do have synergies in combinations of drugs?
20 So I was wondering if you could speak to that.

21 DR. MATTKE: Again, it's very
22 commonly practiced, but there does not seem to

1 be any clear evidence that, regardless of the
2 indication, the effectiveness of the
3 antipsychotic is greater in combination
4 therapy. So if you have psychotic episodes in
5 a depressed patient, I think combination with
6 an antidepressant that is being recommended
7 but not combination of more than one
8 antipsychotic drug.

9 MEMBER NAGAMINE: What about
10 delirium specifically?

11 DR. MATTKE: I am beginning to be
12 way out of my --

13 MEMBER NAGAMINE: Okay. Because
14 that is the common thing that we see --

15 DR. MATTKE: Right.

16 MEMBER NAGAMINE: -- in this
17 population.

18 DR. MATTKE: But do keep in mind
19 this isn't by -- virtue of the data source,
20 this is for patients that are mostly in
21 outpatient care. If you have delirium in a
22 hospitalized patient, I think that's a very

1 different situation where you use intravenous
2 drugs in all kinds of strange combinations.

3 But we really require a lengthy
4 overlap of more than one antipsychotic to
5 label a patient to be on polytherapy. So
6 these very acute situations would not fall
7 under our measure.

8 CO-CHAIR CIPRIANO: Jean and then
9 Lisa.

10 MEMBER de LEON: I have two
11 questions. One, the 19 studies in the meta
12 analysis, were all 19 randomized controlled
13 trials?

14 DR. CAMPBELL: Yes.

15 MEMBER de LEON: Yes, they were?
16 And then this is just that I don't prescribe
17 a lot of antipsychotics. What happens if the
18 drug companies are working on something that
19 works synergistically?

20 We have now decided that the
21 people that are the Medicare beneficiaries are
22 no longer able to access this newer drug that

1 may be synergistic with what is out there
2 according to this measure.

3 DR. CAMPBELL: Right. So if a new
4 drug were introduced to the market, we
5 maintain these measures annually. And the
6 universe of drugs that is included in there
7 right now is the drugs that are currently on
8 the market.

9 So when the measure came up for an
10 annual update, if there was some change in
11 regard to the evidence with regard to this
12 measure, we would capture that in our
13 surveillance and potentially come back to NQF.

14 MEMBER de LEON: If you deemed
15 that the manufacturer had adequate evidence?

16 DR. CAMPBELL: Correct, yes.

17 MEMBER de LEON: Then you would
18 change it?

19 DR. CAMPBELL: Right.

20 MEMBER de LEON: And the patients
21 would not have access to it until you deemed
22 that their randomized controlled studies were

1 adequate. And I do this with devices, not
2 really with medications, but even though there
3 is a lot of research behind a new product, it
4 doesn't ever seem to meet CMS' bar to change.
5 So it's not any study. It's your level of
6 evidence before you deem that you will change
7 that.

8 DR. CAMPBELL: Well, under part D
9 -- and I don't want to get too far afield in
10 the policy area because that is not my area
11 necessarily of expertise, but under Part D,
12 antipsychotics are in a protected class. And
13 so if there were concerns of that nature where
14 a new drug came to market and synergistic
15 effects -- that would be part of, like I said,
16 the measure review and something that we would
17 take into consideration.

18 DR. MATTKE: Also it's not that we
19 are taking away coverage. This is a quantity
20 indicator, not sort of strictly prescriptive.

21 MEMBER de LEON: But you're
22 affecting the prescriber.

1 DR. MATTKE: Yes.

2 MEMBER de LEON: Yes.

3 DR. MATTKE: Yes, but not sort of
4 as strictly as taking it away. You could
5 still prescribe it, but --

6 MEMBER de LEON: But you are
7 affecting the prescriber, who is not going to
8 prescribe it because you are going to mark
9 against them that they are doing this.

10 DR. MATTKE: And I think --

11 MEMBER de LEON: So they won't.

12 DR. MATTKE: At the current rate
13 of prescribing, I think we do a lot more good
14 by making it harder than by sort of being
15 neutral on that issue.

16 MEMBER McGIFFERT: Can I just get
17 in on a follow-up with this conversation?

18 CO-CHAIR CIPRIANO: Yes. You were
19 next anyway, Lisa.

20 MEMBER McGIFFERT: Since we are
21 kind of walking into policy, I mean, I think
22 it is probably a really good idea for CMS to

1 be cautious about adding new drugs before they
2 have been on the market for a while because
3 there is quite a bit of evidence that it takes
4 a while to really get the feedback from a
5 broad use of a drug before you know it is
6 effective and safe.

7 CO-CHAIR CIPRIANO: Pat, is your
8 tent up? Yes?

9 MEMBER QUIGLEY: Thank you, Madam
10 Chair.

11 My comment, I would just like to
12 reemphasize some of the discussion that we had
13 in our workgroup. And that is that one versus
14 two doses does not necessarily indicate
15 quality.

16 And we did emphasize the
17 importance of the correct prescribing the best
18 possible dose and combination of medications
19 to manage such difficult patients.

20 And, realizing that that is
21 oftentimes the approach that geriatric
22 psychiatrists will use or psychiatrists in

1 dealing with head injury patients, traumatic
2 brain injury patients, PTSD patients, we
3 really wanted to emphasize our focus on the
4 best possible combination of medications with
5 the safest dose.

6 And this indicator did look at
7 persistent use of these medications over time.
8 So it was a 12-month period of time. So, you
9 know, they would have to be able to track that
10 someone was on two of these meds over a period
11 of time.

12 But, even when you look at the
13 randomized controlled trials and the
14 medications that are there, this is a tough
15 population to be able to do these kinds of
16 studies on, be able to follow the patients
17 prospectively over time to see if there is
18 really indeed a change in behavior.

19 So there are even limitations with
20 these kinds of studies. And we know that
21 there are always methodological issues with
22 randomized controlled trials.

1 So for behavior management, I
2 would just like to say that in talking with
3 the prescribing practitioners in this area,
4 psychiatry, geriatric psychiatrists, their
5 focus still was on the best possible
6 medications to go give with a single patient
7 at the best possible dose.

8 Thank you.

9 CO-CHAIR CIPRIANO: Okay. Jason?

10 MEMBER ADELMAN: I really did want
11 to just eyeball that article. And I really
12 can't find -- I mean, you said it was the
13 Nancy Correll article? But I don't think
14 that's right.

15 DR. CAMPBELL: Correll.

16 MEMBER ADELMAN: How do you spell
17 Correll?

18 CO-CHAIR CIPRIANO: Go to page 17.

19 MEMBER ADELMAN: Thank you.

20 CO-CHAIR CIPRIANO: It says,
21 "Correll and others."

22 MEMBER ADELMAN: Okay. Thank you.

1 CO-CHAIR CIPRIANO: Okay. Well,
2 while Jason is doing some speed reading here,
3 Chris, I think you are back up.

4 MEMBER MICHALEK: I just had a
5 comment. And it is related to that. We get
6 this list of articles. You can't tell if they
7 are trials or not based on the title. We
8 expect we see an expert panel has reviewed
9 them.

10 But, you know, a lot of us want to
11 try and validate some of that ourselves. So
12 you have to understand our difficulty in that
13 you're telling me that there are 19 randomized
14 controlled trials in that meta analysis that
15 includes patients from 18. You know, I've got
16 to trust you on that, but I don't know that.

17 So, you know, when you are
18 developing these measures, I think it would be
19 helpful for those of us that really want to
20 validate that a little bit more. And,
21 unfortunately, there has been some negative
22 reinforcement in that some of these measures

1 include trials that aren't related to the
2 measure topic. So then it makes us question
3 more, just a point of note to you who are
4 developing the measures.

5 MEMBER THRAEN: Maybe a couple of
6 seminal articles ought to be included when we
7 do this if there are some, like a meta
8 analysis-type thing.

9 MS. BOSSLEY: We can work with
10 developers. What we do is overload you with
11 paper already. It's a balance. We'll keep
12 working on it.

13 CO-CHAIR CIPRIANO: Lisa and Jean,
14 are your tents still up again? Sorry. Okay.
15 Jason?

16 MEMBER ADELMAN: I'm done reading
17 the article.

18 (Laughter.)

19 CO-CHAIR CIPRIANO: We have one
20 more comment if you want time. That was fast.

21 MEMBER ADELMAN: No.

22 CO-CHAIR CIPRIANO: Go ahead.

1 MEMBER ADELMAN: Either way.

2 CO-CHAIR CIPRIANO: Rich, would
3 you like to go ahead?

4 MEMBER WHITE: I may have found
5 it. I was looking for persistent, and in
6 2a.1.1, it does specify 12 months. So they
7 have to get scripts for 2 agents for 12
8 months. And we are finding it in ten percent
9 of the population that you are interested in,
10 Medicare, who have a diagnosis of a psychosis
11 or who are taking at least one.

12 Of the five percent that are
13 taking one, ten percent are on two. Is that
14 correct?

15 DR. CAMPBELL: Okay. Let me just
16 clarify the definitions for you so we're all
17 on the same page. So the denominator is
18 individuals 18 years of age and older who are
19 prescribed at least one routinely scheduled
20 oral antipsychotic. "Routinely" in this case
21 means they have 2 fills of at least 25 day
22 supply each with no more -- a

1 medication/possession ratio of .8. So what we
2 are trying to avoid is someone that has just
3 had just a single prescription for an
4 antipsychotic?

5 And then in terms of the
6 numerator, what we are requiring is that the
7 overlap of therapy between 2 antipsychotics
8 during the 12-month measurement period is 90
9 days or greater. And we did that.

10 Specifically we looked at a
11 sensitivity analysis with our TEP to ensure
12 that we weren't capturing patients that were
13 cross-titrating. So that is the rationale.

14 MEMBER WHITE: You found eight
15 percent incidence of dual therapy?

16 DR. CAMPBELL: Yes, across the 8
17 states 8.9 percent, excluding those
18 beneficiaries that had clozapine, which in the
19 RCT or in the meta analysis was shown to be
20 more effective, the polytherapy that is more
21 effective.

22 MEMBER WHITE: Just a comment. So

1 that won't affect our delirious patients.

2 They won't be delirious for 12 months.

3 CO-CHAIR CIPRIANO: At least we
4 hope not.

5 Jason, are you ready?

6 MEMBER ADELMAN: We have a
7 psychiatrist at Montefiore that sometimes uses
8 Neurontin for a psychothymia. It is not
9 indicated, but he believes it works. And he
10 says that many providers do.

11 You know, unfortunately, we don't
12 have evidence-based medicine for everything.
13 So sometimes doctors use things outside. So
14 I think you need really compelling evidence.

15 And so I looked at some of the
16 articles in the initial section that defends
17 the evidence behind the requests for the
18 measure where this article wasn't listed, and
19 I didn't see it.

20 This particular article, just
21 reading from the abstract because I feel like
22 it should be close to giving aspirin to a

1 heart attack if you are going to make an NQF
2 measure.

3 So all I had to do is read the
4 abstract and the conclusion of the article.
5 In certain clinical situations, antipsychotic
6 code treatment may be superior to monotherapy.
7 However, the database is subject to possible
8 publication bias and too heterogeneous to
9 derive from firm clinical recommendations,
10 underscoring the need for further research.

11 So it just doesn't have the
12 strength to start publicly reporting that
13 doctors are bad, even though I understand the
14 evidence is leaning towards that way and I see
15 the point, to start saying, you know, that
16 doctors are really bad for adding extra-site
17 antipsychotic for a child who is really
18 resistant and is delusional seems like a
19 stretch or adults. I just use that as an
20 example.

21 MEMBER THRAEN: But this is
22 specific to seniors.

1 MEMBER ADELMAN: For anyone,
2 really.

3 MEMBER THRAEN: Well, but if you
4 are talking about Medicare Part D, does
5 Medicare Part D cover non-seniors?

6 DR. CAMPBELL: Yes, yes. We do
7 have some.

8 MEMBER THRAEN: So you're talking
9 about your disabled population?

10 DR. CAMPBELL: Correct.

11 MEMBER THRAEN: Okay.

12 MEMBER QUIGLEY: Madam Chair, I
13 just would like to say that, Jason, I think
14 you confirmed my comments as well.

15 CO-CHAIR CIPRIANO: Okay. Richard
16 again?

17 MEMBER WHITE: So there are
18 societies and guidelines that go along with
19 this exact measure where they say this is a
20 no, no?

21 DR. CAMPBELL: So the most recent
22 publication, the PORT Guidelines for

1 Schizophrenia, do not support the practice of
2 polytherapy. There isn't an evidence-based
3 statement to say specifically not to do it but
4 the guidelines do not confirm that polytherapy
5 should be used.

6 MEMBER WHITE: So why would that
7 be that you don't have a guideline that says
8 this is something that shouldn't be done and,
9 yet, we're doing this measure?

10 CO-CHAIR CIPRIANO: Jason?

11 MEMBER ADELMAN: I left it up
12 before, but I just was -- you know,
13 schizophrenia is one of 12 diseases where you
14 can use antipsychotics.

15 CO-CHAIR CIPRIANO: Okay. Are
16 there any other questions for the measure
17 developer or comments from the panel or the
18 measure developer? Iona?

19 MEMBER THRAEN: I'm confused.

20 CO-CHAIR CIPRIANO: What would you
21 like clarification on?

22 MEMBER WHITE: You need two

1 antipsychotics.

2 (Laughter.)

3 DR. CAMPBELL: I just wanted to
4 mention that this measure did go through an
5 extensive public comment period. And the
6 comments that we received during the public
7 comment were favorable towards the measure.

8 MEMBER ADELMAN: Sorry. I think
9 it's probably right. And I don't want two
10 antipsychotics used on my family members.
11 It's just that the evidence isn't strong
12 enough to start publicly penalizing providers
13 if they do it.

14 They may have reasons that they
15 are justified in trying and we don't have
16 strong enough evidence to say that they are
17 wrong. That is my feeling.

18 DR. WINTERSTEIN: I think just to
19 put this in the analogy of drug approval
20 because you used this argument that there
21 needs to be a clinical trial that proves that
22 aspirin should be used after MI -- and this is

1 the exact analogy that I think we should apply
2 here -- there is no clinical trial that proves
3 that dual therapy is efficacious.

4 So what that means is that you are
5 essentially using anecdotal evidence to
6 establish the benefit of a treatment where
7 there is proven harm. And if you wanted to go
8 to to the FDA with this and ask for approval
9 of dual therapy, it would not make approval.

10 So I think that given there is a
11 safety focus, I think it is important to look
12 at what kind of evidence is there that
13 supports that dual therapy should be used in
14 a patient. And the reality is there isn't.

15 And I do understand. I do work a
16 lot in psychiatry but not in this particular
17 area. There are a lot of empirical treatment
18 approaches. I understand that psychiatry in
19 itself is a lot of trial and error, but we
20 also realize that, in particular, atypical
21 antipsychotics have grown tremendously. Their
22 market share is unbelievable. They have grown

1 tremendously over the last decade for a
2 variety of indications.

3 And I think when we are looking at
4 ten percent of patients here, we are not
5 looking at schizophrenic patients and patients
6 who have delirium, who make a very, very small
7 population. We are looking at patients who
8 are managed for a variety of different
9 diseases or disorders that we have not started
10 to look at.

11 So in terms of weighing efficacy
12 and safety, I think we should take this in
13 mind, keep this in mind when we are looking at
14 this measure here.

15 MEMBER ADELMAN: It's just that,
16 you know, we can make a bucket measure that
17 says any time a provider uses a drug that is
18 not for its indication, it will hold them
19 accountable. But I just don't think we're
20 there yet.

21 Most of the measures that I am
22 familiar with are about a very well

1 evidence-based practice, not the lack thereof
2 and especially if you have, as I said, a
3 patient that is resistant psychotic and people
4 are desperate and a doctor wants to try
5 something. It happens all the time.

6 I am not sure if anybody else
7 knows of another measure that is like this
8 where it is judging a provider for doing
9 something, you know, like this. Sorry.

10 MEMBER NAGAMINE: That may be
11 indicated.

12 DR. CAMPBELL: Just to respond, I
13 mean, there is an existing NQF-endorsed
14 measure in inpatient setting for this same
15 concept. You know, we can't operationalize
16 all of the exclusions in that particular
17 measure, but we have operationalized what I
18 feel like is one of the most important
19 exclusions, which is the therapy of clozapine,
20 the dual therapy, which does have evidence for
21 support. We exclude those patients from
22 measurement.

1 CO-CHAIR CIPRIANO: I just have
2 one question before we go to other speakers.
3 Are there any efforts that have been put
4 forward by the professional societies in this
5 area that have not been successful to
6 reinforce the safety issue so that it has come
7 forward to say if there is a more rigorous
8 enforcement of something like a quality or
9 safety measure, that that will change practice
10 or is it just that you are looking at the
11 evidence coming from the field or, again, is
12 there anything else that you can add to that?

13 DR. CAMPBELL: I'm sorry. No. I
14 don't have anything specifically to add to
15 that question.

16 CO-CHAIR CIPRIANO: All right.
17 Thanks.

18 So we have Bill and then Richard.

19 CO-CHAIR CONWAY: I may be just
20 echoing that point. The debate has been
21 around whether this is effective. This is not
22 an effectiveness panel. We're a safety panel.

1 And we're looking at safety measures. So I'm
2 still struggling to find this evidence of
3 toxicity.

4 And even in your own way, you say,
5 "The evidence on the medium and long-term
6 safety of antipsychotic polytherapy comes
7 primarily from observational studies."

8 I don't know that we have got
9 compelling data that says we have got a safety
10 situation here. I'll grant you you have got
11 an efficiency question. Again, I am asking
12 from the measure developers, where is the
13 compelling safety problem?

14 DR. CAMPBELL: Yes. I mean, we
15 acknowledge, just as what is written in the
16 write-up, that the evidence to support the
17 safety concerns are observational. And the
18 only RTC that I am aware of that we cited in
19 the documentation was related to weight gain.

20 So it was a relatively mild side
21 effect that we saw in an RTC. But the rest of
22 the data that we have are all observational in

1 nature.

2 CO-CHAIR CONWAY: And I am not a
3 psychiatrist. My understanding, weight gain
4 is associated with almost all antipsychotics.
5 So that could happen with monotherapy, too.

6 CO-CHAIR CIPRIANO: Richard?

7 MEMBER WHITE: So I'm a little
8 hard-pressed to understand who is going to be
9 treating someone for 12 months with dual
10 therapy not seeing some kind of benefit. You
11 know, it really strikes me that what you are
12 saying is some really dumb docs out there who
13 are just really drugging their patients.

14 Why in the world would you keep
15 someone on both of those for 12 months at
16 least without some beneficial effect that
17 might be going on or you need to go get the
18 data to drill down on those and show these
19 people are unquestionably being mismanaged?

20 You know, this is travesty. This
21 is tantamount to, you know, tying him up with
22 the drug. I mean, do you have that kind of

1 data? Otherwise I am really hard-pressed to
2 see how the primary care providers want to
3 give them dual therapy.

4 So I guess I just need more
5 evidence that this is really a bad thing that
6 they are doing. I just don't hear that. I
7 just can't imagine anyone doing that, but it
8 might be the case.

9 CO-CHAIR CIPRIANO: Any other
10 comments or questions? Chris?

11 MEMBER MICHALEK: It's not 12
12 months of concomitant therapy, right? It's
13 less than that, isn't it?

14 CO-CHAIR CIPRIANO: Is there
15 anything over 90 days?

16 MEMBER MICHALEK: Ninety days of
17 concomitant therapy. And so the question,
18 there is information out there from
19 psychiatrists as to why they would put
20 patients -- some have argued against the whole
21 polytherapy. You know, this is just something
22 I found on my own. But, you know, this is one

1 person's feeling.

2 You know, rather than conclude
3 that polytherapy is unwanted, we might want to
4 speculate that many treatment-resistant
5 patients need to be given more than one
6 antipsychotic to reach the same therapeutic
7 level as less treatment-resistant patients.

8 And they acknowledge there are no
9 trials for it. Sometimes I think reading what
10 other psychiatrists are saying is that you may
11 be able to avoid some adverse effects. You
12 know, maybe your patient is having an
13 incomplete response but not a partial response
14 and maybe you want to add something in there.

15 I am not saying it is right or
16 wrong. I am just saying that is the thought.
17 That is some of their thought process, you
18 know, for perhaps using polytherapy.

19 CO-CHAIR CIPRIANO: Any other
20 comments or questions?

21 (No response.)

22 CO-CHAIR CIPRIANO: Okay. Then I

1 believe we are ready to vote on this measure.

2 Jessica?

3 MS. WEBER: Importance to measure
4 and report. Are all three subcriteria met:
5 high impact, performance gap, evidence? It is
6 a "Yes"/"No" question. Janet?

7 MEMBER NAGAMINE: No.

8 MS. WEBER: Gina?

9 MEMBER PUGLIESE: No.

10 MS. WEBER: Two yes, 16 no.

11 CO-CHAIR CIPRIANO: Thank you. So
12 this measure is not approved to go forward.

13 And, again, we appreciate all of
14 the efforts and the background and the hard
15 work to bring it forward and hope that we have
16 been able to express the concerns and the
17 issues, which are somewhat controversial, I
18 think, again in terms of trying to meet the
19 bar of identifying the safety issues. And
20 that is really the evidence we have to weigh
21 in order to take positive action on it. So
22 thank you very much.

1 DR. CAMPBELL: Thank you for the
2 opportunity. Appreciate it.

3 CO-CHAIR CIPRIANO: Thank you.

4 NQF MEMBER/PUBLIC COMMENT

5 CO-CHAIR CIPRIANO: Okay.

6 Operator, would you please open the lines for
7 any public comment?

8 OPERATOR: Just a reminder it is
9 *1 if you have a question or comment today.

10 (No response.)

11 OPERATOR: And there is no one in
12 my queue at this time.

13 CO-CHAIR CIPRIANO: Okay. Thank
14 you very much.

15 Is there anyone in the room who
16 would like to make any public comment on any
17 of the items discussed?

18 (No response.)

19 CO-CHAIR CIPRIANO: Seeing none,
20 okay. I believe this concludes our agenda for
21 today. And maybe we can just spend one minute
22 to hear from Heidi about what we can expect in

1 the communications coming forward.

2 As you know, we have deferred a
3 number of items. So we have been talking
4 about scheduling a conference call. And,
5 again, I will turn it over to Heidi to give us
6 a little more direction.

7 MS. BOSSLEY: Okay.

8 WRAP-UP/NEXT STEPS

9 MS. BOSSLEY: I first want to
10 thank everyone. You all have done a
11 phenomenal job in the last two days. And
12 there is still a little bit more to come.

13 You deferred, I think, it looks
14 like, if my memory is correct -- we will go
15 back through our notes. But you deferred two
16 that we're hoping to get considered on a
17 conference call. We'll work to schedule
18 something in January. Give us a few days to
19 figure out the developers, where they are and
20 everything. And then we'll get back to you
21 and schedule it.

22 Then you have one measure that you

1 have deferred to phase two where we are hoping
2 that they can come back with some testing. So
3 you will see that measure again.

4 What we will be doing as staff
5 over the next I would say few weeks -- again,
6 it's a holiday. So it will take a little bit
7 longer than normal maybe. We're going to take
8 all of the information, your discussion, and
9 try to synthesize and provide the rationales
10 of how you came to those decisions you came
11 to. We will circulate that with everyone so
12 that you can have a chance to comment and make
13 any additional edits, any other information
14 you would like provided in that report.

15 It will then go out for comment
16 for 30 days to the membership as well as the
17 public. And we will work to schedule a call
18 after that where you will go through all of
19 the comments and make your final
20 recommendations that go to the Consensus
21 Standards Approval Committee.

22 So I estimate roughly February I

1 think this will go out for comment if we can
2 again wrap up the couple of things that we
3 have left. And then stay tuned for phase two
4 as well. We will send you more information
5 because that will be starting up after the new
6 year, too.

7 PARTICIPANT: When will that
8 start?

9 MS. BOSSLEY: We went through that
10 yesterday. I think it's we'll have you meet
11 sometime in the summer, May or June. So by
12 the time you finish this first phase, you will
13 be moving right into the second phase.

14 PARTICIPANT: And those meeting
15 dates, can you please take college and high
16 school graduation times in to consideration
17 please.

18 MS. BOSSLEY: Yes. Actually,
19 because we have the committee set, what we
20 will probably do is just poll all of you to
21 see availability. And we will try to do that
22 as much in advance as we can. Yes. It is a

1 very good point.

2 CO-CHAIR CONWAY: And I would like
3 to thank the whole panel. This has been a
4 very engaged panel. Thank you for all your
5 work. And we are looking forward to seeing
6 you again. Have a great holiday.

7 CO-CHAIR CIPRIANO: I would add my
8 thanks as well and want to thank our troopers
9 on the phone, particularly Janet for two days
10 and Gina for joining us today. I heard you
11 might be under the weather. And we certainly
12 want to thank our staff for their support and
13 all of the measure developers who have come in
14 to help us. So thank you, everybody. Safe
15 travel.

16 MEMBER PUGLIESE: Happy holidays.
17 (Whereupon, the foregoing matter
18 was concluded at 2:16 p.m.)

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This is to certify that the foregoing transcript

In the matter of: Patient Safety Complications

Before: NQF

Date: 12-16-11

Place: Washington, DC

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