

NATIONAL QUALITY FORUM
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SURGERY ENDORSEMENT MAINTENANCE 2010
STEERING COMMITTEE
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THURSDAY
MAY 5, 2011

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The Steering Committee convened in the John T. "Jack" Elliott Room at the Embassy Suites DC Convention Center at 900 Tenth Street, Northwest, at 9:00 a.m., Arden M. Morris and David F. Torchiana, Co-Chairs, presiding.

PRESENT:

ARDEN M. MORRIS, Co-Chair, MD, MPH, FACS
DAVID F. TORCHIANA, Co-Chair, MD
NASIM AFSAR-MANESH, MD
HOWARD BARNEBEY, MD

JAMES E. CARPENTER, MD
ROBERT R. CIMA, MD, MA, FACS, FASCRS
CURTIS D. COLLINS, PharmD, MS, BCPS AQ-
ID
PETER W. DILLON, MD, MSc
RICHARD P. DUTTON, MD, MBA
PAULA R. GRALING, DNP, RN, CNS, CNOR

VIVIENNE HALPERN, MD, FACS
RUTH KLEINPELL, PhD, RN-CS, FAAN
JOHN MORTON, MD, MPH, FACS
TERRY ROGERS, MD
CHRISTOPHER SAIGAL, MD, MPH, FACS
ALLAN SIPERSTEIN, MD
RENAE STAFFORD, MD, MPH, FACS

CAROL WILHOIT, MD, MS
CHRISTINE S. ZAMBRICKI, CRNA, MS, FAAN

NQF STAFF PRESENT:

HEIDI BOSSLEY

JESSICA BOWER

HELEN BURSTIN, MD, MPH

ALEXIS FORMAN

MELINDA MURPHY, RN, MS

JESSICA WEBER

ALSO PRESENT:

JOHN BOTT *

DALE BRATZLER *

SHERYL DAVIES *

JEFFREY JACOBS

KATHY JENKINS *

WANDA JOHNSON *

FLORA LUM

PATRICK ROMANO

BARBARA RUDOLPH *

DAVID SHAPIRO

JEFFREY SILBER *

DONNA SLOSBURG

* Present via telephone

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

2 (9:00 a.m.)

3 CO-CHAIR MORRIS: Good morning,
4 everybody. Thank you for attending our second
5 day of the Surgery Endorsement Maintenance
6 Steering Committee, and thanks for your work
7 yesterday. Excuse me.

8 We'll just recap very briefly. I
9 thought we had a lot of good ideas and a lot
10 of good discussion, particularly yesterday
11 morning, quite a bit of discussion. I think
12 as the day went on we indicated that a little
13 bit.

14 For today, what I'd like to ask of
15 the Steering Committee members is that you
16 continue to present the measures that you're
17 assigned in a succinct way, and we definitely
18 want to hear your opinion, so we want to hear
19 your opinions about the criteria.

20 You've spent more time with these
21 measures than any other person on the
22 Committee, and we value what we have to say

1 about it. So, for the Steering Committee
2 members who were -- who gave a little bit more
3 information about how they viewed the
4 criteria, that was very helpful.

5 So our meeting today is open, and
6 is it time to start the phones? All right.
7 Dr. Torchiana has a few words, as well.

8 CO-CHAIR TORCHIANA: I would also
9 like to convey my welcome, and I think my
10 reflection on yesterday would be that the
11 discussion is where the richness of the face-
12 to-face meeting is sort of brought out, so the
13 discussion is why we're here.

14 I thought we had numerous
15 excellent discussions yesterday. Some of them
16 were hard to wrap up in a bow at the
17 conclusion, but that doesn't negate the value
18 of the conversation and the thoughts that came
19 out.

20 I'd like to add to what Dr. Morris
21 said that for the developers today we have a
22 number of developers that are both the same as

1 yesterday and then some new ones, again, to
2 try to be very succinct and pointed in your
3 description of the measures so that you can
4 present to the Committee why the NQF should
5 endorse this measure and the value of the
6 measure for the patient population, as opposed
7 to really a more exhaustive history of the
8 measure. That way we'll be able to more
9 evenly address the agenda today, hopefully.
10 So, thanks everyone once again.

11 CO-CHAIR MORRIS: I just want to
12 add one other thing to that, and that is that
13 for measure developers we'd like for you to
14 only comment on your own measures. We don't
15 really want to hear your comments about the
16 other measures that are other discussion until
17 the public and member comment period.

18 We're going to start today with
19 two measures that were left over from
20 yesterday, and we're going to do them in
21 reverse order. We'll start with Measure 0301.
22 I believe that CMS has already or CMS

1 representatives have already introduced this
2 yesterday, so please take it away.

3 MEMBER ASFAR-MANESH: Good
4 morning. So we'll start off by talking about
5 Measure 0301, which is surgery patients with
6 appropriate hair removal. This is part of the
7 SCIP measures supported by the measures stored
8 on CMS.

9 There are a number of exclusions
10 just to keep in mind in the description of
11 this measure. These exclusions include ages
12 less than 18, length of stay greater than 120
13 days, laparoscopic surgeries, patients in
14 clinical trials, and patients who perform
15 their own hair removal.

16 As far as the importance to
17 measure and report this, there is some
18 evidence back and forth, just so that the
19 group is aware, about the fact that
20 appropriate hair removal may reduce incidence
21 of surgical site infections. Actually, in the
22 outpatient measure that's paired with this --

1 I'm sorry, not paired but a complementary
2 measure to this.

3 There are some more citings about
4 three randomized control trials as well as two
5 systemic reviews that show this correlation.
6 However, there doesn't seem to be absolutely
7 clear evidence that this is important.

8 Having said that, the measure when
9 it was first reported in 2005 had a rate of
10 91.5, and now for the last several quarters
11 ending in Quarter 2 of 2010 is now reported at
12 99.6 percent, so very close to being topped
13 off if not topped off.

14 So, really, I think the only thing
15 for us to discuss and where I think we need
16 the Committee's expertise is since the
17 performance for this measure has been
18 consistently high, should we continue to
19 measure and report this with the thought that
20 this is currently integrated into the work
21 processes in the ORs, and so there is minimal
22 performance gap and the flip side of that

1 being that if we stop measuring and reporting
2 this, could we actually revert back to
3 previous performance, which was sub-optimal.

4 This could also, putting it
5 together with the discussions that we had
6 yesterday, could potentially meet the
7 requirements for an inactive measure,
8 something that gets followed up. So I'll wrap
9 it up there, and we'll kind of open it up to
10 discussion as far as what the group feels as
11 far as continuing to measure and report.

12 MEMBER SIPERSTEIN: I want to make
13 a comment. You know, this is one of these
14 SCIP measures, just like pre-op antibiotics
15 and redosing, et cetera, and is often
16 considered a bundle of activities to reduce
17 surgical site infection, although there has
18 been some evidence in the literature that
19 implementation of the bundle in certain
20 patient populations hasn't moved the needle.

21 So when these are reported, we
22 tend to look at the individual metrics, but we

1 also tend to look at any given patient where
2 the entire bundle has been properly
3 implemented.

4 CO-CHAIR MORRIS: Are there any
5 comments or questions?

6 MEMBER DILLON: I also think it's
7 unlikely that we'll see any recidivism here,
8 because certainly in our ORs what it did was
9 it got rid of the razors, and I think
10 everybody has now moved to either electric
11 clippers or not doing it at all.

12 So I don't see a sudden resurgence
13 of people going out and buying Gillette razors
14 to try to get around this. I think it should
15 be put to sleep or inactive or whatever we can
16 do to it.

17 MS. MURPHY: You know, there was a
18 comment within the work group when this was
19 discussed, exactly to your point, that for
20 economic reasons, razors being cheaper than
21 clippers, that there could be a reversion.

22 CO-CHAIR MORRIS: We have -- we

1 purchase clipper bases, and then just the
2 clipper heads are moved out, which are
3 probably even cheaper than razors, but I don't
4 think all the clipper bases are going to go in
5 the trash. Every hospital I've been in has
6 done that. I don't know if anybody has any
7 different opinions.

8 MEMBER MORTON: I think, you know,
9 even though it's up in the nineties, there's
10 still constant push-back from folks who don't
11 think that it works, because different studies
12 have cropped up, you know, refuting the value
13 of the individual measures. So, as much as it
14 looks like it is topped out, I think this is
15 something we still have to be vigilant about,
16 and I wouldn't sunset it just yet.

17 MEMBER DILLON: But at the same
18 time, there is growing information that none
19 of these are truly affecting the incidence of
20 wound infections, and so, again, why continue
21 a, you know, a metric? Why continue a policy
22 that really for all intents and purposes has

1 not been shown to be effective in what it was
2 set out to do?

3 We have changed it. We have
4 topped it out. I think we should be going on
5 and focusing at more aggressive, you know, and
6 better wound care metrics.

7 CO-CHAIR TORCHIANA: Is there an
8 NQF bundle measure for the SCIP bundle?

9 MS. MURPHY: They're each endorsed
10 individually, but one of the things that went
11 through my head as you were talking about it
12 being reported as a part of a bundle is
13 whether or not there would be any potential
14 for moving it to an inactive status if that's
15 what the group wanted with retaining it as a
16 part of a bundle.

17 DR. BURSTIN: So let me just give
18 you a little bit of background here. This is
19 an interesting issue. We're actually taking
20 this issue of inactive endorsement status to
21 our Board next week, so we'll know
22 definitively shortly.

1 But there is, as Ray Gibbons, the
2 Chair of our Cardiovascular Committee, liked
3 to refer to them, the Hall of Fame measures,
4 ones that perhaps have had their life,
5 probably time to put them on a shelf, but the
6 idea would be if there were any concerns about
7 the -- that the rate might, in fact, drop, the
8 idea would be is there a logical place to put
9 some of these measures where they would be on
10 inactive endorsement status, meaning people
11 could do periodic surveillance to make sure
12 the rates aren't dropping, but at the same
13 time we're working through a process.

14 If the rates drop, we could bring
15 it back through active endorsement status,
16 but, again, I think the point that was just
17 raised is really the key one. Is there
18 clearly a relationship between this and the
19 outcome?

20 We went through this fairly
21 carefully this past year, Heidi will know,
22 because we did this for a couple of the

1 surgical specialty societies, that the
2 evidence was still strong with the exception
3 of a couple of key areas, some GU areas and
4 some neurosurgical procedures. Other than
5 that, the evidence was still pretty sound.

6 MEMBER ASFAR-MANESH: Well, and
7 just to clarify, this is -- this is still part
8 of the CMS bundle, correct? So, I mean, as
9 long as the SCIP measures continue to be
10 collected -- it's going to be collected?

11 DR. BURSTIN: Yes and no, so CMS
12 does retire measures, as well, and they view
13 them as topped out, and I'm not sure if Dale
14 Bratzler is on the phone this morning.

15 We've seen some indication that,
16 at least for the value-based purchasing
17 program for CMS, they are probably going to
18 retire this measure. It has not yet been
19 retired for the inpatient payment program, but
20 that is an issue.

21 I do know that there -- it's on
22 the list for IPPF-2 to be retired, so that

1 would be one. If CMS is going to retire it,
2 it'll just go away. I do know Dale has
3 mentioned there is a possibility that there is
4 an all-or-none composite of all the SCIP
5 measures. It has not been submitted to us
6 yet.

7 So usually if NQF removes
8 endorsement, within a period of time it's
9 usually removed by CMS unless they -- in the
10 new section they actually need to put
11 something out in the Federal Register
12 indicating why they want to continue to use an
13 unendorsed measure.

14 MEMBER ASFAR-MANESH: And they did
15 note -- I'm sorry. They did note that they
16 might retire this measure but that the Joint
17 Commission will actually be taking over, it
18 sounds like, if CMS retires the measure is
19 what's noted in the measure.

20 MEMBER MORTON: Could we make the
21 suggestion that there be a bundle?

22 MEMBER CIMA: If you're going to

1 have a bundle, that means someone's going to
2 have to collect the data, so if you're going
3 to have the data, you might as well report it.

4 I mean, if you're going to retire
5 the measure as a stand-alone measure, then
6 leaving it in a bundle means you still have to
7 collect the data, so why -- you know, either
8 you say the measure's a good measure to stand
9 alone and participate in a bundle. I mean, I
10 don't -- it's one or the other.

11 MEMBER MORTON: I guess, as to
12 Allan's point earlier, was there are some data
13 to say that if you're compliant with all the
14 measures, what it be most indicative is the
15 culture of accountability and making sure
16 you're doing the right things at the right
17 time, rather than stressing just the one
18 individual measure.

19 So I think there's a little bit of
20 argument for maintaining it as a composite
21 measure, along with the whole bundle, rather
22 than as a stand-alone. There are data that

1 are supportive of it, and I think sometimes
2 we're in the process of being whipsawed back
3 and forth with the latest study that comes
4 out, but I think the preponderance of the
5 evidence shows that it does have some utility.

6 MEMBER WILHOIT: In the Work Group
7 D materials there is a PDF for the composite
8 measure that does include this. It's number
9 963. So we were sent it. I don't know if
10 it's up or not, but it is in the package of
11 materials.

12 MS. MURPHY: And it was withdrawn.
13 It's not ready for prime time.

14 MEMBER ZAMBRICKI: I just wanted
15 to mention, since I was looking at the
16 antibiotic, which was part of this grouping
17 and in response to Dr. Cima's comments,
18 looking at some current literature there was
19 a paper out of the JAMA within the last year
20 looking at 400,000 patients.

21 It found that, actually, the
22 global use of the measures did show a slight

1 reduction in surgical infection but very
2 powerful statement about the individual item
3 relationships are weak, lack clinical
4 significance, and there was no meaningful
5 association between adherence to the
6 individual measures and decrease in post-op
7 infection, so that would be a reason for the
8 bundling.

9 I think it is a bigger issue for
10 us to look at these, because they're all
11 reported as individual measures, and it does
12 seem like there is some recent -- there as
13 another paper out of the VA really saying the
14 same thing, that looking at five years of
15 experience that there was not a correlation
16 between these individual measures and
17 decreased surgical site infection.

18 CO-CHAIR TORCHIANA: Just
19 anecdotally, the issue with hair removal is
20 more of a what not to do, rather than what to
21 do, so it's eliminating shaving the day before
22 that really was the big advance, and then

1 after that it's all fairly trivial.

2 CO-CHAIR MORRIS: Okay. So we
3 heard some arguments for making this measure
4 inactive, some arguments for bundling it, and
5 some for keeping it. Is everybody ready to go
6 ahead and vote, or any other comments? MEMBER

7 ZAMBRICKI: Could you provide some guidance as
8 far as voting?

9 MEMBER HALPERN: Exactly. So for
10 voting, this would just say that it's, you
11 know, endorsable by NQF, but if we wanted to
12 say, "Yes, we think it's a good measure, but
13 it should be retired at this time," how do we
14 indicate that with the voting?

15 CO-CHAIR MORRIS: First, we would
16 vote to -- correct me if I'm wrong, Melinda,
17 but first we vote whether to endorse it or
18 not, so whether to continue to endorse it, and
19 then secondly we would determine whether we
20 wanted to have it considered for inactive
21 status. Is that what you're asking for?

22 MEMBER ZAMBRICKI: You had

1 presented, it sounded like, three options.

2 One is to bundle, one is to accept, and one is
3 to accept and make it inactive, and so I was
4 just wondering, a yes-or-no vote.

5 MS. MURPHY: So the activity is to
6 evaluate the measure based as submitted, and
7 the way in which you did it yesterday and we
8 talked about was around the issue of
9 importance. Is it important to continue to
10 measure this one in this case?

11 So you could indicate that it was
12 not important based solely on the fact that it
13 was topped out and then continue to evaluate
14 on the other elements if we're looking at it
15 in terms of potential for an inactive status.
16 So importance would be the place where you
17 would indicate whether you believe it is
18 important to continue to measure.

19 CO-CHAIR MORRIS: Does that seem
20 clear? Anybody still a little bit foggy on
21 that?

22 DR. BURSTIN: One more point. We

1 can't evaluate a bundle, because it wasn't
2 submitted to us. You could strongly
3 recommend, regardless of what comes out from
4 the vote, that CMS submit, and in this case
5 probably an all-or-none composite of the key
6 process measures.

7 CO-CHAIR MORRIS: Anybody -- so,
8 Dr. Cima, you had some comments about why you
9 thought that that might be less valuable to
10 have an all-or-none bundled measure,
11 composite measure.

12 MEMBER CIMA: No, I think that the
13 data strongly supports the fact that it should
14 be bundled. I'm just saying, you know, I
15 think it would be better just to not report it
16 individually, but, I mean, one of the things
17 if you're going to have a -- because people
18 are still going to have to collect the data,
19 so the question is should it be a stand-alone
20 reportable thing.

21 If you answer that question, it
22 seems to be it's topped out. The question is

1 that this individual metric, does it need to
2 be reported individually as submitted is one
3 view, and I think it's fine as a bundle.

4 I think it's important as part of
5 the bundle, but, you know, still I think is
6 this question. You're going to be collecting
7 the data. Do people still want to report it?
8 It's a different issue by itself,
9 individually. That's what my thing was.

10 CO-CHAIR MORRIS: Anybody else?
11 No? Time to vote? I'm getting the signal
12 that it's time to vote. All right, so if we
13 think that it's topped out, if you think that
14 it's topped out, that it's no longer important
15 to measure individually, then you would vote
16 no on this first one, and if you think that it
17 should still be measured individually, you'd
18 vote yes.

19 MEMBER ROGERS: I'm sorry, Arden.
20 Isn't it true that if we think it should --
21 they're important and should be bundled, we
22 would have to approve both of them

1 individually and then make a recommendation
2 that they be bundled, no?

3 DR. BURSTIN: No, the policy that
4 we have is that all measures within a
5 composite need to be evaluated as to whether
6 appropriate as a stand-alone measure or only
7 as part of a composite.

8 So you could make the argument
9 this one could be -- maybe has outlived its
10 usefulness as an individual measure but would
11 potentially still be useful now that you
12 evaluated it only within a composite. I know
13 that's confusing, I apologize.

14 CO-CHAIR MORRIS: All right.
15 Let's go ahead and vote.

16 And I'd like everybody to go ahead
17 and press your either 1 or 2 button again.
18 Okay. So four for yes, 15 for no, and it's
19 probably important to record at this point
20 that that's -- that as a committee that we
21 think that this is topped out as an individual
22 measure, and that's the reason for the no

1 vote, and we'll continue through the rest of
2 the vote.

3 Does the measure meet NQF criteria
4 for -- are we going to go through the rest of
5 the vote? Oh. Okay.

6 MS. MURPHY: Do we not need to go
7 through the remainder -- if we're going to put
8 it on inactive status, we need to have
9 assessed that it still meets all of the
10 criteria, so I --

11 DR. BURSTIN: This is relatively
12 new territory for us, so I think that would be
13 fine. The Cardiovascular Committee, they just
14 figure they'd revisit everything they viewed
15 as topped out before later and come back to
16 it. If you're on a roll, go for it.

17 CO-CHAIR MORRIS: All right. So
18 we're engaged in a work in progress here. How
19 about scientific acceptability of measure
20 properties?

21 And, again, please hit your button
22 and then hit Send, aiming at Jessica. Then

1 one more time.

2 Ten say completely. Eight say
3 partially. One says not at all.

4 Usability. Twelve say completely,
5 five say partially, one says minimally, and
6 one says not at all.

7 Feasibility. Thirteen say
8 completely. Five say partially. One says
9 minimally.

10 And then do we need some guidance
11 here? I think we need a little guidance here.
12 Does the measure meet all the NQF criteria for
13 endorsement? Is this -- are we talking about
14 the individual measure?

15 MS. MURPHY: Yes. We are talking
16 about the individual measure here.

17 CO-CHAIR MORRIS: Okay, and we
18 previously voted that it does not meet the
19 importance criteria, so does that mean that we
20 have essentially a no vote premise?

21 DR. BURSTIN: I think you're -- I
22 don't know if there's a need to do this, but

1 I think one question might just be to get a
2 read of the group, and we'd have to hand count
3 or maybe just use this one. Just do a hand
4 count of if the inactive status is an option,
5 would you recommend it for inactive status,
6 rather than --

7 CO-CHAIR MORRIS: I think what --

8 MEMBER HALPERN: My personal would
9 be recommend this as an individual, as an
10 inactive status but that we would recommend
11 continued use in the bundle, that they would
12 have to present us with a bundle.

13 CO-CHAIR MORRIS: All right. I
14 think we all pretty much agree on that. Is
15 there anybody that would like to make any
16 countering comments? Okay.

17 MEMBER DILLON: I would just say
18 that any component of a bundle still has to be
19 supported by whoever the steward is. I mean,
20 that's -- and that still begs the question of
21 whether this should be in a bundle, and that
22 has to be scientifically proven and presented

1 as part of a bundle presentation.

2 I don't think we should be saying
3 we want this in a bundle. We should be saying
4 it should be considered for a bundle.

5 CO-CHAIR MORRIS: Thank you for
6 clarifying that. The next measure is 0515,
7 ambulatory surgery patients with appropriate
8 method of hair removal. Again, Dr. Asfar-
9 Manesh.

10 MEMBER ASFAR-MANESH: Okay. So
11 this is a similar measure to 0301 looking now
12 at the ambulatory surgery patients, and this
13 actually, just to clarify as a deferring point
14 to the previous measure, looks just at all
15 ambulatory surgery patients who had hair
16 removal, so it actually excludes patients who
17 did not have any hair removal with the measure
18 still being ASC Quality Collaboration.

19 So as far as an importance to
20 measure and report this, again, conceptually
21 it's the same as 0301. The measure stewards
22 actually went to some great lengths to make

1 sure that it was harmonized with 0301 and
2 added a number of different components, which
3 they detailed to make sure that that happens.

4 The importance to measure is that
5 we do have, as you said yesterday, 80 percent
6 of surgeries that are now happening in the
7 outpatient settings, so if we are doing
8 something in the inpatient setting it makes
9 sense that it actually gets carried to the
10 outpatient setting.

11 They presented some data analysis
12 that was done. So to give you an idea of the
13 performance on this measure currently, they
14 looked at 192 ambulatory surgery centers
15 between July and September of 2011.

16 The performance on this measure
17 was somewhere between zero to 100 percent, but
18 the mean was actually 96 percent, and the
19 median was 100 percent, so again a pretty high
20 level of performance. There were basically
21 7.3 percent of centers that presented data
22 that was less than 100 percent, so that would

1 really be the performance gap that we would be
2 looking at.

3 So, again, as far as points of
4 discussion, I think very similar to some of
5 the things that we discussed in the inpatient
6 measure as far as being close to being topped
7 off. I was a little bit unclear about the
8 validity testing that they did, just to direct
9 your attention to that on 2c.

10 The validity testing was done by
11 having a questionnaire go out to six nurses
12 asking them five different questions, and this
13 is not my area of strength, so I would
14 appreciate some input from those in the group
15 if you feel that that was appropriate and
16 enough. Otherwise, I'll leave it open to
17 discussion.

18 They do not -- another point is
19 they do not have disparity data, and they
20 explained that as if this is something that's
21 federally reported, then they would have
22 access to that and could provide us with that,

1 but that's another area that's lacking in this
2 measure.

3 CO-CHAIR MORRIS: Any other
4 comments, questions?

5 MEMBER DILLON: I would say I'm
6 not sure that I want to contribute to surgical
7 confusion out there if we have just
8 inactivated one. Then you walk into your
9 surgery center, and now they're counting, you
10 know, how you shave.

11 So I would just point out that if
12 we go one way on one and one the other, we're
13 going to create, you know, surgical confusion,
14 and surgeons don't need to be any more
15 confused than they are on some days.

16 MEMBER STAFFORD: I think you're
17 right about that. The only caveat with that
18 is that there are a lot of freestanding
19 ambulatory surgical centers where the surgeons
20 only operate there, and they don't operate in
21 a hospital. So, while you're right for those
22 of us who work in both worlds, it would be

1 confusing to have them both.

2 There are places where they don't,
3 and that would be the data that I would be
4 really interested in from the developers is do
5 they know when they look at their data in
6 terms of disparities how many of them are
7 freestanding centers and how many are
8 associated with academic centers, because I
9 bet there is some difference in the data.

10 MEMBER HALPERN: I also don't
11 understand why they don't occlude people who
12 didn't have hair removal.

13 MEMBER ASFAR-MANESH: So they
14 actually explained that. There's about 75
15 percent of outpatient surgeries are actually
16 ones that would not require hair removal, so
17 the two big categories are cataract surgeries
18 and injections for pain. That's why they
19 actually -- they just wanted to decrease the
20 burden to people who would be collecting it by
21 taking out the 75 percent of outpatient cases.

22 MEMBER HALPERN: So why don't they

1 take out those ones that don't require hair
2 removal, rather than taking out all those who
3 didn't have hair removed, because then you
4 might be missing somebody who didn't have
5 their hair removed?

6 CO-CHAIR MORRIS: Can the measure
7 developers speak to that?

8 MS. SLOSBURG: I can speak to a
9 couple things. One is the first issue
10 regarding topped out, and I think we talked
11 about this yesterday that ambulatory surgery
12 centers do not have any federal mandate to
13 report.

14 So in our database right now we're
15 up to about 800 ASCs, which is less than 15
16 percent, and, as you were saying, there are a
17 lot of surgery centers the physicians just go
18 to the surgery center and not to the hospital.
19 So I think if you did take a look at the other
20 surgery centers, I don't think the compliance
21 rate would be as high.

22 When we started out, we were

1 similar to CMS where we had a low rate, and
2 each quarter we improved. So that speaks to
3 topped out, so we would like to have this
4 measure so that when we do have a federal
5 mandate we can look at all surgery centers and
6 see where we are, and if we are, then we can
7 move on.

8 Regarding the question about the
9 no hair removal, you know, we just never, I
10 guess, never thought of it that way, but we
11 certainly could look at it that way.

12 We did try to harmonize with the
13 hospital, and the main reason was because of
14 cataract and GI being such a large portion.
15 That would mean that someone would have to
16 actually go and count those patients, and
17 that's a huge burden on ASCs.

18 It's a lot easier to look at who
19 had hair removal and then walk through those
20 medical records than having to pull all those
21 cataracts and all those GI cases when you know
22 there was no hair removal, so that's the

1 reason for it. We also uses ICD-9 versus CPT.
2 Sorry.

3 MEMBER HALPERN: Why not just
4 eliminate those cases that you know don't have
5 hair removal and look at everything else,
6 though?

7 MS. SLOSBURG: I mean, my
8 understanding would be if it's in the
9 numerator or the denominator, then you have to
10 actually look at those cases to say it's a no,
11 correct?

12 MEMBER HALPERN: I'm saying
13 exclude those cases that don't require hair
14 removal. Make that your exclusion instead of
15 making no hair removal your exclusion.

16 MS. SLOSBURG: Okay. I mean, we
17 can certainly look at that.

18 MEMBER CIMA: I mean, I sort of --
19 I mean, I certainly agree with Peter on this,
20 but the issue becomes this is directed at
21 surgical site infection reduction, okay.
22 There is no data in there about ASC surgical

1 site infection.

2 MS. SLOSBURG: There is no data
3 out there.

4 MEMBER CIMA: I know. I know.
5 I'm saying that as just a point of fact.
6 There is no data available, so you have no
7 idea if this is going to have any impact. We
8 have plenty of data to say individual measures
9 have been reported in the SCIP criteria, have
10 not been shown to be effective.

11 So why -- and we just voted to
12 inactivate because of lack of importance in
13 the inpatient setting. So this seems to be a
14 measure just to have a measure that follows
15 along a measure that we didn't think was an
16 adequate measure, and so should we put
17 ourselves through that?

18 MS. SLOSBURG: Well, I --

19 MEMBER CIMA: What's the utility
20 of this data if as itself it doesn't fit and
21 you have no data to show that surgical site
22 infections is even a problem in the outpatient

1 setting? So how are you going to show
2 improvement?

3 MS. SLOSBURG: Well, the only --
4 I'm going to let Dr. Shapiro speak to that.
5 The other thing is that in the SCIP measures
6 the only other measure that would really be
7 appropriate to ASCs is the IV antibiotic
8 timing, and we did try to harmonize with that
9 measure. We could bundle those two.

10 MR. SHAPIRO: I think the only --
11 I think the reason that we would really
12 request that you continue to endorse this
13 measure in the ASC setting, even given what
14 I've -- I heard that very good discussion
15 about the one before, the inpatient and
16 outpatient settings -- is where this industry
17 is in reporting and doing their data
18 collection.

19 All of the data that you see is
20 only based on less than a fourth of the
21 surgery centers that are Medicare-certified
22 out there. What we've tried to do is

1 harmonize measures with the existing CMS
2 measures.

3 I realize today may be the
4 beginning of a sea change, but I would urge
5 this Committee to continue endorsement of this
6 measure to allow us to get to come back to you
7 with some better statistics on a greater
8 proportion of ASCs, because my fear as a
9 clinician is that there is a lack of
10 penetration in the ASCs to the extent that
11 there is in the larger surgical community of
12 these techniques and of the importance of
13 these techniques in preventing HAIs and
14 surgical site infections.

15 So, for those reasons, I think
16 because we are at a different place than the
17 other facilities about which you changed your
18 endorsement prior to this, I really urge this
19 Committee to let the ASC community continue to
20 use this as a measure to assess our ability to
21 conform with what at least previously has been
22 shown to be process measures that will reduce

1 infection in our patients.

2 MEMBER DUTTON: From the national
3 anesthesia registry, two-thirds of all surgery
4 centers are hospital-based and probably fall
5 under both sets of guidelines. I would
6 strongly recommend keeping our thinking about
7 this in line with our thinking about the
8 previous measure to reduce confusion. The
9 ASCs can have the same bundle that the
10 inpatient facilities have and arguably should
11 have the same bundle.

12 CO-CHAIR MORRIS: I think another
13 point that you made yesterday, Richard, and
14 that I sort of expected for you to make today
15 was that endorsing these measures is not a
16 means to collect data for research to see
17 where we stand.

18 It's supposed to be based on
19 actual data that indicates that we'll be able
20 to make a difference in quality. So I think
21 that you make a strong argument, and clearly
22 you have the best of intentions, but the goals

1 of NQF endorsement are a little bit different
2 than that.

3 MEMBER MORTON: Well, I agree with
4 what Peter and others have said that if we
5 didn't vote the other measure, we shouldn't
6 vote this one. It would be inconsistent.

7 MEMBER WILHOIT: One question I
8 had is about some of the differences between
9 this measure and the other one, and that was
10 that in the denominator those patients who
11 perform their own hair removal are excluded,
12 but it seems like if a razor increases the
13 risk of infection, it would increase the risk
14 regardless of who does the shaving.

15 And then in the numerator,
16 patients with hair removal from the scrotum
17 are handled differently, and they weren't in
18 the other measure, and so I wasn't sure why
19 those differences were there.

20 MEMBER ASFAR-MANESH: So the
21 scrotal surgery actually is the same in the
22 inpatient one, as well. The inpatient one

1 actually has an exclusion for neurosurgery and
2 scrotal, and, actually, the measure developers
3 try to harmonize with the inpatient measure to
4 add the scrotal excluded through neurosurgery,
5 because they don't have neurosurgery cases in
6 the outpatient setting.

7 MEMBER WILHOIT: Although it's
8 handled, instead of being handled as an
9 exclusion, it's handled as a numerator-
10 positive, so it's handled in a different way,
11 rather than lining up.

12 CO-CHAIR MORRIS: All right.
13 Let's go ahead and vote. Does the measure
14 meet NQF criteria for importance to measure
15 and report, and, as before, if you think that
16 it's topped out or that it should be part of
17 a bundle but not stand-alone, then you would
18 vote no. And if you believe that it should be
19 a stand-alone measure, then you would vote
20 yes. We have six yes votes and 13 no votes.

21 Because we've talked about it as a
22 bundle, I think that we should continue with

1 this vote, since we're sort of inventing how
2 this is done. So, next, scientific
3 acceptability of measure properties. Five say
4 completely. Thirteen say partially. One says
5 not at all.

6 Usability. Seven say completely.
7 Nine says partially. Two say minimally, and
8 one says not at all.

9 Feasibility. Thirteen say
10 completely. Four say partially. Two say
11 minimally.

12 And then here again, as before, I
13 think that we don't actually need to vote on
14 does the measure meet all the NQF criteria for
15 endorsement, because we voted no for
16 importance. So I think that the Committee
17 would like to respectfully recommend that this
18 be considered for a bundle measure by the
19 developers.

20 Okay, and so our next step is a
21 brief introduction of the measures for today
22 by the developers, and some of the developers

1 from yesterday spoke about measures for today,
2 but many developers are getting their first
3 opportunity to speak, so we'd like to go ahead
4 and start with the developers for the American
5 Academy of Ophthalmology, et cetera.

6 MS. LUM: Hi, good morning. I
7 want to first thank you for the opportunity to
8 speak, and I want to give credit, actually, to
9 the NQF committees for stimulating our
10 interest. They really strongly urged that we
11 look at patient-reported outcome. We already
12 have two cataract clinical outcome measures,
13 so these are amplifying it.

14 Do you -- I'm sorry, a question.
15 Do you want me to address both measures at
16 once? I don't know if that would be a little
17 bit briefer, or else do you want me to do it
18 separately?

19 CO-CHAIR MORRIS: We'd like you to
20 develop -- to address both at once and to be
21 pretty succinct with it.

22 MS. LUM: Okay. Great. The

1 visual function measure we believe fits into
2 the National Priority Partnership's priority
3 of population health by providing an index of
4 visual health. Patient satisfaction fits
5 perfectly with the patient and family
6 engagement.

7 We also think that these line up
8 really well with the NQF goals. Visual
9 function is an AHRQ-tested and validated
10 instrument that provides additional
11 information on the role of visual impairment
12 other than visual acuity, as we said, which is
13 a clinical measure, and that's measured by the
14 clinician.

15 This is a patient-reported
16 measure. How do patients do on a daily basis
17 reading small print, reading a book, seeing
18 steps and curbs, reading traffic and street
19 signs?

20 The patient satisfaction measure
21 could be added to the NQF portfolio of patient
22 experience measure, which already includes the

1 CAPs, the HCAPs, and the family evaluation of
2 hospice care. This was approved by the CAPS
3 consortium and developed with the same
4 scientific rigor and standardization as all
5 the other CAPS instruments.

6 The survey asked patients about
7 information that they received prior to
8 surgery, including risk-benefits,
9 alternatives, information about their care
10 during surgery, post-surgical instructions,
11 and the behavior of the surgeon -- Did they
12 listen? Did they spend time with the patient?
13 Did they allow them to ask questions? -- and
14 an overall rating of the quality of the
15 surgeon. So, in terms of
16 importance, as you know, cataract surgery, the
17 most performed procedure in Medicare
18 beneficiaries, about three million
19 beneficiaries, but there is no systematic
20 approach.

21 So we think that these two
22 measures really complement the clinical

1 measures that we already have, post-op
2 complications, which we consider a never
3 event, kind of a measure of surgeon
4 proficiency, the visual acuity measure that we
5 have already that really talks to
6 appropriateness of care, the patient
7 population that really should be operated
8 upon.

9 Then now we have a visual function
10 initiative that talks about what really
11 matters to the patient, what affects them in
12 everyday life, and then patient satisfaction
13 as a measure of the patient experience with
14 care, and we think that surgeons can really
15 look at the results of these measures in a
16 comprehensive picture of what happens in these
17 patients and enhance patient outcome and their
18 interaction with patients.

19 I did want to also address some
20 specific issues that came up in the work group
21 discussions last week. The visual function
22 measure, there was a comment that it was a

1 complex numerator, and that's because we
2 approached it, I think, thinking of it more as
3 a CMS measure for PQRS.

4 CO-CHAIR MORRIS: I'm going to --
5 I'm actually going to ask you to stop there --

6 MS. LUM: Okay.

7 CO-CHAIR MORRIS: Since we just
8 wanted you to introduce the measure. You'll
9 have an opportunity to speak about these
10 things in just a few moments. Dr. Barnebey,
11 would you like to go ahead and present?

12 MEMBER BARNEBEY: Okay. Good
13 morning. So there are two measures. You want
14 me to address them together or separately?

15 CO-CHAIR MORRIS: You can address
16 them separately.

17 MEMBER BARNEBEY: Okay. So the
18 first one looks at using a survey, a VF-14 or,
19 actually, a shorter version of it, which has
20 actually been validated scientifically. It's
21 a pretty strong measure looking at patient
22 outcomes, so this is different than the other

1 measures, which is more of an objective
2 measure.

3 So in terms of importance, you
4 know, cataract surgery is perhaps the most
5 frequent surgery done in the U.S., at least
6 for CMS purposes, and they're looking at in
7 terms of, I guess, looking at the gap measure
8 maybe of about 90 percent patient
9 satisfaction, so there is still an opportunity
10 to improve things further.

11 The scientific data, you know,
12 looks strong. I didn't see anything that was
13 prospective studies, but, you know, there was
14 some -- the research there and the scientific
15 validation of the instrument looks strong.

16 One of the questions is usability,
17 and I think the way the information was
18 presented, if it's segmented out in terms of
19 groups that have no comorbidities and those
20 which do have comorbidities, I think that will
21 be more useful.

22 Then, finally, the issue is

1 feasibility, because the data there suggests
2 that these particular surveys were
3 administered, you know, by a trained person,
4 whereas doing the surveys by mail or
5 electronic, I didn't see the science out there
6 to show that that's there, so there's some
7 potential in terms of a feasibility issue, but
8 overall I thought it was pretty strong.

9 MEMBER STAFFORD: Excuse me. Are
10 you talking about 1549?

11 MEMBER BARNEBEY: No, I'm talking
12 about 1536.

13 MEMBER STAFFORD: So that's a
14 survey?

15 MEMBER BARNEBEY: Yes.

16 MEMBER STAFFORD: Okay. Thanks.

17 CO-CHAIR MORRIS: Any other
18 comments or questions that came up in the work
19 group meeting from the Committee members?

20 MS. MURPHY: There was in the work
21 group meeting some discussion about the fact
22 that it is a self-administered survey that's

1 been validated for assisted administration,
2 and there is a notation in 4e1 in the
3 documentation that the elderly would
4 potentially need assistance in order to be
5 able to complete the survey. It also, in
6 terms of burden, speaks to the potential
7 necessity of a need for follow-up with
8 individuals in order to get them completed.

9 MEMBER MORTON: I guess the only
10 question I had is if we do the survey, what's
11 the actionable item about the survey? What do
12 we learn? What do we take back to improve our
13 practice and care of patients?

14 MEMBER HALPERN: And I would ask,
15 if it's the patients administering their own
16 survey, is there a validation with true visual
17 acuity as measured objectively?

18 MEMBER BARNEBEY: And, I guess,
19 when I was reading this, I was looking at this
20 as maybe a paired measure with the other
21 clinical outcome, which was 0565, so there is
22 already a measure out there looking at the

1 visual acuity as an outcome, as well as
2 complications of surgery, and I would look at
3 this, if we look at harmonization, as a paired
4 measure, you know, not to replace it.

5 CO-CHAIR MORRIS: Can the
6 developers tell us whether or not they
7 intended for this to be paired?

8 MS. LUM: Well, actually,
9 originally we had submitted a composite
10 measure, which would have been the two
11 clinical outcome measures, as well as these
12 two patient-reported outcomes, but because
13 these measures had not come up before as
14 individual measures, we were advised to submit
15 them as individual measures, but the intention
16 has always been from the Academy's side as a
17 composite.

18 CO-CHAIR MORRIS: Okay.

19 DR. BURSTIN: How do you define
20 improvement? Like what's the degree on the
21 scale of improvement is a question I had asked
22 earlier.

1 MS. LUM: The VF-14 is scored from
2 zero to 100, so 100 being perfect that you've
3 done -- that you can perform all the
4 activities, zero being not. So the
5 improvement would be a score -- an improvement
6 from the score pre and post on that scale.

7 DR. BURSTIN: If you went up two
8 points, that would count as an -- I mean, I'm
9 just trying to get a sense of the scale.

10 MS. LUM: There has not been a
11 defined step improvement. I think we could
12 stipulate it as part of this measure. As part
13 of the scale and how it's been used throughout
14 ophthalmology, there has not been a defined,
15 I guess, interval that would be considered
16 improvement.

17 The other thing I was going to say
18 is there have been two studies that have
19 looked at self-administered VF-14 compared to
20 interview-administered and found that that was
21 also a valid way to administer the test.

22 MEMBER BARNEBEY: If I could ask a

1 question of the developers, my understanding
2 is you're suggesting not the VF-14 but the VF-
3 8r, instead, which is a shorter version, but
4 it's been clinically validated to be
5 acceptable.

6 MS. LUM: That's right. For that
7 feasibility issue, patient response, patient
8 ability to return the questionnaires and
9 response rate, we have recommended a shorter
10 version. As you know, there is a rich
11 literature on visual function and several
12 instruments out there, but we were advised
13 also to propose one instrument that would be
14 used for this measure.

15 CO-CHAIR MORRIS: Can you address
16 the other comments and questions that the
17 Committee has raised so far before we ask you
18 some additional questions?

19 MS. LUM: Sure. I think your
20 question is about how can this affect
21 clinician behavior, and I think the whole
22 rationale of cataract surgery is to improve

1 visual function.

2 So if you find the patients
3 without noticeable or significant improvement
4 on visual function, then that will stimulate
5 the surgeons to look back on those patients
6 and see what characteristics about them would
7 have maybe prevented, should have prevented
8 them from being selected for cataract surgery
9 or if there were any other factors that might
10 have been able to be ameliorated prior to
11 surgery that would have improved their outcome
12 after surgery.

13 CO-CHAIR MORRIS: I think there was
14 a question about -- I'm sorry. We will, I
15 promise, we'll get to you, Dr. Rogers, but I
16 think Dr. Morton had asked a question about
17 actually burden, didn't you? Wasn't it about
18 burden on the provider?

19 MEMBER MORTON: Burden on the
20 provider, and I guess after hearing the
21 comment I'm just wondering what's the
22 incremental gain of the survey in addition to

1 just the clinic visit, where I would think you
2 would get some idea of function at that point?

3 MS. LUM: I guess the advantage
4 would be that it's a standardized instrument,
5 and it asks about several realms of visual
6 function, not just one. The clinician may not
7 have time to ask every patient in a systematic
8 approach, and the other question was about
9 burden, and that's why I think we've addressed
10 the shorter questionnaire.

11 People have done this in practice.
12 I mean, it has been mainly used in a research
13 setting, but I think because it's so
14 important, a patient's improvement after
15 surgery, I don't think it poses an undue
16 burden on the provider or the patient.

17 MEMBER DUTTON: I think, in some
18 way, this is a way of quantifying that
19 conversation between the doctor and the
20 patient. I think we're always going to have
21 trouble where science collides with patient-
22 centeredness in these measures, but I think

1 the patient-centered ones are very important.
2 I mean, if you go have your cataract fixed,
3 and I have, you want to see better afterwards.

4 CO-CHAIR MORRIS: I am sorry. Dr.
5 Rogers, would you like to have --

6 MEMBER ROGERS: Just using the
7 Wilhoit approach here, 2C1, there's probably
8 just a typo that addresses the return rate on
9 your validity testing. I'm concerned that of
10 414 patients, only 210 returned the
11 questionnaire.

12 It is good for a survey, but it
13 may not be good for the business that we're
14 in, and I have concerns about that. You know,
15 normally, people who are pleased will return
16 or have some specific complaint, so we have no
17 idea about the other half.

18 Secondly, there's an issue about
19 51 returned the VF-15 post-operatively. I
20 assume it's a typo, but I just want to make
21 sure there's no other secret method you have
22 out there that's named the 15, as opposed to

1 the 14.

2 MS. LUM: No, I'm sorry, that must
3 be an error, but, yes, the return rate I think
4 has been looked at 50 percent, which is high
5 for a questionnaire, but we're hoping if it's
6 for measurement purposes the physician's
7 office would probably undertake a more
8 directed effort to try to get those patients
9 to return their questionnaires. They'll see
10 them back at post-op visits, and they can kind
11 of ask them or badger them for their
12 questionnaires.

13 MEMBER CIMA: I mean, that's a big
14 issue in the exclusion criteria for the
15 denominator, using Carol's approach. It says,
16 "Patient refuses to participate." How do you
17 define -- I mean, if they just don't return
18 it, then they exclude it, so then you're
19 cherry-picking people for your survey results.

20 The other thing is that, getting
21 to Richard's point, though, is if you have an
22 objective measure of visual performance, then

1 do you -- I mean, you can ask the patient are
2 they seeing better, but you also have a
3 measurement of them seeing better.

4 I mean, they go hand-in-hand, but
5 one that's a flawed measure to be paired with
6 one that's an accurate measure, I'm not sure
7 it's -- does it add value?

8 MS. LUM: Well, actually, some
9 people would say visual acuity is not a
10 complete measure of visual function. Visual
11 function encompasses a lot of things that
12 aren't included in visual acuity such as
13 peripheral vision, visual processing, contrast
14 sensitivity, glare, acuity under glare
15 conditions.

16 So visual acuity actually is a
17 very -- it's just one dimension of visual
18 function, whereas this takes into account a
19 lot of different dimensions of visual
20 function, actually gets to what does the
21 patient do every day that's affected by
22 vision.

1 MEMBER DUTTON: I'd agree with
2 that. You can turn the argument exactly
3 around and say that the strict science of
4 measuring, you know, focus in the eye, isn't
5 really capturing what the patient wants out of
6 the surgery.

7 MEMBER ROGERS: And if I can make
8 a comment, I don't think there's anything to
9 suggest that the VF-14 as an instrument is
10 flawed. There really isn't any science to
11 support that.

12 I do have a question to
13 developers. There are new implants that are
14 now being used in a small group of people,
15 multi-focal implants, and I wonder if 90 days
16 is an adequate period of time to really be
17 measuring that group of people. I was
18 wondering if that was considered or discussed
19 when you developed the measure.

20 MS. LUM: You're right, because,
21 obviously, that wasn't considered in the
22 development of the VF-14, and I think the

1 questions are valid, but you're right. The
2 time period, I think, to harmonize with the
3 other measures, have been 90 days. Ninety
4 days is the visual acuity measure, so we would
5 have to think, I guess, about how to keep that
6 harmonization if we change it from 90 days.

7 MEMBER ROGERS: Because that could
8 really skew your results.

9 MEMBER WILHOIT: I like this
10 measure, and I like that it's survey and that
11 it's patient-centered and so on, but it just
12 doesn't seem very well defined.

13 First of all, some of the comments
14 were, "Well, the physician could badger the
15 patient to get the survey in." Well, that
16 right there adds bias. The method by which
17 the survey is performed is really key.

18 So, for example, for assessment of
19 health plans, when the CAP survey is done, we
20 have to hire a vendor, and we can't even know
21 who the patients are who were surveyed. The
22 vendor does the sampling, and we can't even

1 know who those people are so that we're not
2 badgering the person to get the surveys in.
3 So I think that that becomes really key,
4 because if I badger my patients and you don't,
5 we may have different -- we may have bias
6 based on that.

7 Second, I think, you know, as
8 specified, and this is what Helen raised:
9 what's improvement? Well, the numerator is
10 based on improvement, and is improvement one
11 point or five points or ten points? Until
12 that's defined, we don't even know what we're
13 measuring.

14 Also, if you look at the
15 numerator, and that's in 2a3, there's, "The
16 numerator includes," is what it says, although
17 it seems like some of these would be
18 exclusions, "patients who did not complete
19 their visual function assessment within 90
20 days."

21 So if somebody didn't complete the
22 assessment, you get credit is what it says, so

1 you get credit for improvement even if you
2 don't know, and then D is patients who did not
3 have an improvement in their visual function,
4 and there is no documented medical or patient
5 reason for not doing so.

6 Well, there are so many notes in
7 that, I'm not sure what it's saying, but it
8 doesn't seem like it would be a numerator
9 event. And then, in the denominator, it
10 includes all patients, but for a survey
11 measure there is burden.

12 There is cost to doing a survey,
13 and particularly if you require a vendor or
14 something like that to avoid bias, so
15 consideration of sampling might be a
16 possibility for high-volume centers, but
17 that's something to think about.

18 The numerator time frame is a
19 year, and yet it's specified as being 90 days,
20 so there is a disconnect there, and then under
21 exclusions, 2a9, is there -- it's actually
22 2a10. If you document a patient reason for

1 not improving visual function or document a
2 medical reason for not improving visual
3 function, the person is excluded.

4 Well, that sounds to me like if
5 there's a complication, I can code that there
6 was a reason, which was a complication, and
7 suddenly the person is excluded. So, I really
8 like this measure, but I think it needs a lot
9 more refinement before we're ready to assess
10 it.

11 CO-CHAIR MORRIS: Okay. So just
12 to recap the Committee comments, first of all,
13 it's unclear what really constitutes
14 improvement in this scale. Secondly, the
15 burden on provider is unclear.

16 The developer said that they
17 didn't think there would be too much burden on
18 the provider, but we know that there is a time
19 and effort and also a cost component. Also,
20 there are concerns that the provider going
21 after the patient to complete the survey may
22 bias their survey results.

1 There was some lack of clarity in
2 the exclusions, including maybe too extensive
3 exclusions, and then, lastly, the numerator
4 time frame was disparate within the language
5 of the measure.

6 Any other comments before we vote?

7 And, you know what? I should also say the
8 positive side. Sometimes I leave that out.
9 So there is enthusiasm for the patient-
10 reported side of this, patient-centeredness,
11 which is certainly a laudable goal and one
12 that we need to continue to push forward on.

13 So it's not that the measure in
14 principle is not regarded favorably. It is
15 regarded favorably, but just there are some
16 problems within it that could use fixing.

17 MS. LUM: Thanks. I just wanted
18 to comment. In terms of the numerator, I'm
19 sorry if it wasn't clear, but, yes, the whole
20 reporting period would be over a year, but it
21 would be 90 days that the patient would be --
22 by 90 days, the patient would be asked for

1 their visual function or satisfaction reason.

2 The other part of it is, as I
3 said, the numerator was complex, because we
4 approached it as a reporting measure. If it
5 was a performance measure, yes, we would only
6 count those in the numerator who had
7 improvement in visual function or
8 satisfaction.

9 And we included the others
10 because, I'm sorry, that's -- we had been in
11 that mind set because of how PQRS measures are
12 constructed and that when you report, you get
13 credit for everybody, even if they didn't
14 actually show an improvement.

15 So, sorry about that. We could
16 simplify, definitely simplify the numerator
17 just for the reporting purposes.

18 In terms of the exclusion, we
19 thought it made sense that if the patient
20 refused to participate, I think that would be
21 at the outset, not because they turned out to
22 have a complication after cataract surgery or

1 that there was a medical reason to do the
2 cataract surgery, not because you want to
3 improve their visual function after cataract
4 surgery but because there is another condition
5 or just to visualize the back of the eye.

6 We know that the vast majority of
7 cataract surgery doesn't include those
8 exclusions, so, I mean, I think we could
9 support a case that there would be no
10 exclusions in this measure that would simplify
11 it.

12 We know there's a few cases, but
13 overall we think the vast majority of
14 surgeries we could look at the measure that
15 way, not expecting a perfect 100 percent but
16 knowing that those exclusions could go away.

17 CO-CHAIR MORRIS: Thank you for
18 clarifying that. Now we're going to go ahead
19 and vote on the measure as written. Does the
20 measure meet NQF criteria for importance to
21 measure and report? Eighteen say yes. One
22 says no.

1 Scientific acceptability of
2 measure properties. Two say completely.
3 Twelve say partially. Four say minimally.
4 One says not at all.

5 Usability. One says completely.
6 Fifteen say partially. One says minimally.
7 Two say not at all.

8 Feasibility. One says completely.
9 Twelve say partially. Fourteen say minimally.
10 Two say not at all.

11 Lastly, does the measure meet all
12 the NQF criteria for endorsement? Nine say
13 yes, and ten say no.

14 DR. BURSTIN: Especially since
15 this is one of the first examples of a
16 patient-reported outcome like that, so I think
17 it would be really useful if the Committee had
18 specific suggestions or questions back to
19 ophthalmology that they could work on.

20 I mean, for example, we do have a
21 similar measure on the depression side now of
22 the use of the PHQ-9, which is the classic

1 scale we use for depression at baselines.
2 There's a process measure that says, "Did you
3 do the PHQ-9?" Then there is a measure that
4 says the actual rate at zero, six, and 12
5 months.

6 So I think there are some
7 interesting areas that I would hope the
8 Committee could give advice, because this is
9 a great direction we really want to go, and I
10 think it just really comes down to the
11 scientific acceptability of measure
12 properties. Is it really ready for prime
13 time?

14 MEMBER WILHOIT: I would say
15 cleaning up the numerator, cleaning up the
16 denominator, cleaning up the exclusions I
17 think would -- I mean, I'd love to look at
18 this again on a follow-up call. I voted no,
19 and I was really close, and if it were a clean
20 measure, I think we'd want to go -- I'd want
21 to go for it.

22 CO-CHAIR MORRIS: So, we can

1 revisit this on a follow-up call if you guys
2 would like to work with it some more.

3 MS. LUM: Definitely. Thank you.

4 CO-CHAIR MORRIS: Okay, and then
5 the next measure, also, Dr. Barnebey.

6 MEMBER DILLON: Just on that last
7 one, don't forget to add in what a meaningful
8 scale is in terms of response.

9 MEMBER CIMA: And the methodology.

10 DR. BURSTIN: Exactly. It's still
11 not clear, for example. Is it a delta
12 measure? Is there a pre-op number, a post-op
13 number? Is there a delta we're looking at?
14 It's just it's still -- the numerator is still
15 very, very fuzzy.

16 MEMBER CIMA: Also the survey
17 methodology. I mean, that's a big issue here.
18 I mean, I don't know if the developers really
19 have contacted their membership and see the
20 burden that an individual practitioner is
21 going to have to go through.

22 I mean, most of these are done at

1 an ASC. You're not looking at, you know, a
2 big hospital system that has, you know, other
3 things they're doing.

4 You're looking at a guy or girl
5 out on their own. They've got one person
6 doing their scheduling. Now you're going to
7 ask them to do this. I mean, it could be a
8 big burden to do it appropriately.

9 CO-CHAIR MORRIS: All of the
10 comments from today will be transcribed and
11 posted, as well, so you'll be able to refer
12 back to them.

13 MEMBER BARNEBEY: Okay, the second
14 cataract measure being proposed is 1549,
15 looking at patient satisfaction following
16 cataract surgery. In terms of, you know,
17 importance, obviously we talked about cataract
18 surgery being a very common occurrence and
19 something that needs to be measured and
20 perhaps improved upon.

21 The one thing that this measure
22 looks at which is different is, again, looking

1 at more the patient's perspective on their
2 experience. As opposed to looking at visual
3 function, this one is more of an experiential
4 type of measure, and I think, in terms of the
5 scientific merit, it was harder for me to put
6 my arms around this.

7 There is a model out there that
8 apparently has been clinically validated, but
9 I wasn't familiar with it, and I was
10 wondering, of the different types of surgical
11 especially referenced, you know, how many of
12 those were particularly applicable to
13 ophthalmology?

14 In terms of useable, I had
15 problems with the math in the equation with
16 this one, as well, so I guess I need some help
17 in terms of how that would translate into a
18 useable measure.

19 Then feasibility, again, it's the
20 burden of getting the information and that
21 sort of thing, so this one I was a little less
22 clear on. I clearly see the value of it, but

1 it's a new process for me to look at and I
2 think for most of us to look at, as well, so
3 I have some questions specifically for the
4 developers.

5 The two particular questions are
6 the modeling that you did in terms of the
7 questionnaire that was field-tested that you
8 worked in conjunction with the American
9 College of Surgeons and also the mathematical
10 model that you developed. To me it seemed a
11 little confusing.

12 DR. BURSTIN: And I'll just
13 indicate that we did go to AHRQ to ask them to
14 actually submit the surgical CAPS tool they've
15 been working closely with ACS on that. They
16 don't feel ready to do that at this time.

17 CO-CHAIR MORRIS: Any other
18 questions or comments for the developer?
19 Okay.

20 MS. LUM: Yes, in terms of the
21 CAPS, the surgical CAP, we did it as a cross-
22 surgical collaboration with the Surgical

1 Quality Alliance, so you're right. It's not
2 specific to ophthalmology, but we feel that it
3 can address a lot of the important concerns
4 about did the surgeon listen to the patient,
5 did they -- was the patient asking questions,
6 were they provided the pre-op instructions,
7 post-operative instructions.

8 In terms of -- I guess I'm not
9 sure in terms of the mathematical model. What
10 did you -- were you referring to?

11 MEMBER BARNEBEY: In terms of
12 understanding how the results were presented,
13 it just wasn't to me intuitive when I was
14 looking at the measures and how they were
15 broken down and presented.

16 MS. LUM: So this is how the CAPS
17 is -- SCAPS is scored, then, so there's
18 different composites for how the SCAPS is
19 scored. I have them here.

20 Then you would look across, so
21 it's information to help you prepare for
22 surgery, how well surgeons communicate with

1 patients before surgery, surgeon's
2 attentiveness on day of surgery, information
3 to help you recover, how well surgeon
4 communicates with patients after surgery,
5 helpful, courteous, and respectful staff at
6 surgeon's office, and an overall rating of the
7 surgeon, which is zero to ten.

8 Then there's different ways of
9 presenting the data, but basically the
10 proportional scoring method is there's three
11 options for the responses, yes, definitely,
12 yes, somewhat, and no, and you would just
13 calculate the average proportion across the
14 category for each composite. That's how
15 usually -- that's how the SCAPS would be --
16 the results of the SCAPS would be shown or
17 displayed.

18 MEMBER WILHOIT: I think this may
19 be another one where the numerator statement
20 isn't at all clear, because the numerator
21 statement doesn't reflect any of that. The
22 numerator statement also, again, seems to

1 include -- it seems like the rate would almost
2 come out to be 100 percent. So the measure is
3 satisfaction, but what seems to be measured is
4 whether you measured satisfaction.

5 Well, those are very different.
6 This is being presented as a public
7 accountability measure, and whether you
8 assessed satisfaction is of no interest from
9 a public accountability standpoint.

10 So, again, I think the concept is
11 one of great interest, but I'm not at all
12 clear on exactly, you know, what is
13 satisfaction. Is that -- you know, what is --
14 what counts as satisfaction? Is it one
15 question? Is it ten questions? Is it a
16 composite? Is it a -- you know, what's the
17 score? I think there's just lots of
18 questions.

19 CO-CHAIR MORRIS: Any other
20 comments or questions for the developer?
21 Would you like to say anything about what
22 counts as satisfaction? Have you all

1 discussed that in your development group?

2 MS. LUM: Yes, and I'm sorry for
3 the confusion again in the numerator. It
4 definitely is what is satisfaction, not that
5 you just measure satisfaction, but it would be
6 the result that patients were satisfied after
7 cataract surgery.

8 In terms of the SCAPS, again, it's
9 like the VF-14. They haven't defined, I
10 guess, a base level of satisfaction.
11 Definitely we look at the proportional scores.

12 You'd want the yes, definitely,
13 yes, somewhat, obviously, the majority versus
14 the no responses in each of the composite
15 measures and then the rating of the surgeon,
16 which is zero to ten, ten being the best.
17 Obviously, we want it greater than five, but
18 maybe we can also regroup and try to clarify
19 those things in the measure after this
20 meeting.

21 MS. MURPHY: Would you mind to say
22 just another word of when you say composite

1 measures, to what are you referring
2 specifically?

3 MS. LUM: So the SCAPS consist of
4 41 questions, so they're broken out into, you
5 know, pre-surgical, during surgery, after
6 surgery, and staff, so those are the
7 composites -- sorry -- that I was referring to
8 that SCAPS breaks it down into.

9 CO-CHAIR TORCHIANA: I had a
10 question on the feasibility issue. How
11 universal is membership in the American
12 Academy of Ophthalmology? Is that a very
13 general group that virtually all
14 ophthalmologists belong to?

15 MS. LUM: Right. We have 94
16 percent of all practicing ophthalmologists in
17 the United States.

18 CO-CHAIR TORCHIANA: Could I make
19 a suggestion that maybe the Academy could work
20 out a way of becoming the vendor for the
21 survey and that that might facilitate it for
22 the broad practice?

1 MS. LUM: That is a good
2 suggestion. We do have a PQRS registry, and
3 my thoughts also were to serve as a vendor to
4 serve as the web administrator of the surveys
5 and also be able to score them and aggregate
6 the scores.

7 MEMBER WILHOIT: Again, I think
8 it's worth considering whether really it's all
9 patients who had surgery or whether it's a
10 sample. Sampling certainly helps control
11 cost.

12 MS. LUM: Similar to the visual
13 function, which I guess we had envisioned
14 these as composite measures, and under the
15 PQRS it is a sample of patients, just 30
16 patients, as well, so I think the burden
17 requirements, we had been thinking that it
18 would be a sample of patients and not all the
19 patients.

20 MEMBER WILHOIT: But the
21 denominator statement is all.

22 CO-CHAIR MORRIS: Okay. So let's

1 move on to a vote of the measure as written.

2 First of all, importance to measure and
3 report. Thirteen say yes. Six say no.

4 Scientific acceptability of
5 measure properties. One says completely. Ten
6 say partially. Five say minimally. Three say
7 not at all.

8 Please hit your buttons one more
9 time and hit the Send button. Three say
10 completely. Ten say partially. Five say
11 minimally. One says not at all.

12 Feasibility. One says completely.
13 Ten say partially. Six say minimally. Two
14 says not -- two say not at all.

15 Does the measure meet all of the
16 NQF criteria for endorsement? Five says yes,
17 and 14 say no, and I think that this is very
18 similar to the previous measure that we would
19 be interested in seeing a revised version of
20 this measure and that we think that patient-
21 reported outcomes are very important.

22 We're going to take a short break,

1 15 minutes. Let's reconvene just before
2 10:30.

3 (Whereupon, the foregoing matter
4 went off the record at 10:14 a.m. and resumed
5 at 10:33 a.m.)

6 CO-CHAIR MORRIS: We're going to
7 go ahead and get started again, and we're
8 moving on to the General, Prophylaxis and
9 Wound Dehiscence section. The first measure
10 that we'll be discussing is 528, and that will
11 be discussed by Dr. Collins.

12 MEMBER COLLINS: Yes, okay, thank
13 you. So a subject matter pretty near and dear
14 to my heart here. The first is 0528, which I
15 believe is a SIT measure number two up for re-
16 endorsement.

17 This particular measurement is the
18 surgery patients who receive the correct
19 prophylactic antibiotics consistent with
20 current guidelines based on their procedure,
21 and the procedures listed in our packet are CT
22 surg, vascular surgery, colon surgery, hip and

1 knee, arthroplasty, and vaginal and abdominal
2 hysterectomies are listed.

3 There's a -- there is a comment
4 about an appendix. However, I didn't see that
5 for other procedures, but I know that other
6 procedures such as neuro surg and other
7 procedures are being rolled out as we go.

8 I think this is a very important
9 measure. Selection of the appropriate
10 antibiotic I feel goes without saying, as well
11 as the importance of not selecting agents that
12 are too broad from a collateral damage
13 standpoint.

14 So, not only is there good
15 evidence for based on the antimicrobial
16 susceptibilities but also the spectrums of the
17 agents, so I do think it's important, and the
18 work group did, as well. The science behind
19 it I think is pretty appropriate.

20 Some of the justification for
21 antibiotic selection listed in our packet I
22 don't feel was very rigorous. The Stanford

1 guide and the Johns Hopkins antibiotic guide
2 were listed as justification for selection of
3 a couple different agents. However, I know
4 there's a Technical Advisory Panel that
5 reviews selections quarterly, I believe.

6 So the scientific rigor I think is
7 good. However, I do think there is a measure
8 to harmonize and continue to harmonize with
9 national guidelines as they come out, which I
10 think CMS is doing. The work group thought it
11 was very useable and feasible, as well, with
12 compliance greater than 95 percent.

13 So, points of discussion, I assume
14 we'll go into the bundle discussion, as well
15 as whether this measure is topped out, and
16 I'll turn it over to the group for discussion.

17 CO-CHAIR MORRIS: Anybody want to
18 start?

19 MEMBER ZAMBRICKI: I would just
20 comment that looking at the literature it
21 seems like there's the closest correlation
22 between this measure, selection of antibiotic,

1 and surgical site infection as compared to the
2 timing measure, so I think this is a stronger
3 measure than the timing.

4 MR. BRATZLER: This is Dale
5 Bratzler. Can I [inaudible]10:37:01 the
6 developer make a quick comment?

7 CO-CHAIR MORRIS: Sure.

8 MR. BRATZLER: So I'm just going
9 to make a couple of quick comments about the
10 three measures, and then I'll go back on mute,
11 the three measures that are being considered,
12 selection, timing, and discontinuation.

13 First, the measures all three are
14 actually are strongly evidenced, and new
15 guidelines will be published this year through
16 four different specialty societies. All three
17 measures are still strongly enforced in the
18 new guidelines that are going to come out.

19 There still is opportunity for
20 improvement in all the measures. I mean, if
21 you look at national rates, they've gone up
22 dramatically, but by different surgery type

1 there are some variations.

2 Finally, I actually would argue
3 the point that was just made about the
4 strength of evidence around antibiotic
5 selection versus timing. I can't go into all
6 the details right now, but there have been a
7 spate of articles looking at different
8 measures, trying to show whether or not
9 they're associated with patient outcomes.

10 And I will simply say that most of
11 those have some fairly large methodologic
12 flaws, the biggest of which is they try to use
13 performance rate published on --

14 (Inaudible due to telephonic interference)
15 -- to predict outcomes at the hospital level,
16 something you really can't do, because that
17 approach doesn't take into account all of the
18 exclusions from these performance measures.

19 And then we're in the editing
20 process right now of a very large study of all
21 the SCIP --

22 (Inaudible due to telephonic interference)

1 -- for three years that shows you definitely
2 want to go to a --

3 (Inaudible due to telephonic interference)

4 -- measures if you're eligible --

5 (Inaudible due to telephonic interference).

6 So I'll just say that there is
7 strong --

8 CO-CHAIR MORRIS: Dale, your voice
9 is kind of going in and out. Is it possible
10 to make him a little bit louder? I'm not sure
11 exactly why that's happening, but I just want
12 to make you aware of it.

13 MR. BRATZLER: Okay. I'm getting
14 big feedback sometimes when I speak. So I'll
15 just -- I'll just end by saying there is
16 strong evidence base for all three measures.
17 All three measures will be strongly supported
18 in new multi-specialty society guidelines that
19 will be coming out this year.

20 Those societies include Infectious
21 Disease Society, SHEA, Surgical Infection
22 Society, and the American Society of Health

1 System Pharmacists. The four societies have
2 been working now for the last couple of years
3 on new guidelines. These three measures are
4 all consistent and strongly supported in the
5 new guidelines.

6 Finally, we have really good
7 patient level data adjusted for the hospital
8 effect, all the appropriate risk assessment
9 methodologies that show that at the patient
10 level you want to be in a hospital that passes
11 these measures.

12 The measures are associated with
13 improved patient outcomes, in contrast to some
14 of the papers that have come out that have had
15 strong, substantial methodologic flaws. So
16 more will be coming on that soon.

17 CO-CHAIR MORRIS: Thank you.
18 Paula, did you have something you wanted to
19 add?

20 MEMBER GRALING: Well, my question
21 was, again, where laparoscopy is in the
22 exclusion criteria, and I think we've talked

1 around the table about with the trends in
2 surgery that that's a concern.

3 MR. BRATZLER: I think, Wanda,
4 you're on the call. Haven't we removed the
5 laparoscopy exclusion?

6 MS. JOHNSON: For January 2012, it
7 will be coming out.

8 MR. BRATZLER: So we've addressed
9 it.

10 CO-CHAIR MORRIS: Could you repeat
11 that?

12 MR. BRATZLER: We have addressed
13 that issue. In January of 2012, the
14 specification manual removes that exclusion.

15 CO-CHAIR MORRIS: Okay. Thank
16 you. Any other comments, questions? Dr.
17 Morton?

18 MEMBER MORTON: I think I speak in
19 support of the measure. I think
20 appropriateness of antibiotics is pretty
21 critical.

22 I think the question about topping

1 out is probably still there and whether or not
2 it fits within a composite, but certainly we
3 want to give the appropriate kind of
4 antibiotic, and before some of these measures
5 were in place there was a wild, wild West
6 about which kind of antibiotics were being
7 used, so I think it's a very useful measure.

8 MEMBER COLLINS: You know, and a
9 point of clarification, too, I was referring
10 to individual agents within the submission
11 here. I'm very happy to hear that the
12 national, you know, kind of four group
13 guidelines will be factored into the SIP
14 initiatives for antibiotic selection, timing,
15 and such.

16 I know those are coming out. I
17 believe anticipated publication is around
18 September of those guidelines, so, as a whole,
19 I was referring to just the individual
20 choice of, you know, maybe a specific agent,
21 not the overall choice.

22 CO-CHAIR MORRIS: Are we -- are we

1 ready for a vote? Okay. So, importance to
2 measure and report. Eighteen say yes. None
3 say no.

4 Scientific acceptability of
5 measure properties. Fifteen say completely.
6 Three say partially.

7 Usability. Sixteen say
8 completely. Two say partially.

9 Feasibility. Fifteen say
10 completely. Three say partially.

11 Does the measure meet all of the
12 NQF criteria for endorsement? Eighteen say
13 yes. None say no.

14 Apparently, we also should permit
15 the STS and the ASC to introduce their
16 measures. This is going to be -- this is a
17 daily opportunity, so we'd like to invite the
18 STS and then the ASC to introduce their
19 measures before we proceed to them.

20 MR. JACOBS: I'm Jeff Jacobs from
21 the Society of Thoracic Surgeons, and I think
22 it's clear in the packet that there's three

1 antibiotic-related measurements that STS has
2 put forward that are bold measures that have
3 previously been reviewed. One is related to
4 appropriate choice of antibiotic, one is
5 related to timing, and one is related to the
6 length of antibiotic usage.

7 There's extensive justification in
8 the peer reviewed literature for all three of
9 these measures, including manuscripts written
10 by the STS Evidence-Based Task Force, that
11 discusses the level of evidence to support
12 each one of these three measures. I don't
13 think I really need to go through those in
14 great detail, because that's all supplied in
15 the packet.

16 MS. SLOSBURG: Just to reiterate,
17 yesterday we did try to harmonize with the
18 SCIP measure for the IV antibiotic timing.

19 CO-CHAIR MORRIS: Okay. So the
20 next measure is Measure 128, duration of
21 prophylaxis for cardiac surgery patients. Dr.
22 Kleinpell will be presenting this.

1 MEMBER KLEINPELL: Great. Thank
2 you. This is Measure 128. It's duration of
3 antibiotic prophylaxis for cardiac surgery
4 patients. It's a maintenance measure. It was
5 first released in 2004. The measure steward
6 is STS.

7 With respect to this measure, we
8 actually looked at the categories. Obviously,
9 it is important with respect to prolonged
10 antibiotics and the percent of antimicrobial
11 resistance. With respect to scientific
12 acceptability, I think our group had the most
13 discussion about this because of the time line
14 of 48 hours versus 24 hours.

15 Connie, unfortunately, she's not
16 here, but with her involvement with respect to
17 the Infectious Disease Society she actually
18 brought forth some references for us. It was
19 interesting to look at some of those with
20 respect to the development of these guidelines
21 for cardiac surgery.

22 It was developed originally by the

1 American Society of Health Systems
2 Pharmacists, and they identified that expert
3 opinion was a driving force with some respects
4 with this time line of 48 hours. So we really
5 questioned, going back and forth, 24 versus 48
6 hours with respect to the evidence for
7 scientific acceptability of this measure.

8 Some of the other things we noted
9 within it itself, there are some denominator
10 exclusions listed, but we noted that they are
11 -- their exclusions could not be captured in
12 the previous version of the STS database.

13 However, it was indicated that the
14 new cardiac surgery database, which was
15 released this January of 2011, will enable
16 exclusion data to be captured, and so that is
17 forthcoming.

18 We noted that disparities of care
19 were provided. For the most part, there still
20 is a gap ranging from about 83 percent to 100
21 percent, but the mean is around 94 percent
22 itself.

1 There are no direct costs. It's
2 indicated with respect to the measure but
3 really no specific information about costs
4 involved in maintenance of this measure.

5 So I think for us the areas of
6 controversy, again, was really along the
7 timing and the evidence that supports that.
8 Now, you did tell us that there was some
9 forthcoming guidelines from the other
10 societies, and I'm not sure to the degree to
11 which they will give us more information on
12 the issue of timing with respect to cardiac
13 surgery antibiotic prophylaxis.

14 MEMBER COLLINS: You know, I can
15 comment on that. The upcoming guidelines,
16 which I have seen a draft recommend 24 to 48
17 hours, they say the evidence is inconclusive
18 for one or the other, so they do allow that
19 range.

20 MEMBER KLEINPELL: So, I guess,
21 with that in mind, does this mean when we see
22 it again next year that this might be changed,

1 then, to 24 to 48 hours, or can the measure
2 developer speak to that?

3 MR. JACOBS: I think that there's
4 very limited experience of doing cardiac
5 surgery with only 24 hours of antibiotic
6 prophylaxis, and the risks associated with an
7 infection after heart surgery is probably
8 worse than after most operations, because it's
9 mediastenitis, which generally leads to death.

10 I think that prior to making a
11 society-based recommendation of changing the
12 length of antibiotic prophylaxis from 48 hours
13 to 24 hours after cardiac surgery, I think
14 that topic would have to be studied in greater
15 detail in cardiac surgical patients. The
16 evidence base in the literature simply does
17 not support changing prophylaxis for cardiac
18 surgical patients to 24 hours.

19 MEMBER HALPERN: And I have to say
20 the same thing kind of exists for some
21 vascular patients, you know, again because of
22 the risks associated with being wrong is a

1 graft infection, and a graft infection can
2 lead to limb or life loss, so we have a
3 similar issue going on in vascular surgery
4 patients.

5 MR. JACOBS: So, I would say it
6 may be very reasonable to ultimately change
7 this to 24 hours, but I think it's very
8 premature to do that now, because it's simply
9 not been studied.

10 MEMBER HALPERN: Also, I mean, you
11 know, the reason for 24-hour coverage is
12 that's theoretically when the skin seals, but
13 if you look at like older people with very
14 loose, kind of yucky skin, they don't seal at
15 24 hours, so it may be actually more patient-
16 specific than has ever been looked at.

17 MEMBER CARPENTER: We'll get into
18 this in another topic, but orthopedics is a
19 similar problem with major implants and risk
20 for infection and the 24-hour range. There is
21 no data one way or the other, so it's been
22 selected at 24 hours for majority of

1 surgeries, cardiac surgeries excluded from
2 that for some reason, to a 48-hour window.
3 You know, there's a question should we be
4 consistent across the measures.

5 CO-CHAIR MORRIS: Any other
6 questions or comments? Let's go ahead and
7 vote on this measure.

8 MR. BRATZLER: This is Dale. I
9 just one to make one --
10 (Inaudible due to telephonic interference)
11 -- guideline is going to explicitly recommend
12 less than 24 hours for all operations based on
13 no good evidence of prolongation being useful.
14 Just a point of --

15 CO-CHAIR TORCHIANA: I'm not sure
16 we heard that comment, Dale. Could you repeat
17 it?

18 MR. BRATZLER: I said the new
19 Multi-Specialty Society guideline is explicit
20 of less than 24 hours for all operations, no
21 exceptions.

22 MEMBER COLLINS: That must have

1 changed since public draft comments, then. Is
2 that correct?

3 MR. BRATZLER: I don't remember
4 exactly. It's been quite a while back that
5 the draft was out there, but the guideline is
6 explicit now that less than 24 hours for all
7 operations. Actually, for almost all types of
8 operations there are studies that have looked
9 at single-dose prophylaxis.

10 You know, I think STS a number of
11 years ago, they chose 48 hours, made that
12 recommendation based on the fact that there
13 weren't studies that compared 24 to 48, but
14 they're actually, you know, limited, I
15 recognize, limited studies of single-dose
16 prophylaxis even in cardiac surgery.

17 I think our emphasis is much more
18 in the guidelines on doing the up-front things
19 right, correct dosing, correct antibiotic,
20 redosing in the OR, which have all been shown
21 in fairly good trials to reduce infection
22 rates, and part of the big push on antibiotic

1 stewardship is to reduce unnecessary use of
2 antibiotics.

3 CO-CHAIR MORRIS: Okay. We'll ask
4 for the remaining comments about measures that
5 are not their own to be held until the public
6 and member comment period unless it's a member
7 of the Committee and people who are the
8 developers of the comments that are being
9 discussed. Let's --

10 MR. JACOBS: Can I respond to that
11 from STS?

12 CO-CHAIR MORRIS: Sure.

13 MR. JACOBS: I would just say that
14 I want to reiterate what I said before that
15 ultimately it may be appropriate to change
16 cardiac surgical prophylaxis to 24 hours but
17 that the evidence base simply does not exist
18 in the literature.

19 CO-CHAIR MORRIS: Yes, you told us
20 that. Thank you. Let's go ahead and vote on
21 this measure unless anybody on the Committee
22 has anything else that they'd like to say

1 about it. Okay.

2 Does the measure meet NQF criteria
3 for importance to measure and report?

4 Eighteen say yes. One says no.

5 Scientific acceptability of
6 measure properties. Ten say completely. Six
7 say partially. Two say minimally. One says
8 not at all.

9 Usability. Thirteen say
10 completely. Six say partially.

11 Feasibility. Eleven say
12 completely. Eight say partially.

13 Does the measure meet all the NQF
14 criteria for endorsement? Seventeen say yes.
15 Two say no.

16 The next measure we're going to
17 lump back up again to Dr. Collins, 126,
18 selection of antibiotic prophylaxis for
19 cardiac surgery patients, and this is the STS
20 Measure 126.

21 MEMBER COLLINS: So, yes, this is
22 a measure very similar to 0528 from CMS. This

1 is selection of antibiotic prophylaxis for
2 cardiac surgery patients submitted by the STS.

3 The numerator first is the
4 appropriate choice of antibiotic, denominator,
5 number of surgeries. To meet criteria,
6 patients must receive either first- or second-
7 generation cephalosporin or vanco or a
8 fluoroquinolone if there are allergies or
9 contraindications there.

10 Much like 0528, the work group
11 felt this was an important measure,
12 scientifically acceptable. It's been active
13 since 2007, so I feel it's both useable and
14 feasible, as well. The issue of whether it's
15 topped out could come up again at 92 percent
16 compliance on this.

17 CO-CHAIR MORRIS: Anything else
18 from the Committee, questions or comments for
19 the developer? You made a comment previously
20 that mediastinitis leads to death, so that's
21 a pretty extreme sequelae of inadequate
22 coverage, and so 92 --

1 So something, I guess, that we
2 should think about in terms of being topped
3 out, is 92 percent actually topped out for
4 this measure? I guess in my opinion it's not,
5 but I'd be certainly happy to hear anybody
6 else's opinions about that.

7 Okay. Should we go ahead and
8 vote, then? This is a quick discussion.

9 Does the measure meet NQF criteria
10 for importance to measure and report?
11 Nineteen say yes.

12 Scientific acceptability of
13 measure properties. Fifteen say completely.
14 Four say partially.

15 Usability. Seventeen say
16 completely. Two say partially.

17 Feasibility. Eighteen say
18 completely, and one says partially.

19 Lastly, does the measure meet all
20 the NQF criteria for endorsement? Nineteen
21 say yes. None say no. None abstain.

22 The next measure is Measure 0125,

1 timing of antibiotic prophylaxis for cardiac
2 surgery patients, and this is going to be
3 introduced by Ms. Zambricki.

4 MEMBER ZAMBRICKI: Hello,
5 everyone. My measure is the percent of
6 patients 18 and older undergoing cardiac
7 surgery receiving prophylactic antibiotics
8 within one hour of surgical incision or start
9 of procedure.

10 The importance to measure, I think
11 the summary of the evidence regarding deep
12 sternal wound infection is very strong. Our
13 group had quite a bit of discussion about is
14 there evidence of a link between the measure
15 focus and the desired outcome.

16 Is that link strong, because
17 that's one of the criteria for importance to
18 measure, and I think there is controversy
19 about that. It sounds like there's a new
20 study coming out, but the idea that exactly
21 one hour before incision and one hour and ten
22 minutes is not acceptable, one hour is

1 acceptable, I think there is some controversy
2 about that in the field.

3 What is the exact timing that is
4 necessary to have a link between decreased
5 surgical site infection or not? And there
6 have been some studies recently that show that
7 that link is not a powerful link, but it
8 sounds like there are studies coming out, so
9 it's just a tough, tough issue I think right
10 now, that importance to measure, for us.

11 The importance to measure section
12 by the sponsor, for the rating of strength of
13 evidence they left that blank and put "Not
14 applicable." For the, "Is there controversy?"
15 they left that not applicable, so they really
16 did not address the issue of the rating of the
17 evidence.

18 In terms of scientific
19 acceptability, the exclusion laparoscopic is
20 still there, but we understand that that is
21 going to be taken away. It's interesting,
22 because they do include patients for whom no

1 incision is required but make an exclusion for
2 patients with laparoscopy, so that's -- it
3 would be interesting to hear the explanation
4 of that thinking.

5 In terms of the testing -- oh, I
6 guess I should go back, the importance to
7 measure. I think there's a real question
8 about whether a gap exists for this measure.
9 The median performance is 99.2 percent, and
10 the mean is 98 percent, so it seems as though
11 this should have consideration as far as being
12 a topped out measure.

13 Testing, there was no data on
14 exclusions, because there was some type of a
15 database change with STS. They said that that
16 would be provided in future years, and in
17 terms of usability, there's a lot of similar
18 measures, so the idea of harmonization is an
19 important one.

20 I think that question of is there
21 distinctive improved or added value, the
22 supporters said not applicable, and I think

1 that gets back to the question about the
2 controversy in the literature.

3 CO-CHAIR MORRIS: Anything else
4 from the Committee in terms of questions or
5 comments for our developer?

6 MEMBER ROGERS: I'm sorry,
7 Christine, I didn't quite understand the issue
8 of an hour versus an hour ten. Is the
9 controversy with respect to that specific
10 timing or some variation in timing?

11 MEMBER ZAMBRICKI: Well, I think
12 the overall controversy is is there a
13 connection between the SCIP measures and
14 decreased surgical site infection for
15 individual SCIP measures, and there is
16 recently literature in JAMA and others with
17 large patient populations -- at the VA there
18 was 60,000, and JAMA I think it was 400,000
19 patients, or it may have been vice versa --
20 showing no correlation between individual SCIP
21 measures, of which this is one, and decreased
22 surgical site infection.

1 I would say in the field, and I'm
2 interested in what the surgeons think, but in
3 the field there is a lot of, I think,
4 credibility problem with surgeons who get
5 dinged because the case is delayed. Now they
6 haven't met this SCIP measure and ask, "Well,
7 does this really make a difference in
8 infection if it's 15 minutes late or if it's
9 one hour?"

10 So I think that's just kind of
11 background noise in the field as far as the
12 credibility issue, but in terms of the
13 literature and the exact time interval, it's
14 kind of -- there must be some time interval
15 that's important, but it is not conclusive.

16 I know Connie's not here from
17 Infectious Disease. She had presented us with
18 some data that was quite dated, but it did
19 suggest that 30 minutes might be appropriate.

20 So is it 30 minutes? Is it one
21 hour? Is it an hour and a half? Is it two
22 hours? It seems like there is controversy

1 about that.

2 MEMBER ROGERS: So there's no
3 controversy --

4 MEMBER HALPERN: I would also say
5 maybe even longer would be needed. We have a
6 PharmD with us, but, you know, getting tissue
7 levels, you don't have tissue levels for some
8 antibiotics in an hour.

9 MEMBER ZAMBRICKI: It's not even
10 an hour, because it's within an hour, so
11 people sometimes will bring the patient in the
12 OR, push it in, and it's gone in four minutes
13 before.

14 MEMBER HALPERN: Right, and you
15 haven't gotten tissue, skin tissue levels --

16 MEMBER ZAMBRICKI: Yes.

17 MEMBER HALPERN: -- because the
18 volume of distribution may be -- and
19 especially in the obese patients where the
20 volume of distribution is high.

21 MEMBER COLLINS: Yes, I would
22 concur. It's absolutely variable by

1 antibiotic, you know, and by procedure. The
2 data I think is very good for extended periods
3 of time. Administered very much too early or
4 even within 15 minutes, there's harmful data
5 there. It's difficult to -- you know, I see
6 the discussion of exactly one hour versus one
7 hour, five minutes.

8 I see why that is a discussion
9 point. I don't know. I'm not sure of a
10 better way to go about it, though. I think
11 one hour has been studied, and I don't know if
12 I have answers to this.

13 MEMBER MORTON: I agree with
14 Curtis. I mean, it's a tough one to just
15 figure out if one hour is exactly right or if
16 it's 30 minutes, but you've got to set a goal
17 at some point, and it's the goal that's been
18 set, I think, through compromise. There's a
19 lot of old data to show that, you know, the
20 antibiotic does get into the tissue around
21 that time.

22 I know that people are trying --

1 have to game the system to some degree, you
2 know, as long as you do it before the
3 incision, but it's a start. I don't know how
4 else to do it other than to refer back to the
5 developer and say that, you know, you need to
6 have a better idea of when the antibiotic is
7 actually getting into the tissue.

8 Regardless of those studies that
9 came out, I'd like to hear from the developer,
10 because I heard some mention earlier that
11 there was some methodological concerns about
12 it, that there were a lot of exclusions that
13 were associated with those studies, and to get
14 a better handle on what they think the
15 scientific validity of those studies are.

16 CO-CHAIR MORRIS: Jeff, would you
17 like to respond to that?

18 MR. JACOBS: So, what I'd like to
19 do is just read two sentences from the measure
20 submission form to clarify exactly what the
21 recommended timing is based on specific
22 antibiotics, and then I'll move from there to

1 addressing the question.

2 We say that "in patients for whom
3 cefazolin is the appropriate prophylactic
4 antibiotic for cardiac surgery, administration
5 within 60 minutes of skin incision is
6 indicated (Class I, level of evidence A)."

7 Then we go on to say, "In patients
8 for whom vancomycin is an appropriate
9 prophylactic antibiotic for cardiac surgery,
10 a dose of 1 to 1.5 grams or a weight-adjusted
11 dose of 15 milligrams per kilogram IV slowly
12 over one hour with completion within one hour
13 of skin incision is recommended (Class I,
14 level of evidence A)."

15 And the reference for these two is
16 a manuscript that was published in the "Annals
17 of Thoracic Surgery" by the STS Evidence-Based
18 Task force. In this particular manuscript,
19 the first author is Rich Engelman, and this is
20 a task force that spent a substantial period
21 of time reviewing all the literature about
22 antibiotic prophylaxis and came up with

1 consensus-based recommendations, including
2 class and level of evidence.

3 So I think that these
4 recommendations, they are, first of all, made
5 on an antibiotic-specific strategy. Second,
6 there is a level of evidence provided here.

7 Clearly, it wasn't filled out in
8 the appropriate place on the form, but it was
9 placed in this location, and this level of
10 evidence came from an expert panel reviewing
11 multiple manuscripts and multiple studies
12 about this topic.

13 CO-CHAIR MORRIS: Can you tell us
14 what was the year of publication for that
15 citation?

16 MR. JACOBS: This is April 2007,
17 "Annals of Thoracic Surgery", which is the
18 most recent multi-specialty evidence-based
19 medicine review of the literature that's been
20 undertaken and published.

21 MEMBER MORTON: This supporting
22 data is from an expert panel that reviewed the

1 existing literature?

2 MR. JACOBS: Everything that had
3 been published up through that time, and the
4 reference list to that is substantial. It's
5 massive.

6 CO-CHAIR MORRIS: Any other
7 questions or comments? Let's go ahead and
8 vote.

9 MEMBER ZAMBRICKI: I would just
10 ask one question, and that is the performance,
11 99.2 percent, and 98 percent mean, 99.2
12 percent median. Any thoughts on that?

13 MR. JACOBS: Yes, I think that if
14 I was having heart surgery at a hospital that
15 did 500 cases and I was one of the two
16 patients that missed that and ended up dying
17 of mediastenitis, I'd feel real bad. It's a
18 very high-stake game, and I think that this 99
19 percent isn't acceptable for this, because if
20 one percent of your patients die from this,
21 it's a big problem.

22 CO-CHAIR MORRIS: Any other

1 comments? All right. Let's go ahead and
2 vote. Importance to measure and report.
3 Seventeen said yes. Two said no.

4 Scientific acceptability of
5 measure properties. Eleven said completely.
6 Eight said partially.

7 Usability. Thirteen said
8 completely. Six said partially.

9 Feasibility. Fifteen said
10 completely. Four said partially.

11 Does the measure meet all the NQF
12 criteria for endorsement? Seventeen said yes.
13 Two said no.

14 So now we'll move on to Measure
15 265, prophylactic intravenous antibiotic
16 timing, and this was to be presented by Steve
17 Findlay, but instead he has comments that will
18 be read by Alexis? By Alexis. We'll also ask
19 for the people who were present on that work
20 group telephone call to please chime in even
21 more than usual.

22 MS. FORMAN: Performance on this

1 measure has been above 95 percent for five or
2 more years. On the Work Group D call there
3 were questions about the requirement that
4 antibiotics be given within one hour, rather
5 than one to two hours or so.

6 Doubts about the strength of
7 evidence for one hour, so discussion of that
8 and questions to the steward should be prompt.
9 That was the main issue.

10 Disparities data is not collected
11 or available on this measure, so even though
12 it looks topped out, since there is now a
13 routine practice, there still may be a need to
14 preserve the measure. Scoring on the measure
15 for usability, science feasibility was all CRP
16 in importance to measure and meeting the
17 criteria.

18 The stewards, as they did
19 yesterday, are likely to argue that this is a
20 key measure for them. Personally, I think the
21 measure is close to topped out, if not there
22 already.

1 CO-CHAIR MORRIS: Any other
2 comments from folks who were present on the
3 work group call?

4 MEMBER KLEINPELL: Well, I know we
5 did have some discussion with respect to the
6 fact that there is no data on disparities, so
7 I think that's something that we would look to
8 have the measure developer provide if any of
9 that data is possible.

10 We also had some discussion with
11 respect to the definition and the issue that
12 it says on time, and then the clarification of
13 on time is within one hour of incision time,
14 so it was questioned, well, couldn't that just
15 be put into the statement? Instead of saying
16 on time, say within one hour of incision time,
17 because then it's clear, but that's semantics,
18 I guess, but that did come up in our
19 discussion, as well.

20 CO-CHAIR MORRIS: Okay. Would the
21 ASC like to respond to that?

22 MS. SLOSBURG: We can definitely

1 add the one hour to the -- instead of on time
2 if you think that's clearer.

3 MEMBER KLEINPELL: It makes it
4 just more clear. Then you don't have to go to
5 the subscript information and all that. So,
6 great. Thank you.

7 MEMBER CARPENTER: In what ways is
8 this different than the SCIP measure, other
9 than it's outpatient?

10 MS. SLOSBURG: I don't know that
11 it's different other than we look at, instead
12 of procedure codes, we look at all patients
13 who received an IV antibiotic prophylaxis.
14 It's less burdensome for collecting data from
15 ASCs.

16 And, again, to the issue of topped
17 out, we've got about 900 out of the 5,200
18 reporting right now, and, again, right now we
19 do not have disparity data because it is not
20 mandated, but once it is, we will.

21 CO-CHAIR MORRIS: Anybody else
22 want to comment about that?

1 MEMBER KLEINPELL: I think I would
2 advocate, just based on that alone, that this
3 should be retained, then, even though it is
4 topped -- you know, the scoring is high. We
5 just don't have that information on
6 disparities, and you indicate that it's really
7 a sub-portion of all the centers that are
8 providing this data.

9 CO-CHAIR MORRIS: Okay. So we've
10 asked for the developer to change the language
11 a little bit regarding clarifying what on time
12 means. Let's go ahead and vote on the
13 measure.

14 Does the measure meet NQF criteria
15 for importance to measure and report?
16 Seventeen say yes. Two say no.

17 Scientific acceptability of
18 measure properties. Ten say completely. Two
19 say -- nine say partially.

20 Usability. Twelve say completely.
21 Seven say partially.

22 Feasibility. Thirteen say

1 completely. Six say partially.

2 Does the measure meet all the NQF
3 criteria for endorsement? Eighteen say yes.
4 One says no.

5 The next measure is 0527,
6 prophylactic antibiotic received within one
7 hour prior to surgical incision. This is a
8 SCIP measure being presented by Ms. Zambricki
9 again.

10 MEMBER ZAMBRICKI: This is another
11 in a series of antibiotic timing measures and
12 also makes the exception for two hours for
13 vancomycin. I'd say the only thing different
14 with this measure is that the compliance is
15 97.1 percent, which is a little different, a
16 little lower than the cardiac surgery measure.

17 So I think it raises the question
18 of whether this is topped out or not, 97.1
19 percent, a lot of improvement in the last nine
20 years. When it was first measured, it was
21 55.7 percent, so that's a lot of -- a lot of
22 change. I think the questions regarding the

1 timing are still the same questions as they
2 are for the other measures.

3 MEMBER HALPERN: Are the
4 exclusions the same as in the other CMS
5 measure?

6 MEMBER ZAMBRICKI: You know, I
7 have to look back and see that.

8 MEMBER HALPERN: It said see --

9 MEMBER ZAMBRICKI: I think it
10 still is the laparoscopic. I'll look at it
11 while everybody's talking about other things.

12 MEMBER HALPERN: Well, the reason
13 I ask, actually, because I missed this the
14 first time I was reading the other measure on
15 the prophylactic selection, is that they
16 actually have as an exclusion those that did
17 not receive antibiotics, so I wondered about
18 that.

19 MEMBER ZAMBRICKI: Yes, these
20 exclusions are length of stay greater than 120
21 days, hysterectomy and C-section, preoperative
22 infections disease, performed entirely by

1 laparoscopy, enrolled in clinical trials,
2 physician, advanced practice nurse, physician
3 assistant documented infection prior to
4 surgical procedure, procedures requiring
5 general or spinal anesthesia that occurred
6 within three days prior to or after the
7 procedure interest, receiving antibiotics more
8 than 24 hours prior to surgery, receiving
9 antibiotics within 24 hours prior to arrival.

10 MR. BRATZLER: This is Dale. I
11 can answer that question about that one
12 specification. If the patient gets no
13 antibiotic, they fail the measure on
14 antibiotic timing, but because we assess, you
15 know, antibiotic choice, they are excluded
16 from the antibiotic choicer measure. So they
17 fail one, but they don't fail both. It's to
18 avoid double jeopardy on a measure.

19 CO-CHAIR MORRIS: Is that clear to
20 everybody? Does that answer your question?
21 Okay. Any other issues that anybody wants to
22 raise?

1 MEMBER ZAMBRICKI: I was just
2 wondering about the laparoscopic procedures
3 for this sponsor.

4 CO-CHAIR MORRIS: Dale, has that
5 been removed, and can you also address that
6 question about whether this should be
7 considered topped out?

8 MR. BRATZLER: Yes, so the
9 laparoscopy exclusion has been removed, also,
10 so for all of the SCIP measures. You know, I
11 guess it depends on how you define topped out.

12 There is variation between
13 surgeries, so, you know, you heard earlier
14 that cardiac surgery has high rates of
15 performance, but I can tell you the rates of
16 performance for general surgery are lower. So
17 it does depend on the type of surgery.

18 There is variation between types
19 of surgery. I don't have the disparity data,
20 though I actually think Wanda has provided it
21 or can provide it, but there is some variation
22 between different types of surgeries.

1 MEMBER COLLINS: I guess I would
2 argue against this being tapped out for the
3 reasons we've heard and the importance of this
4 with the other procedures, as well.

5 CO-CHAIR MORRIS: Any other
6 thoughts about that among the group?

7 MEMBER STAFFORD: I'll just say
8 looking at the disparity data there is a fair
9 amount of disparity based on age, geographic
10 location, and things, so while the overall
11 numbers might look topped out, it looks like
12 there's a fair room for improvement in quite
13 a few places.

14 In fact, you probably don't want
15 to live in the U.S. territories looking at all
16 the disparity data for the SCIP measures, so
17 if you're going to Guam, be careful.

18 CO-CHAIR MORRIS: Okay, let's go
19 ahead and vote on this measure. First of all,
20 importance to measure and report. Nineteen
21 say yes. None say no.

22 Scientific acceptability of

1 measure properties. Thirteen say completely.
2 Six say partially.

3 Usability. Fourteen say
4 completely. Five say partially.

5 Feasibility. Eighteen say
6 completely. One says partially.

7 Lastly, does the measure meet all
8 the NQF criteria for endorsement? We need one
9 more vote here. Seventeen say yes. One says
10 no.

11 Do you -- okay. So, there we are.
12 The next measure is Measure 0529, prophylactic
13 antibiotics discontinued within 24 hours after
14 surgery end time, and this will be presented
15 by Dr. Kleinpell.

16 MEMBER KLEINPELL: Right, 0529,
17 prophylactic antibiotics discontinued within
18 24 hours after anesthesia end time with the
19 exception that it's 48 hours for cardiac
20 surgery.

21 It's a maintenance measure. It's
22 been in use since 2001. The measured steward

1 is CMS. With respect to this measure,
2 obviously we've indicated the importance in
3 terms of antibiotic therapy before and
4 discontinuing within an appropriate time line.

5 With respect to scientific
6 acceptability, you know, again the issue is
7 that there is evidence, obviously, about
8 prophylactic antibiotics. Connie had raised
9 the issue, however, that there is some but not
10 a lot that single-does prophylaxis versus 24
11 prophylaxis, so again that whole time line is
12 still -- we don't have the evidence to
13 substantiate what is actually better for
14 patients.

15 She actually indicated there
16 should be a movement for no post-operative
17 antibiotic prophylaxis, as there isn't
18 evidence that supports any post-op
19 prophylaxis, and again that's from her
20 perspective from the Infectious Disease
21 Society, but she's not with us to further
22 expand on that.

1 So we did have some discussion
2 with respect to that. We noted that the
3 exclusions still listed laparoscopic
4 procedures, so we wanted clarification on
5 whether that was removed.

6 With respect to other aspects, we
7 noted that the national average is 95.5
8 percent. However, there still is a gap,
9 particularly with respect to disparities of
10 care. It's about 88.7 percent with Hispanics,
11 so therefore, obviously, it's continued
12 importance in terms of monitoring.

13 In terms of usability, it
14 currently is in use for the Hospital Inpatient
15 Quality Reporting Program under CMS, and it's
16 also part of the SCIP measure set.

17 We did have one issue with respect
18 to feasibility. It's indicated that the
19 specifications, which includes coding and data
20 elements, are modified every six months,
21 according to feedback provided by clinicians
22 and hospital staff collecting the data, and so

1 we were wondering how this really -- how these
2 potential modifications of specifications
3 every six months is communicated to NQF and
4 stakeholders and how it's expected that that
5 may affect performance rates from quarter to
6 quarter, so that was really our only other
7 additional point.

8 Connie also highlighted there were
9 no studies performed on cost of
10 implementation. It was an additional comment
11 that she had, as well.

12 CO-CHAIR MORRIS: Any other
13 comments? Dr. Collins?

14 MEMBER COLLINS: I don't have many
15 comments. I think we did a nice job of
16 summarizing there. I think I would -- the 24-
17 hour mark is pretty standard for this measure,
18 and I would concur about looking at further
19 data, shortening that duration when possible
20 if the data is there.

21 MEMBER CARPENTER: Just from a
22 practical standpoint, I think this is not met.

1 Most of the times this is not met it's because
2 there is a small delay in administration of
3 the antibiotic, so it's 25 hours. A lot of
4 these drugs are Q-12, Q-8, so that last dose
5 is right at -- if people give 24 hours of
6 antibiotics, which frequently they do.

7 Maybe it's not necessary, but
8 that's still built into a lot of post-op
9 protocols. That last dose is right on the
10 edge, and so a lot of the times this is not
11 met because of a nursing administration,
12 pharmacy delivery, patient availability issue,
13 rather than a quality of care issue regarding
14 this.

15 Now, maybe that should lead people
16 to give, you know, 16 hours or 12 hours or
17 something. That's another issue, but, you
18 know, I don't think we should change it.

19 It's pretty standard now, but you
20 wonder if 26 hours or something like that
21 would have been a better, you know, time frame
22 in terms of the numerator rather than strict

1 24 hours. Just a comment.

2 CO-CHAIR MORRIS: I think what
3 you're describing here is more of an annoyance
4 than anything else. Like Dr. Morton pointed
5 out earlier, we have to have some target, and
6 you're sort of saying that, too.

7 Any other comments or questions?
8 Okay. So one of the -- one of the interesting
9 issues for me that came up in the preceding
10 measure was that we've seen a real shift in
11 hitting the measure, from 55.7 percent to 97.1
12 percent over a long period of time.

13 One of the things that hasn't come
14 up with some of these maintenance measures is
15 have they had an impact? Have they -- it has
16 come up for some, but not all of the measures
17 have they had an impact, and it's certainly
18 something that I think we should be paying
19 attention to. Is this doing anything?

20 So there was a question about
21 evidence of a quarterly change in performance,
22 I think. Did that come from you? Okay. So

1 we'd like to ask CMS to address that and also
2 the laparoscopy question, as with the previous
3 measures.

4 MEMBER HALPERN: And I think it
5 also goes back to what Christine was saying.
6 Are we actually affecting the end point, which
7 is the patient?

8 MR. BRATZLER: So this is Dale.
9 I'm not sure I completely understand the
10 question, but across the board the laparoscopy
11 has been issued January 2012, so it's out of
12 these measures.

13 Remember that this measure is not
14 about impacting infection rates, because when
15 you look at all of the published studies that
16 have compared short duration antibiotic
17 prophylaxis for long duration or single dose
18 to long duration, the outcomes for virtually
19 every single one of those studies is the same,
20 that surgical site infection rates are no
21 different.

22 Prolonging antibiotics doesn't

1 lower infection rates. It certainly doesn't
2 increase them, but it doesn't lower them.
3 This measure is about antibiotic stewardship,
4 stopping the use of unnecessary antibiotics.

5 So, in terms of measuring an
6 outcome, it's one of the flaws in some of the
7 studies that have been published that I
8 mentioned earlier that are looking at
9 composite SCIP measures. This measure has
10 never been shown in clinical studies to impact
11 infection rates, and so it doesn't make sense
12 to have it in a composite that's looking at,
13 you know, reducing infection rate.

14 So this is, I think, maybe one of
15 the best performance measures that we've ever
16 had in the country related to antibiotic
17 stewardship, because, as noted earlier, the
18 national performance on this has gone from 55
19 percent to 95 percent over about eight years,
20 a dramatic reduction in unnecessary
21 antibiotics.

22 MEMBER ZAMBRICKI: I have a

1 scientific question. I agree with you. This
2 is about antibiotic stewardship, and I was
3 wondering. Is there evidence that there is
4 benefit to reducing surgical site infection
5 with any antibiotics once the wound is closed?

6 MR. BRATZLER: Well, I would argue
7 that -- so there is some experimental data
8 that showed that there is a short period of
9 time after surgical closure that the wound is
10 vulnerable, so I never argue with the surgeon
11 if they want to give, you know, a single dose
12 at the end of the case. You know, I think
13 there's a theoretical concern that wound
14 contamination could occur.

15 Beyond the immediate post-
16 operative period, I've never seen any studies
17 that show convincingly that you can reduce
18 surgical site infection rates by continuing
19 antibiotics, and yet we know from a number of
20 studies that you can increase the rates of C-
21 difficile colonization.

22 Then the cardiac surgery

1 literature at 48 hours, the only paper that
2 looked at 48, less than 48 versus greater than
3 48, when an infection occurs in a patient, it
4 didn't -- I want to highlight again the
5 infection rates were no different less than
6 48, greater than 48.

7 Infection rates, surgical site
8 infection rates were no different, as has been
9 shown in all studies, but when an infection
10 did occur, those patients that had received
11 more than two days of antibiotics had 60
12 percent increased risk of a resistant
13 organism. You just select out, colonize the
14 patient with resistant organisms.

15 So we strongly think that this is
16 an important measure, and we're actually -- I
17 think of all of the accomplishments of SCIP,
18 this may be one of the most important.

19 MEMBER HALPERN: How does -- how
20 does -- you know, in vascular surgery we have
21 a lot of procedures that are not 100 percent
22 clean, because there's like a gangrenous toe,

1 and I have to say I always get -- coding those
2 patients appropriately in terms of clean
3 contaminated, contaminated, I don't know where
4 they fall in, and how does -- how do those
5 kind of cases weight into your 24-hour
6 antibiotic rules?

7 MR. BRATZLER: Yes, that's a real
8 good question. So if there is documentation
9 of infection before, during, or after the
10 operation within 48 hours for most operations,
11 72 hours for cardiac surgery, the case is
12 excluded from this performance measure.

13 Wanda can correct me if I'm wrong,
14 but I believe gangrene that's documented
15 actually is considered documentation of
16 infection, recognizing that sometimes it's
17 just ischemia, but those cases would be
18 excluded.

19 MS. JOHNSON: I believe that's
20 correct, and I know we've gone round and round
21 with abstractors on this that gangrene is
22 considered an infection.

1 MR. BRATZLER: So the case is not
2 included in the denominator for this measure.

3 CO-CHAIR MORRIS: Okay. Any other
4 --

5 MEMBER MORTON: I think he makes a
6 great point. This isn't about preventing
7 surgical site infection. It's about
8 appropriate use, and I think it's pretty
9 critical, because we've seen C-diff rates go
10 up over the last ten years, so it's an
11 important measure from that point of view.

12 CO-CHAIR MORRIS: Okay. Do you
13 want to add another comment to that?

14 MEMBER COLLINS: From an
15 antibiotic stewardship standpoint to at least,
16 you know, in our institution this has had a
17 big impact, and I feel it will and has
18 nationwide, as well, really cutting back on
19 durations of therapy, which, you know, can
20 extend for too long, which puts patients at
21 risk. So I concur with the impact that this
22 has on antimicrobial stewardship and

1 stewardship practitioners across the country.

2 MEMBER STAFFORD: Yes, and I would
3 say, not only that, it's about resource
4 utilization and cost, so you've got nursing
5 administration cost. You've got pharmacy
6 preparation cost, extra tubing, all of that
7 the healthcare system somehow some way pays
8 for, and so, irregardless of the other issues,
9 that's also one of the big issues with this,
10 and that's another reason that this is a
11 really important measure.

12 CO-CHAIR MORRIS: Okay. Let's go
13 ahead and vote. Does the measure met NQF
14 criteria for importance to measure and report?
15 Nineteen say yes.

16 Scientific acceptability of
17 measure properties. Fourteen say completely,
18 four partially, one minimally.

19 Usability. Eighteen say
20 completely, one partially.

21 Feasibility. Sixteen say
22 completely. Three say partially.

1 Does the measure meet all the NQF
2 criteria for endorsement? Nineteen say yes.

3 Next, we'd like to open the floor
4 to NQF member and public comment, and I
5 thought that we had given some time for member
6 and public comment last night, but apparently
7 there were some -- there was a member that
8 would like to comment about the discussion
9 from yesterday, as well.

10 Anybody on the phones for member
11 and public comment?

12 OPERATOR: Star 1 to signal. We
13 have Barbara Rudolph, I believe.

14 MS. RUDOLPH: Yes, hello? Can you
15 hear me?

16 CO-CHAIR MORRIS: Yes, we can hear
17 you.

18 MS. RUDOLPH: Okay. Thank you. I
19 wanted to make a couple comments. The first
20 one relates to some of the AHRQ measures that
21 were voted down. I just want to remind the
22 Committee that these measures are being widely

1 used. At least about 20 states, these
2 measures are being reported publicly, and --

3 CO-CHAIR MORRIS: I'm sorry, could
4 you speak a little bit louder?

5 MS. RUDOLPH: The measures -- I
6 wanted to talk a little bit about the AHRQ
7 measures that were turned down yesterday in
8 the vote and just sort of remind folks that
9 these measures are being widely used not only
10 by state health data organizations that
11 publicly report information but also by state
12 Medicaid programs and state public health
13 programs who rely on the state hospital
14 discharge data and utilize the AHRQ measures.

15 So I just -- I think it's
16 important to think about the widespread use of
17 these measures and the fact that most entities
18 that public report to day only have access to
19 state hospital discharge measures data sets.

20 So when you think about things
21 like 30-day mortality, you're really limiting
22 the ability of entities to measure, because

1 the only party that can actually do that is
2 Medicare, because they're the only ones that
3 have enough cases to be able to actually use
4 that 30-day measure and where they have
5 information, because they have the
6 longitudinal data.

7 So I would strongly urge you to
8 consider not merging and not pairing the 30-
9 day and the inpatient failure-to-rescue
10 measures, because that would essentially mean
11 that there would be no public reporting, so
12 please consider the use part, as well as some
13 of the other components.

14 The second -- my second comment
15 relates more to the continued use by CMS of
16 the clustered hierarchical models where
17 they're using random effects as the
18 estimation, as opposed to fixed effects, and
19 there's been recent research that shows that
20 when you place --

21 When you use those kinds of random
22 effects models, you essentially focus on

1 specificity, rather than balancing sensitivity
2 with specificity, and the difference there is
3 you end up protecting hospitals and not
4 providing any good information for either
5 consumers or purchasers.

6 If you look at the CMS reports,
7 you'll see that out of 4,500-some hospitals,
8 and you have five or six or seven who are
9 above average and an equal amount who are
10 below average, and that really gives
11 absolutely no information, and I think it
12 misleads the public in terms of saying that
13 these hospitals are okay, because they've been
14 pulled to the average by the estimation
15 techniques.

16 So just something to think about.
17 The article, most recent articles by Kipnis,
18 Escobar, and Draper, and it's in medical care,
19 the May 2010 volume. So those are my comments
20 for today.

21 CO-CHAIR MORRIS: Thank you for
22 your comments. A couple of things that I

1 wanted to just clarify. One of the measures
2 that you discussed, Measure 0351, which was
3 the AHRQ death measure, we discussed that
4 adjacent to a discussion of the failure-to-
5 rescue measures.

6 Just so that the Committee
7 understands, we did not vote that down. We
8 voted in support of that. I'm sure that this
9 will come up for further discussion. We voted
10 in support of the AHRQ death measure.

11 MS. RUDOLPH: I was actually
12 addressing the competing, the discussion for
13 the competing measures at that point.

14 CO-CHAIR MORRIS: Okay.

15 MS. RUDOLPH: I know you had
16 discussed yesterday potentially pairing them
17 or just harmonizing them to the 30-day and
18 eliminating the inpatient. So I would be
19 very, I guess, cautious about doing that just
20 because, as I said, there's so many groups
21 that are currently publicly reporting those
22 who don't have access to 30-day, and you're

1 also limiting the population then. Medicare
2 only addresses the over-65, so for commercial
3 payers and others the inpatient measure is
4 very important.

5 MS. MURPHY: Barb, it's Melinda
6 Murphy. The discussion about pairing or
7 linking them was a discussion that was made by
8 the developer. The Committee has not had that
9 discussion, and it will have -- as you said,
10 the three measures will be discussed whenever
11 there is the discussion of related and
12 competing measures.

13 MS. RUDOLPH: Okay. Actually, I
14 have one more comment. When, you know, there
15 are competing measures -- for example, I don't
16 know if you're going to discuss the survival
17 predictors or not, but I really wasn't aware
18 that there was going to be this discussion,
19 and we don't have our developer ready, so if
20 there's a possibility, if that's going to be
21 discussed, I'd like to ask for an extension.

22 MS. MURPHY: Related and competing

1 measures with respect to those measures that
2 have been discussed yesterday and today will
3 not occur today. Helen's going to give us
4 some background and a bit of setup for that,
5 and then we'll actually convene a conference
6 call to talk about related and competing
7 measures, and all of the affected developers
8 will be notified in advance and invited to
9 that meeting.

10 MS. RUDOLPH: Okay. Great. Thank
11 you.

12 DR. BURSTIN: We'll start the
13 discussion today, Barb, but certainly the
14 detailed discussion we'll have on a subsequent
15 call. We'll make sure you have sufficient
16 notice to get your developers in line. The
17 one measures we will talk about today, because
18 the developers will be here this afternoon,
19 are the pediatric heart surgery measures.

20 MS. RUDOLPH: Okay. Okay, great.
21 Thank you.

22 CO-CHAIR MORRIS: Is there any

1 other public and member comment? Helen, would
2 you like to frame out the discussion of the
3 related and competing measures that will occur
4 after lunch?

5 DR. BURSTIN: Sure. So, briefly,
6 we do still have those two additional
7 measures. Patrick will be back this -- we
8 have not done the post-operative wound
9 dehiscence yet, right? There's two additional
10 measures still to do. Patrick will be back
11 this afternoon. I emailed him to see if he
12 can get back sooner.

13 But the other thing we'd like you
14 to do today is actually just at least look at
15 the measures that are before you, and I
16 believe you have a table that outlines for you
17 the measures that at least we would consider
18 related or competing.

19 We also provided for you guidance
20 that we've put out for comment recently
21 specifically on our guidance of how you would
22 even begin looking at relating and competing

1 measures and so would turn your attention to
2 those documents. Is it easily findable on the
3 thumb drive?

4 MS. MURPHY: It would be in the
5 materials for the May meeting. It'll be in
6 that PDF.

7 MS. FORMAN: It's the materials
8 that went out on April 26 with the eight
9 attachments, and it's Attachment 5, and I'll
10 put it up here on the screen.

11 MS. MURPHY: So the Surgery
12 Steering Committee materials PDF that has nine
13 attachments, and Attachment 5 is related and
14 competing measures. That's the table. It
15 starts out with the memo. You scroll down.
16 You can see the table.

17 DR. BURSTIN: Great. So this is
18 basically just offering you an approach, and,
19 again, this is not a new criteria, and over
20 the last couple of years we have always had
21 committees do related and competing measures.

22 The two big differences are, one,

1 for the first time you will actually, because
2 of this new endorsement maintenance process,
3 have all the measures put together in the same
4 project, so you have the chance to look across
5 the measures and see whether one measure is
6 superior, whether another measure is superior.

7 But the key thing, also, is when
8 there are more than one measure in a given
9 area, when is it okay to have them coexist?
10 When do they need to be harmonized, and if so,
11 what's involved in harmonization? So we've
12 tried to just give the Steering Committee just
13 more guidance overall to specifically help you
14 with that decision-making.

15 Could you scroll down to the part
16 where you get to the nice flow chart, Alexis?
17 Keep going. All right. So if you could just
18 stop right there for a second.

19 So the first question is
20 determining whether there's actually a need to
21 see if there is assessment of competing or
22 related measures. We've kind of done that for

1 you by laying out for you which measures we
2 believe address, as we've defined it,
3 competing measures, the same concepts for the
4 measure focus, meaning the target population,
5 process, condition, event. The example, you
6 know, we've talked about several of these like
7 failure-to-rescue over the last couple of
8 days.

9 If you then go down to the next --
10 pull up that page there. Perfect. So here's
11 where we really look to your input and your
12 insight, so we would ask you to --

13 All these measures that you're
14 going to be looking at have now been deemed as
15 being ones that meet all the NQF endorsement
16 criteria. So that's the first lens.

17 We don't get to related or
18 competing until you get through that first
19 step. The key thing then will be to look at
20 some elements of each of the criteria to help
21 you make that first assessment.

22 So the first one on impact,

1 opportunity, and evidence relates to the
2 importance to measure and report, and in this
3 instance we would see if, for example, there's
4 any differences there. Is one measure
5 superior, for example, because it may provide
6 a different, a broader patient population, a
7 bigger opportunity for improvement, for
8 example?

9 Scientific reliability and
10 validity, we could actually pull up your
11 ratings to see if, in fact, you think there
12 were differences and one being more highly
13 reliable, valid, and precise than another one.
14 And then, all else being equal, our preference
15 would be that when we can, we want to get to
16 the measures with the broadest possible
17 population who could be measured.

18 So, there are some instances, for
19 example, where there are measures that may be
20 Medicare only or measures that may be, you
21 know, a very narrow population. The
22 preference would be a measure that allows the

1 maximum number of people to use the measure
2 for reporting.

3 Usability, this is an important
4 one, because this is where it actually gets at
5 how usable it is for the accountability
6 functions. Can people actually get those data
7 and use them for public reporting?

8 That was the exact issue Barb just
9 brought up for us on the telephone, for
10 example, that, you know, in their experience
11 the AHRQ measure is more usable, because the
12 end audiences have had access to that measure,
13 have used it for years for public reporting,
14 and have found it useful, in addition to how
15 useful is it for quality improvement.

16 That's where I think a lot of the
17 discussions you've been having today about
18 this is actionable, this isn't actionable
19 would come up, and we'd ask you to take a look
20 across the two of them.

21 In terms of feasibility, if
22 there's two related measures and one has

1 significantly less burden on the data
2 collector to do it, that would be one to
3 consider, but, again, we want to try to move
4 towards where we know the puck needs to go.

5 So we want to move towards
6 measures that will get us closer towards EHRs
7 and sometimes, for example, a claims-based
8 measure may work now, but maybe a registry-
9 based measure could work in an EHR environment
10 to follow. So it's not a clear-cut split,
11 meaning claims always wins here.

12 Then, finally, if a competing
13 measure doesn't have clear superiority, and,
14 unfortunately, I think a lot of the times we
15 wind up being in this bottom bucket, this is
16 where we would ask you to look to see if
17 there's a justification for multiple measures
18 in a given topical area and really consider
19 whether the added value of having those two
20 measures offsets the potential burden, the
21 potential burden in terms of confusion, the
22 one you guys talked about earlier in terms of,

1 "I do this in a hospital. I don't do this in
2 the outpatient side," but also to get at the
3 issue of whether you then wind up with
4 confusion.

5 If people have different scores on
6 different measures or if you think about this
7 moving towards a more, you know, high-stakes
8 payment model, would you have clinicians and
9 hospitals ranked differently depending on the
10 measure that's selected?

11 So those are the kind of pluses
12 and minuses that we would ask you to weigh,
13 and in general one of the things we've tried
14 to do is point out that when we can -- you're
15 fine, actually -- we would like to try to get
16 to the measure that gets us to, as I
17 mentioned, the broadest possible population,
18 and when you want more than one measure,
19 justifying it.

20 So, again, one thing to consider
21 is you may have a registry-based measure in
22 front of you. You may have a claims-based

1 measure in front of you. You would need to
2 consider, first of all, are they equivalent?
3 Are they really rising to the same level on
4 each of those criteria?

5 And then, at the end of the day,
6 do you see added value that you could justify
7 by saying, "The world as it is right now could
8 actually live in this world of having both of
9 those and justifying it?" So that's what we'd
10 like you to think through, and that's it.

11 So we'll walk you through this.
12 Again, this is very new. We are -- we
13 literally just closed comment on it about a
14 week ago. You guys are forging a new path for
15 us, as cardiovascular did, as well.

16 It's not a new criterion. It's
17 really just that we're trying to give you as
18 much as we can, sort of some decision trees to
19 standardize our work across committees, sort
20 of like the exercise we went through on
21 competing, which we're now writing up the flow
22 chart for based on this discussion this

1 morning.

2 So, that's what we'll do. We're
3 not going to get through all the discussion
4 today. I think what we'd like to do is for
5 the competing measures, particularly for the
6 developers who are here this afternoon around
7 pediatric heart surgery, to hear from the
8 developers the differences between the
9 measures.

10 That's a little bit of a unique
11 situation. We had two measures that came
12 through, a pediatric heart surgery project
13 that we just did, one from Children's Hospital
14 Boston, one from STS. At the end of the day,
15 the Steering Committee couldn't make an
16 assessment of which they thought was superior.

17 It went to our CSAC, and their
18 feeling was, "Well, the third measure that's
19 competed is in your committee," so this would
20 be the logical place to have this committee
21 not have to reevaluate the first two measures
22 -- that's been done -- but to at least give an

1 assessment of how the measures look when they
2 compete head-to-head.

3 Is there a consideration for
4 having more than one of those, more than two
5 of those? Are there questions you would pose
6 back to the developers?

7 We're not going to make that --
8 ask you to make that decision today, because
9 we've just provided you those materials in the
10 past week, but at least as we have this
11 discussion to have you lay out what are the
12 key questions you would want to ask the
13 developers.

14 Is there additional information
15 you would like the developers to come back
16 with, and at times are there things that two
17 of the developers could do together to bring
18 their measure together, for example, as
19 another option? So I'll stop and see if
20 there's questions. Yes?

21 MEMBER CARPENTER: The term
22 "harmonization" has been used multiple times,

1 I think for different purposes sometimes, and
2 sometimes we think, well, that takes two
3 similar measures and put them into one. I
4 don't think that's how this is being used
5 here.

6 It seems that it's more looking at
7 the definitions, the numerator, denominator,
8 the data that's collected and trying to make
9 that as similar as possible, in part to
10 relieve the data burden. Is that -- how
11 should we be thinking about the term
12 "harmonization"? How should we use that in
13 our discussion?

14 DR. BURSTIN: It's an excellent
15 question. When we talk about -- when we're
16 talking about harmonization, we're talking
17 about where there is the same measure focus
18 for perhaps different patient populations.

19 So an excellent example is the
20 exercise you just went through about the
21 ambulatory surgery environment versus the
22 inpatient surgery environment. They've got

1 different data sources.

2 It's got to be by definition a
3 different measure to allow us to capture that
4 data, but at the end of the day we've got to
5 be making sure the science is consistent, the
6 way the measure is constructed is consistent.
7 That's harmonization.

8 At times, we do actually have
9 examples of when two measures can, in fact, be
10 put together into one. We just did this
11 recently. It's somewhat painful, takes a long
12 time, but, for example, we had a measure that
13 already existed of doing cervical spine films
14 for patients with trauma, what the indications
15 were.

16 We then had a measure submitted
17 that said CT scans for patients with cervical
18 trauma. That's like, "Wait. This will create
19 the wrong incentives out there if there's
20 two," so instead those two developers decided
21 to work together and actually came back to NQF
22 about six months later with a combined measure

1 of CT plus cervical spine and MR.

2 We've been doing some work, for
3 example, between the American College of
4 Surgeons and CDC on two competing surgical
5 site infection measures which, given how high-
6 profile SSIs are, the idea of sending out to
7 the universe two competing surgical site
8 infection measures just did not seem optimal,
9 so they have now been working for more than
10 six months on trying to bring those measures
11 together. So there are examples of both.

12 When we're talking about
13 competing, we're really saying same patient
14 population, same process of care identified.
15 Sometimes they're on different data sources,
16 different data platforms, which might be one
17 reason to consider.

18 And even if you decide to put
19 through competing measures and say there's
20 justification for both, if they're really on
21 the same population and they're really looking
22 at the same measure focus, that's where

1 harmonization comes into play.

2 We don't want things defined
3 slightly differently so that you wind up with
4 apples and oranges, even though we know we may
5 get very different rates of performance when
6 you change the data platform, and I think
7 we're just going to have to live with that for
8 the next X number of years until we all move
9 to the, we hope, the electronic, interoperable
10 electronic platform.

11 CO-CHAIR MORRIS: I think it's
12 time for lunch, then. Right now it's 11:55.
13 Is Patrick going to be here at 1:00? Okay.
14 We want him to be available. Let's -- no
15 response yet, right, from him?

16 DR. BURSTIN: I can email him.

17 CO-CHAIR MORRIS: Okay. Let's --
18 okay, let's say 12:45 we'll come back.
19 Everybody get that, 12:45? Okay.

20 (Whereupon, the foregoing matter
21 went off the record at 11:56 a.m., and resumed
22 at 12:45 p.m.)

1 CO-CHAIR MORRIS: Okay. It is
2 time to start back up again. We have two more
3 measures to discuss prior to moving into the
4 next part of our meeting, and this is a
5 continuation of general prophylaxis and wound
6 dehiscence. The next measure is 0367, post-
7 operative wound dehiscence, to be presented by
8 Dr. Cima.

9 MEMBER CIMA: So, these are --
10 there are two of them. I'll just discuss them
11 both together, because they basically come off
12 -- it's basically the same template. It's
13 just one's a pediatric -- associated with
14 pediatric patients. One's -- the other one is
15 adult.

16 Going reverse and back in the
17 order, feasibility and usability, no one had
18 any questions about that. I'm glad Dr. Romano
19 provided an updated reference.

20 It is clear that using
21 administrative databases that you're able to
22 identify these cases quite readily and that

1 they truly are what they are, by and large,
2 for the most part, what they say they are.
3 They are wound dehiscence.

4 So usability and feasibility I
5 think no one had any concerns about. Where we
6 really got -- where the real issue hit the
7 road was whether it's a measure to be reported
8 and also the fundamental underpinnings of
9 reporting it.

10 What I was most struck by, and I
11 hope this is simply a clerical error and not
12 an attempt to use the data in a way that may
13 not support it, the summary of evidence of the
14 reason for doing this is referenced throughout
15 the paper on one paper from 1989, and I just
16 want to read it.

17 It says, "Based on a two-stage
18 review of randomly selected deaths, Hannon et
19 al reported the cases with the secondary
20 diagnosis of wound disruptions were three
21 times more likely to have received care that
22 departed from professionally recognized

1 standards, in cases without the codes, 4.3
2 percent versus 1.7 percent after adjusting for
3 patient demographics, group geography, and
4 hospital characteristics." Basically, that is
5 his rationale for doing this.

6 Given the profound nature of that,
7 I actually had that paper pulled, and,
8 unfortunately, there is no separate analysis
9 based on wound dehiscence. The actual data is
10 based upon cases with a infection and/or wound
11 disruption reported as a secondary diagnosis.

12 So there is no separate analysis
13 based on wound dehiscence. Therefore, the
14 statement there is incorrect. Furthermore,
15 when they say that adjusted from recognized
16 professional standards of care, a quote from
17 the paper's authors, "In addition to the three
18 targeting criterias that were not significant
19 for other quality of care judgment, wound
20 disruptions or infections was also not
21 significant," so the paper's authors also
22 said.

1 So what this really led us down,
2 the feeling was the justification for this,
3 the scientific justification and the whole
4 rest of the thing that flow from it are not
5 supported by it. Furthermore, further
6 analysis and also in the paper provided by Dr.
7 Romano talking about preventability of the
8 event, in a review of the literature basically
9 the vast majority of the literature would say
10 that this is a non-preventable event.

11 It's related mainly to non-
12 modifiable factors such as morbidity, AIDS,
13 diabetes, obesity, underlying live function
14 disease, and in this paper Dr. Romano so
15 kindly provided this morning, if you look at
16 the post-op wound dehiscence rate, non-
17 preventable ranks as 25 percent of them.
18 Uncertain of what caused it is 41 percent.

19 So that's consistent with what's
20 in the literature of somewhere between only 20
21 to 25 percent of cases have anything that they
22 can say is a possible modifiable factor, so

1 the scientific rationale for it and
2 everything, especially the rationale that it's
3 a huge standard of care problem is not
4 supported by the literature.

5 As far as the demonstration of
6 performance gap, looking at it over the
7 extensive amount of data that was provided,
8 the estimate is anywhere on range,
9 particularly about one to three events per
10 thousand with it being higher in the older age
11 population, which is consistent with what we
12 see in the literature, but it's certainly not
13 a modifiable factor.

14 There is no real disparity data
15 that is cited and provided by the developers,
16 but there is no real difference in
17 disparities. Again, it's mainly tied somewhat
18 into age and possibly underlying diseases.

19 The data cited on disparities
20 mainly goes more to the methodology, as
21 opposed to specific to wound dehiscence, so
22 the methodology just shows there is

1 differences in PSIs based on disparities, but
2 there's no specific data related to wound
3 dehiscence.

4 Then, finally, other than this
5 updated version the data, there's some issues
6 about what's in, excluded and in. This is
7 supposed to be only abdominal pelvic surgery
8 that is reported, and in the document as
9 presented there's things like inguinal hernia
10 repairs and stuff like that are presented,
11 which really would not -- would dilute the
12 things, but I think more recent analysis of
13 the PSI and some of the improvements that have
14 been made to it clearly show that it's a valid
15 measure and a reliable measure.

16 So really the main issue just
17 revolved around the scientific underpinnings
18 here, the rationale for it. Is there
19 opportunity for improvement? But the other
20 ones, certainly the methodology and everything
21 is top notch. So that was the -- and the only
22 difference is one's a pediatric and one's not.

1 CO-CHAIR MORRIS: Anybody else on
2 the Committee with questions, comments about
3 this measure?

4 MEMBER DUTTON: Sure. I have one
5 comment, one question. The fact that right
6 now we think that most of the causes of this
7 are unpreventable doesn't necessarily mean we
8 shouldn't measure it, in my opinion.

9 Fifteen years ago, we thought
10 central line infections were unpreventable and
11 so on, and there's countless examples of that,
12 so measuring that might provide an impetus to
13 find ways to prevent it, but then the more
14 specific technical thing, I spent many years
15 working in a trauma center.

16 We do a lot of damage control
17 procedures. We deliberately leave abdomens
18 open on a fairly frequent basis and then
19 obviously come back and re-close them at some
20 later point, which as far as I can tell from
21 reading the numerator and denominator
22 statement here, those would count as misses on

1 this, and that's incorrect.

2 MEMBER CIMA: That, actually, is a
3 coding standard, and it depends on how it's
4 coded in the institution. So if the
5 institution knows that it was a patient that
6 was left open, they don't count -- they don't
7 code it the same way.

8 I explored that with our coders,
9 and they said there's a way of differentiating
10 that, although that was one of the initial
11 issues with the PSI-14, from the way I
12 understood it, that coders were not
13 distinguishing that, and people who were
14 intentionally left open such as cardiac cases
15 where the chest was left open, those were
16 being coded.

17 That's been apparently remedied.
18 I can't speak to that 100 percent, but my
19 understanding is there is a way of
20 differentiating that in the codes.

21 MEMBER DUTTON: Thank you.

22 CO-CHAIR MORRIS: Peter.

1 MEMBER DILLON: I think the points
2 that you brought up in general about the
3 validity of this as a quality measure are
4 crucial to understand, so let me just make a
5 few comments about 6-7, and realize that I'm,
6 you know, I may well be biased in my
7 interpretation of this, but we don't know that
8 this is a problem in the surgical care of
9 children at all.

10 There is absolutely no literature,
11 and what I'm worried about is it's a classic
12 case of having cited that article, as you
13 said, which was just sort of cookie-cutter all
14 the way through.

15 You know, it's a case of children
16 are not small adults, and to take or to
17 extrapolate an article from the adult
18 literature and say it's a problem in the
19 pediatric surgical literature is -- or in the
20 pediatric surgical care I think is totally
21 inappropriate.

22 In addition, this is an incredibly

1 small complication, and that's the problem.
2 I don't think you're going to -- we can't even
3 pick this up in our NSQIP data right now in
4 order to be able to discern performance
5 differences within institutions with the
6 incredibly small numbers that this is going to
7 be at least pertaining to this one metric.

8 So, as I said, I'm concerned about
9 the small numbers, and it's also a tremendous
10 -- it's going to be a tremendous data burden.
11 The denominator is way too big. They've got
12 way too many procedures included in it, so I
13 have serious concerns about the validity of
14 this metric right now as a quality measure in
15 children's care.

16 CO-CHAIR MORRIS: When you say a
17 very infrequent event, are you referring to
18 pediatric, adult, or both?

19 MEMBER DILLON: Pediatric.

20 MEMBER ZAMBRICKI: I would like to
21 comment on the frequency. Even in the adult
22 literature that was accompanying this measure,

1 the rate was less than two per thousand, and
2 out of that one of the studies identified 66
3 percent of those were not preventable because
4 of patient conditions.

5 So I'm not sure you could say the
6 998 that didn't have it were providing quality
7 care because they didn't have a dehiscence.
8 It's just such a small number of occurrence,
9 and then over half of those aren't preventable
10 and aren't an indicator of quality, so one in
11 a thousand.

12 CO-CHAIR MORRIS: I'm a little
13 concerned about that number. I think that it
14 should actually be a lot higher, which makes
15 me wonder if the capture is inadequate here.
16 Any of the other surgeons or clinicians want
17 to speak to that?

18 MS. DAVIES: This is Cheryl
19 Davies, one of the developers. If I could
20 just address one point on the 66 percent for
21 the preventability on the pediatric measure.

22 MS. MURPHY: I'm sorry, who is

1 speaking, please?

2 MS. DAVIES: I'm sorry. This is
3 Cheryl Davis from the RQI team.

4 MS. MURPHY: Okay.

5 MS. DAVIES: So that study was
6 done with a previous definition, and so wanted
7 to just note that that also included some
8 staged procedures, and that's why they were
9 included in the non-preventable category, and
10 since then we have now excluded some of those
11 staged procedures.

12 Now, that being said, we don't
13 have enough detail about that study to know
14 exactly how that would change the
15 preventability ratings, so we're not able to
16 give an updated number for that, but we
17 suspect that a good chunk of those were staged
18 procedures that are now excluded from the
19 indicator.

20 MR. ROMANO: Could I address the
21 other questions? I'm sorry.

22 CO-CHAIR MORRIS: Sure, but

1 anybody else on the -- so I asked a question.
2 Any other clinicians find that number to be a
3 bit low, two per thousand?

4 MEMBER SIPERSTEIN: A comment. At
5 our institution, I would agree with you that
6 our reported number is less than what
7 everybody clinically thinks the incidence is,
8 so I think the true incidence is probably
9 higher, and it's a vagary of coding, at least
10 at our place.

11 MEMBER DUTTON: I deal with poor
12 protoplasm. I'm certain our incidence is
13 higher, but we also have a lot of procedures
14 I'm not sure how you'd score. You know, the
15 wound partially opened at the bedside, packed,
16 that kind of thing.

17 MEMBER CIMA: There are some
18 classifications on this. This is fascial
19 dehiscence, so not wound disruptions and
20 stuff, and that's where one of the initial
21 coding issues was was wound disruption versus
22 fascial dehiscence. This PSI is fascial

1 dehiscence that requires re-operative closure.

2 So I personally looked at every
3 single one of these in my institution and then
4 kind of correlated it with other measures, our
5 OR schedule and stuff, and found it to be very
6 close, and our rates are about this number.

7 If you make it -- if you use that
8 definition, wounds that are opened in the ICU
9 and left open are not included in this, this
10 PSI, so it may be, you know, vagaries of the
11 coding, as Allan said, but I don't see this
12 number being much higher. At least, in my
13 experience, it's higher than what this is.

14 MEMBER STAFFORD: Yes, I would
15 agree with that. I think there is dehiscence,
16 and there is dehiscence, and, you know, I
17 mean, it's not uncommon for the fascia to
18 separate a little bit. You have a little bit
19 of fluid. You never have to do anything about
20 that. It's the ones that you have to take
21 back to the operating room that are probably
22 the ones that are more actionable when you

1 think about it.

2 That being said, especially if
3 you're talking about an elderly population,
4 the risk factors for dehiscence are going to
5 be a lot higher, as well, so, I mean, I think
6 if you use a very strict definition it's
7 probably more reasonable than --

8 I think, Arden, what you're
9 talking about is the number probably is higher
10 when we think about just some dehiscence, but
11 even at the fascial level, but it's the actual
12 number that you actually have to re-operate on
13 is a different subject, and that probably is
14 more the smaller number.

15 MEMBER MORTON: I agree with Barb.
16 We look at all of these as part of our
17 Professional Practice Evaluation Committee.
18 We look at all the PSIs, and we actually look
19 at these when they come up, and it's been
20 pretty consistent. What the PSI reports is
21 what we see in practice.

22 CO-CHAIR MORRIS: So I guess the

1 question, then, is is this measure -- are
2 there enough events to actually measure with
3 this? And it sounds as though the thinking is
4 that they're not necessarily preventable.
5 Those few events are not necessarily
6 preventable.

7 DR. BURSTIN: Just one overarching
8 comment here. These are intended to be
9 patient safety indicators, so they are
10 frequently very rare events, so there's not
11 necessarily -- when it's a safety issue, I
12 don't think there's necessarily a threshold
13 for how many is enough.

14 Again, it's a claims-based
15 measure, so it's not something for which there
16 is a lot of data burden to collect, and the
17 question is, for each of those events, you
18 know, what are the downstream implications for
19 that patient, and are there learnings that
20 happen at that hospital as a result of knowing
21 that, the way you --

22 MEMBER CIMA: The issue is a

1 safety event implies that you can alter the
2 course by doing something. The vast majority
3 of these you cannot, so is it a valid patient
4 safety event? I mean, that's why one of the
5 complaints against this one is that it is an
6 event.

7 Is it -- should it say that an
8 institution that has an event is not safe?
9 That's not the point. We're not asked to do
10 that here. We're asking is this a quality
11 measure that's important to measure and
12 report, and is it scientifically valid?

13 MEMBER ZAMBRICKI: Just another
14 point. If I recall from the demographic data,
15 there was a slight increase in the rate in
16 academic medical centers, which I think brings
17 up the point that the patients, many of us
18 could predict what patients are going to
19 dehisce, you know, people with bad tissue
20 problems, vascular, just sick patients.

21 I think a lot of those patients
22 get sent to academic centers, so it's possible

1 the better surgeons take care of the patients
2 and can actually have a higher rate, because
3 they are getting the referrals of these sick
4 patients to their facilities.

5 MR. ROMANO: Could I address?

6 CO-CHAIR MORRIS: Sure.

7 MR. ROMANO: This is Patrick
8 Romano representing AHRQ. So I think -- I
9 think I can address almost all of these
10 comments. So, first of all, the data burden
11 is zero, because the data are already
12 collected in the routine course of hospital
13 activities.

14 In terms of the coding issue, yes,
15 this code is specific for wound disruption, so
16 if a hospital is using it in cases that were
17 left open deliberately, that's incorrect
18 coding. In the paper from the VA -- it's at
19 your seats -- you can see that there was a
20 positive predictive value of 87 percent, a
21 confirmation rate.

22 When you look at the false

1 positives, seven out of those 15 false
2 positives were cases where the abdomen was
3 intentionally left open, so there is some
4 degree of miscoding. What we found, of
5 course, is that as coders learn how to use the
6 codes and attend to it that this problem goes
7 away.

8 In the pediatric study, I call
9 your attention to Table 2, and it's a little
10 bit tricky to read, but the numbers for post-
11 operative wound dehiscence, there were a total
12 of 102 cases in the children's hospitals that
13 participated in this study, but only 52 of
14 those were reviews.

15 So for three or five percent they
16 found a coding error. That's in the third
17 column of numbers, and then in five cases or
18 ten percent they found that the event was
19 actually present on admission. So, again,
20 it's about 85 percent that were confirmed.

21 Now, then, to the preventability
22 issue. So they reported that 34 percent of

1 the events were preventable according to
2 retrospective review of the medical records in
3 the pediatric study.

4 In the adult study from the VA,
5 they don't specifically assign a percentage,
6 but they do report on page four the reasons
7 for the wound dehiscence, 32 percent fascial
8 tearing, 12 percent necrotic fascia, clearly
9 a patient factor, 11 percent breakage of
10 suture material, nine percent intra-abdominal
11 infection, two percent unraveling of sutures.

12 They further report that about 70
13 percent of those fascial closures were done by
14 trainees. Unfortunately, we don't have a
15 comparison group of patients who didn't have
16 dehiscence, so we don't know what the
17 comparable percentage of fascial closures that
18 were intact done by trainees is. So there's
19 limited data on preventability.

20 However, this estimate of 30
21 percent or so is in the same ballpark as for
22 other risk-adjusted outcome measures, so if

1 you look at risk-adjusted mortality measures,
2 the risk-adjusted complication measures that
3 were discussed yesterday, I think that the
4 empirical literature suggests that something
5 between 20 and 50 percent preventability is
6 the typical range that we see for risk-
7 adjusted outcome measures. That pretty much
8 comes with the territory.

9 In terms of the issue of
10 importance, the importance of this indicator
11 as it was originally endorsed by the NQF was
12 based not on the prevalence but on the impact,
13 so the average case, because of the tight way
14 in which these cases are defined based on
15 return to the operating room, the average case
16 that experiences this complication in two
17 fairly sophisticated case control analyses
18 incurred an extra nine days in the hospital,
19 an extra \$40,000 in excess hospital charges,
20 and a ten percent excess risk of attributable
21 mortality.

22 So the argument is that although

1 these events are uncommon, they're very
2 serious events that have profound implications
3 for the patient care and for the healthcare
4 system. So I think that addresses the issue
5 of importance, preventability, and the coding
6 issue.

7 MEMBER HALPERN: What happens to
8 those patients who are like trauma or, in my
9 case, ruptured aneurisms who wind up with
10 abdominal compartment who get opened at the
11 bedside but not for dehiscence reasons but
12 because you need to relieve the inter-
13 abdominal pressure?

14 MR. ROMANO: This code is specific
15 for a situation where the wound is disrupted,
16 where the wound opens up spontaneously after
17 surgery and the patient has to go back to the
18 operating room to have that defect fixed, so
19 it would not apply to a compartment syndrome
20 kind of situation, because in that case there
21 may be some leakage, but there is not a
22 spontaneous fascial dehiscence that's

1 occurring.

2 MEMBER CIMA: Just to respond to
3 Dr. Romano's comments about the studies that
4 showed the mortality and the assessment, yes,
5 there is an association. All the literature
6 supports that.

7 The problem with those studies is
8 that you, and as noted in the original study
9 in '89, this is -- and also in the pediatric
10 studies -- a very high percentage of these are
11 associated with some other process, usually an
12 intra-abdominal infection.

13 Therefore, and this is one of the
14 big issues we see in the administrative data
15 set tying to economic factors, is, yes, wound
16 disruption and requiring a closure does add to
17 hospital length of stay and cost.

18 However, the vast majority of the
19 time in the literature and in those studies
20 that were cited, there was a secondary or
21 probably the primary cause of the disruption
22 was an intra-abdominal infection or intra-

1 abdominal catastrophe which then is the
2 primary reason why the patient has increased
3 length of stay and cost, and the secondary
4 coding of the dehiscence was partly associated
5 with it.

6 It's a coordinated confounder that
7 goes with it. They move together, and to
8 assume that this is the best marker is
9 probably a false statement.

10 MEMBER STAFFORD: I would agree
11 with that. I think what you're saying is that
12 this is really a surrogate for something else
13 that's going on, and should we -- should a
14 measure be intra-abdominal, deep intra-
15 abdominal infection associated with a
16 procedure? That might get you more bang for
17 the buck.

18 From a surgeon's standpoint,
19 that's really -- when we stand up at M&M and
20 say we had a wound dehiscence, the first
21 question everybody says is, "Well, what caused
22 it?" That's what they want to know. It's not

1 that there was a dehiscence, but what was the
2 underlying cause for that?

3 So I think in that sense it's
4 important, and then the other question I would
5 have for Dr. Romano is since this measure has
6 been endorsed, do you have any evidence that
7 it's made any difference in patient care and
8 outcomes?

9 CO-CHAIR MORRIS: That's an
10 important question. Dr. Romano, do you have
11 a response?

12 MR. ROMANO: Yes. So the -- I can
13 pull up the national numbers. I know that
14 some individuals around this table have been
15 involved in local efforts to address this
16 problem, and so I can't speak to those
17 efforts.

18 I will say that the other fact --
19 the risk adjustment model for this indicator
20 does include heart failure, hypertension,
21 chronic lung disease, obesity, anorexia or
22 weight loss, and alcohol-related conditions,

1 so many of the conditions that are associated
2 with poor tissue are included and have the
3 expected effects in the risk adjustment model,
4 as well as, of course, age and some underlying
5 abdominopelvic conditions.

6 Also, to address another question
7 that was raised, there was a linkage study
8 that was done with NSQIP. It was reported. It
9 is one of the studies that was cited in the
10 submission. It was an HSR a few years ago.

11 In the NSQIP linkage study, we did
12 find that about 35 percent of the events were
13 missed, so there was some proportion of the
14 cases that were missed based on linkage with
15 NSQIP.

16 Now, admittedly, the definitions
17 are a little bit different, so we couldn't
18 drill down to the finest level in terms of
19 whether those cases that were missed in the
20 PSI but were picked up by NSQIP, what was the
21 nature of those cases. We can't say.

22 Finally, again I refer you to the

1 paper from the VA that's in front of you that
2 comments on some of the associated conditions.
3 Forty-three percent of the events were
4 associated with the evisceration of abdominal
5 contents.

6 Twenty-eight percent had fluid
7 draining from the wound. Thirteen percent had
8 some coughing or physical exertion that may
9 have triggered the dehiscence. Wound
10 infection was only found in nine percent, and
11 only three patients with a perforated hollow
12 viscus.

13 So at least in this series it was
14 a relatively small number that had a wound-
15 related infection, although certainly I
16 concede the point that this is to some extent
17 a marker of more serious things that may be
18 going on.

19 MR. BOTT: If I can jump in for
20 one second, this is John Bott with AHRQ. So
21 this is a question we've been asked in past
22 steering committees. Have we seen an

1 improvement as a result of the use of the
2 measure?

3 Our budget and our focus for AHRQ
4 for the quality indicator project is
5 developing and maintaining the quality
6 indicators and improving them where there is
7 opportunity. So that's what our focus is, and
8 so when users have questions about the
9 measures, being responsive to that.

10 If they have suggestions for
11 improvements or how they could be refined, we
12 catalog that and prioritize it and act on
13 those. Our focus has not been the cataloging
14 and tracking so much of how people have used
15 them and where but to be responsive to what
16 their concerns are to continue to improve the
17 measures.

18 We did complete, of course, the
19 application, the NQF form, and it does ask who
20 is using them, and we put in there who we were
21 aware of that we are readily aware of by
22 people contacting us, but we have not

1 canvassed the many groups who use the measures
2 to understand the way in which they've made an
3 impact now.

4 That's not to say that couldn't
5 become an aspect of AHRQ's future work in
6 supporting the indicators, but that, of
7 course, is resources we currently do not have
8 in the quality indicator projected.

9 MR. ROMANO: I did pull up the
10 national trend data, which shows a decrease
11 from 3.2 per thousand cases in 1994. At the
12 advent of the quality indicator program, it
13 was 2.62, and the most recent data are 2.48,
14 so it suggests a modest downward trend, but I
15 would, of course, be reluctant to attribute
16 that to the use of this indicator.

17 MEMBER MORTON: I have one comment
18 is that I agree with Bob. This is probably a
19 surrogate measure. It's looking at other
20 processes of care that impact the outcome of
21 dehiscence.

22 I liken it a lot to someone having

1 a temperature. We're not sure exactly what's
2 going on, what's the reasoning behind the
3 temperature, but it allows you to kind of dig
4 in a little deeper and see what's going on.

5 Utility for these PSIs are clearly
6 around the fact that they're readily
7 available. You search where there is light,
8 and all of these different measures are
9 actually fairly easy to obtain, and correct me
10 if I'm wrong. I think they've been endorsed
11 by a lot of the state public reporting
12 agencies around quality.

13 This one is probably maybe not the
14 strongest of the bunch for the PSIs, but I
15 think there is some utility to having these
16 things available. There are a lot of
17 hospitals that don't have NSQIP, that don't
18 have registries, but they can get this sort of
19 data through the PSIs pretty readily available
20 through the billing information, and then you
21 can kind of dig in and see what's going on.

22 MEMBER DILLON: Yes, but that

1 should be the institutional's M&M process,
2 rather than at the sort of the national level.
3 I guess one thing I would say is that I think
4 it's very important that if we're going to
5 support a metric that it's a meaningful
6 metric, and obviously that presents a
7 challenge here.

8 I will propose, perhaps, an idea,
9 at least on the pediatric one. Since there is
10 so little data to support it, one thing that
11 I would ask that we could consider if the NQF
12 is amenable to it would be to have a HRQ,
13 NQRI, and NSQIP, a peds NSQIP process get-
14 together, and take a look at this as a true
15 outcome measure in terms of quality.

16 The peds NSQIP will start having
17 data in about six more months, so there is the
18 possibility that we could combine forces
19 before considering this as a metric that
20 should be passed. Just a -- just a
21 consideration.

22 CO-CHAIR MORRIS: Any other

1 comments or thoughts?

2 MEMBER STAFFORD: Just two other
3 comments, just thinking about it and thinking
4 about it more as, I think, what most of us
5 surgeons think about this as being a surrogate
6 marker. I really liken this to the IHI
7 trigger tool where you go through a chart and
8 you, you know, you see --

9 You're trying to find out about
10 hypoglycemia, so you actually look through the
11 pharmacy records for how many amps of D-50
12 were given during a period of time, and then
13 you go through the chart and you look to see
14 what the reason for that was. I really think
15 that's how I see this, and I think that's how
16 most of us use it at M&M on a daily basis.

17 Now, granted, folks in private
18 practice, depending on where they are, may not
19 have a robust M&M, and so I think we also have
20 to remember that those of us who are in
21 academics there is a whole other world out
22 there, and how they use these indicators may

1 or may not be valuable to them, so I think for
2 a lot of us we may have a bit of that bias.

3 All of that being said, because I
4 think it's clearly something to look at, but
5 whether it should be an indicator that gets an
6 official stamp which then CMS and other folks
7 may use as a pay-for-performance issue is a
8 whole other target.

9 Again, that's what I kind of want
10 to keep us all thinking about is when we put
11 a stamp on something from the NQF, that has
12 some say in the real world, and these things
13 then tend to get picked up by other groups,
14 Leapfrog and CMS, et cetera, so I really think
15 it's something to think about.

16 MEMBER CIMA: That's the big issue
17 here, the difference between trigger tools and
18 IHIs. It's internally done and developed.
19 Using this as a safety indicator, is it truly
20 a marker of safety?

21 That's a very different thing, you
22 know, and I would submit that there hasn't

1 been any significant association with this
2 marker, because it is so infrequent that
3 hospitals rarely ever do anything with it.

4 I can show you in our -- you know,
5 looking over 100,000 operations a year, this
6 is -- this is so low a frequency event that we
7 can't do anything with it, so it just is
8 there, and so it's not meaningful.

9 CO-CHAIR MORRIS: Any other
10 comments? All right. So basically, to sum
11 up, we talked about how this is a patient
12 safety measure, so therefore it should be a
13 rare event, that it's really more focused on
14 impact on the patient, rather than prevalence,
15 and that seems appropriate, but on the other
16 hand, that it doesn't seem to really be
17 preventable or actionable for the most part.

18 Richard brought up the excellent
19 point that central line infections were not
20 deemed preventable or actionable previously,
21 but still I think that that's the overlying
22 opinion of the group that these aren't really,

1 for the most part, preventable or actionable.
2 So the implications for patient safety may be
3 pretty modest, but the implications for
4 provider -- for potentially negative provider
5 sequelae may not be quite as modest.

6 I think that something else that
7 came out of this discussion that we could
8 potentially recommend to NQF is that measure
9 developers who would like for measures to be
10 maintained provide support for the impact of
11 the measure since the time that it was
12 previously endorsed, so basically providing a
13 little more data about the actual impact.

14 I think that we should consider
15 charging the developers with this. It seems
16 like the appropriate place to put that
17 responsibility, and then the developers can
18 figure out best how to do that within their
19 resources.

20 Let's -- if there is anything
21 else, if anybody feels like their point was
22 not summarized here, please speak up, and then

1 we'll move on to the vote.

2 MEMBER CIMA: I will say one other
3 thing for the developers. If you're going to
4 cite literature, it's very important to cite
5 it correctly.

6 That really turned the argument on
7 this was, you know, the level of -- we're
8 reading this. I know it's a lot to put it
9 through, but if you want us to read it, then
10 it's got to be accurate, and this was
11 blatantly not accurate.

12 MR. ROMANO: I would like to
13 apologize for the misleading presentation of
14 that evidence in the submission. It was not
15 an intentional effort to mislead the panel,
16 and, again, I tried to provide the best and
17 most current papers here for your review, so
18 I apologize for that.

19 CO-CHAIR MORRIS: Okay, let's go
20 ahead and move on to the vote, then. Does the
21 measure meet NQF criteria for importance to
22 measure and report? Just so everybody is

1 aware, this is the pediatric measure, 0367.

2 Five said yes. Fourteen said no.

3 Now, we need to provide a reason
4 for maintenance measures that we consider --
5 that we deem not important, correct? Okay, so
6 we'll stop here, since we're not really
7 talking about inactive or emeritus or Hall of
8 Fame status.

9 So we'll move on to voting on
10 0368, and this is the adult measure, unless
11 anybody has anything else to add. Okay.

12 MR. ROMANO: Can I ask a question?
13 Just it would -- it would be helpful, because
14 this is a contradiction of a previous NQF
15 endorsement panel, so I think it will be
16 important for the record to state clearly why
17 it's no longer considered important.

18 CO-CHAIR MORRIS: We had our
19 discussion. This will be transcribed and
20 posted. Is there -- is there more that we
21 should say about that? I mean, just basically
22 I'd be re-listing the discussion that we just

1 had.

2 MS. MURPHY: We will have all of
3 the information written up in the context of
4 the measure regarding the discussion.

5 DR. BURSTIN: I suspect it would
6 probably be grounded in 1c, around the outcome
7 or the evidence in terms of the evidence for
8 the measure focus being in question in terms
9 of the link of the measure to the outcome of
10 interest, but, again, we can clean that up a
11 bit.

12 CO-CHAIR MORRIS: Okay. Let's go
13 ahead and vote on the adult measure. Are you
14 ready, Jessica? Okay. So we're voting on the
15 adult measure now, importance to measure and
16 report.

17 Okay, we're going to do a show of
18 hands. This is the last vote for today. Oh,
19 here we go. Okay, six votes for yes, 13 votes
20 for no.

21 Let's open the phone for public
22 and member comment regarding this last

1 portion. Anybody on the telephone?

2 Okay, the last section we are
3 going to be talking about at 1:30, and Dr.
4 Torchiana is going to take over here. We just
5 want to make sure all of our developers are
6 available.

7 CO-CHAIR TORCHIANA: So the 1:30
8 topic is under Attachment 6, related and
9 competing pediatric and congenital cardiac
10 surgery measures. So when Arden and I were
11 talking earlier today, we hoped that we would
12 get to this topic before 1:30, and the
13 question is do we have our developers here.

14 There's Dr. Jacobs from STS is
15 here. Kathy Jenkins from Children's Hospital
16 of Boston? On the telephone? Kathy, are you
17 on the telephone? Not as yet, and then there
18 is an AHRQ developer, Patrick.

19 So we have a choice of waiting
20 four minutes, or we could have the Children's
21 developer go last, assuming she comes on by
22 1:30. Why don't we do that, rather than

1 flipping the agenda around?

2 MS. MURPHY: Well, I wonder, only
3 from the standpoint of everybody hearing all
4 of parts of the discussion, if maybe we can do
5 just a couple minutes on this gaps document.
6 That's the very last item on the agenda.
7 Would that be okay?

8 CO-CHAIR TORCHIANA: Well, that's
9 what we had discussed doing. My thought was
10 if we ask the STS then AHRQ to basically
11 describe the rationale behind their measures
12 that hopefully by that time we would have
13 filibustered up to 1:30, and we would have our
14 Children's representative on the phone.

15 Is it possible she's on the phone
16 and muted?

17 DR. BURSTIN: Operator, can you
18 please check if Dr. Kathy Jenkins is perhaps
19 on the non-speaking line?

20 OPERATOR: She is not online at
21 this time.

22 CO-CHAIR TORCHIANA: She is not.

1 Okay, I'll fold my tent. Let's do the other.

2 MS. MURPHY: So, in the materials
3 that you received for this meeting, and I'm
4 referring to the document that had the nine
5 attachments, there is Attachment Number 8. I
6 don't know if we can -- Alexis, are you going
7 to be able -- okay. Good. And all this is
8 just a little bit of an introduction to this.
9 That's all I want to do to have you take a
10 look.

11 One of the items that we are doing
12 with each of the steering committees as they
13 look at their area of assignment is asking
14 them also to look at it in terms of where
15 there might be gaps in measurement.

16 So what this document provides to
17 you, down the left side are a list of the
18 surgery measures that are currently NQF-
19 endorsed, and the yellow highlight focuses on
20 those measures that are in consideration in
21 the work you're doing right now.

22 So you can see the ones you're

1 working with right now and the remainder of
2 the NQF-endorsed surgery-related measures, and
3 then across the top of it what we've done is
4 identify different domains of care or service
5 within which you might consider whether or not
6 there should be a measure.

7 All that we are asking that you
8 do, and not do it today, but to take a look
9 over this and identify where you believe
10 either in the current topic areas, or you can
11 add additional topic areas across these
12 domains, where we should look for additional
13 measures at some point in time.

14 CO-CHAIR TORCHIANA: Melinda,
15 could I ask where the domains were defined?

16 MS. MURPHY: If you're looking --
17 are you looking at where the definitions
18 appear on here or --

19 CO-CHAIR TORCHIANA: No, I'm just
20 curious that so many outcomes measures are
21 under care coordination and management, since
22 there is no outcomes domain.

1 MS. MURPHY: In the discussion of
2 work done with the National Priorities
3 Partnership and some of the work that's been
4 done with the new group looking at
5 measurement, they have identified and defined
6 -- to some extent helped us in identifying
7 where topic areas fit within the domains.
8 Helen, is there anything?

9 DR. BURSTIN: Most of these
10 correspond to the domains that are recently
11 released, National Quality Strategy, so this
12 does relate to that. I'm not sure patient
13 outcomes are there, per se, but those relate
14 quite well to the domains that the Secretary
15 recently promulgated.

16 MS. MURPHY: So this is a homework
17 assignment. So if you would take that away,
18 take a look at it when you have an opportunity
19 and provide us some feedback.

20 DR. BURSTIN: Peter, I wonder if
21 you want to mention the pediatric surgery
22 discussion you and I had recently.

1 MEMBER DILLON: I can. It's still
2 embryologic, but we will convene or will
3 discuss with NQF and take these surgical
4 measures and focus them on the 18-and-under
5 population with a group of multi-specialty
6 surgeons, and we'll take a look at ones that
7 we think should be then brought forward as
8 potential measures within the children's
9 surgical care. We've just -- we've been
10 trading, you know, the NQF lists, and we'll
11 start to focus on those.

12 DR. BURSTIN: So far, the idea
13 there was to see how many of the measures that
14 are labeled as adult are labeled as adult just
15 because that's what the developer did and
16 wasn't really thoughtful and could consider
17 whether, in fact, if you looked, some of those
18 measures could be applicable to children, as
19 well, with some adaptations. So I just wanted
20 to let you guys know that's happening.

21 MEMBER DUTTON: Well, there's a --
22 well, a lot of these are -- many of these have

1 anesthesia implications. There are no
2 specific anesthesia or pain management
3 measures in here, so I need to think about it
4 a little bit, but you'll get some from us, as
5 well.

6 MR. SILBER: Hi. Jeff Silber on
7 the line. Hello?

8 MS. MURPHY: Yes, Dr. Silber?

9 MR. SILBER: Hi.

10 MS. MURPHY: Hi. So we're just
11 finishing up one other --

12 MR. SILBER: Okay.

13 MS. MURPHY: -- quick discussion.
14 So that's the -- that's the gaps work for you,
15 please. Thank you very much, and we have not
16 identified a deadline, but we'd appreciate it
17 whenever you can do that for us. If you just
18 send it back to either me or Alexis or
19 Jessica, then we'll compile it all and give it
20 back to the Committee as a whole.

21 MEMBER ROGERS: So, Melinda, just
22 to make sure -- this is Terry. Hello? This

1 is consistent with my past academic
2 experience. I just want to make sure about
3 the assignment. I see --

4 MS. MURPHY: I bet you always made
5 As.

6 MEMBER ROGERS: I'll just let that
7 one go. So we're to review again the
8 initiatives that we've looked at for the past
9 day and a half and see whether in these new
10 gap areas there are some issues that we may
11 have missed and that we should want to
12 consider. In those, we mark a box plus,
13 minus, a comment. Is that -- is that what
14 you're asking?

15 MS. MURPHY: Right, except I think
16 it's a little more simple in terms of we're
17 not asking that you go back and take a look at
18 the specifications of those measures, the
19 topic areas. So are there any topic areas
20 that we should now be looking for measures to
21 fill gaps? Thank you.

22 CO-CHAIR TORCHIANA: So, Melinda,

1 would you like us to start with the pediatric
2 measures, or should we go to the failure-to-
3 rescue measures?

4 MS. MURPHY: I guess this is my
5 moment of confusion, one of many. We had the
6 discussion about the failure to rescue
7 measures, so discussion about them will be --
8 the next discussion about the failure-to-
9 rescue measures relate to related and
10 competing, which we are not taking up today.

11 The only ones that we're taking up
12 today in terms of related and competing are
13 the peds measures in terms of the ones that
14 are related and competing, so that is measure
15 PCS 1809, which is STS Measure 2109, which is
16 Children's Hospital Boston, and 0339. This is
17 the mortality measures, which is AHRQ measure,
18 and then the related volume measures.

19 MR. SILBER: Could I ask a
20 question? A little bit of confusion, because
21 I have a bit of a window. We had scheduled an
22 hour.

1 I thought that I was calling back
2 in today about my FTR measures because of an
3 issue of distinguishing them between the
4 original, which is my measures, and the AHRQ
5 measure. It's not going to be discussed
6 today, because otherwise I don't know if you
7 need me on the call.

8 CO-CHAIR TORCHIANA: I think we
9 won't need you on the call today, Dr. Silber.

10 MR. SILBER: Okay. Is this
11 because it's being rescheduled or because it's
12 already endorsed and it isn't an issue?

13 MS. MURPHY: Dr. Silber, the
14 discussion about them with respect to related
15 and competing will be scheduled with this
16 Committee at a later point. It will be a
17 conference call, and we will notify all of the
18 developers and invite and be certain we have
19 them available for that discussion.

20 MR. SILBER: Okay.

21 MS. MURPHY: Thank you.

22 MR. SILBER: Can you hold for just

1 one minute? So I guess it's just not today.

2 Okay. We will -- we didn't understand, and
3 sorry to bother you, then. Thank you.

4 CO-CHAIR TORCHIANA: Thank you.

5 Okay. So the next section is Attachment 5,
6 related and competing measures. We have three
7 developers. Melinda has outlined the three
8 measures that we're here to discuss.

9 So we'll begin with the
10 developers. Let's start with STS, and I would
11 ask just to sort of establish the format of
12 what we hope to accomplish in the next hour
13 that we'd like to begin with each of the
14 developers describing their measures. We
15 would ask that you refrain from any comments
16 on the competing measures during that
17 preliminary step.

18 We then would ask that the
19 Committee discuss the various measures and
20 discuss the issues raised with the goal that
21 as we get through this conversation we will be
22 able to help define issues that we might ask

1 the developers to return with around data
2 evidence or modifications so that this can be
3 brought to closure in a subsequent conference
4 on the telephone. So let's start with the
5 developers, Dr. Jacobs, for the STS measures.

6 MR. JACOBS: Thank you. My name
7 is Jeff Jacobs. I'm the Chair of the STS
8 Congenital Heart Surgery Database, and the
9 background for this discussion is based on the
10 fact that in pediatric heart surgery there is
11 a vast array of operations, each one of those
12 operations being done in limited amounts.

13 So, unlike adult heart surgery,
14 where you have hundreds of thousands of
15 coronary bypass grafting operations or aortic
16 valve replacement or mitral valve replacement,
17 in pediatric heart surgery there is over a
18 hundred basic types of operations that are
19 done on the hearts of children, and the risk
20 ranges tremendously from one operation to the
21 next, and there's not high volumes of any of
22 those operations.

1 So, in order to assess the
2 mortality after congenital heart surgical
3 operations, a methodology is needed to assess
4 the complexity of the operation performed, and
5 the measure that we propose is based on a tool
6 called the STS/EACTS Congenital Heart Surgery
7 Mortality Categories.

8 What we did was we had -- we
9 pulled data from the STS database and our
10 counterpart database in Europe, the EACTS
11 database, that was gathered using identical
12 nomenclature and terminology, and based on
13 that pool of data we had access to over 75,000
14 pediatric heart surgery operations that were
15 divided into 148 major operative procedures.

16 Those were then analyzed and
17 grouped into five categories or buckets of
18 increasing operative complexity set up in a
19 way to maximize the ability to discriminate
20 between one category and the next category and
21 to maximize the similarities within any given
22 category.

1 What we then had was a tool that
2 had five categories of complexity with
3 Complexity 1 being operations that are the
4 least likely to result in mortality and
5 Complexity 5 operations that are most likely
6 to result in mortality.

7 In Category 1, mortality is around
8 0.5 to 1.0 percent, and in Category 5
9 mortality is over 20 percent. By having these
10 five categories, one can then report mortality
11 using similar categories that allow for
12 meaningful comparison between institutions.

13 STS feels it is very important to
14 use a tool that functions in a clinical
15 database, rather than assessing outcomes after
16 pediatric heart surgery from administrative
17 data because of multiple publications that
18 document the flaws and coding of congenital
19 heart lesions utilizing ICD-9 codes and
20 administrative data.

21 The one example I would give for
22 that is the most talked about and focused upon

1 operation in pediatric heart surgery that's
2 used to assess programmatic performance is the
3 Norwood operation. This is an operation that
4 has between 15 and a 25 percent mortality
5 after the operation, so one in five to one in
6 four babies that have this operation do not
7 survive and die before they go home.

8 In a clinical database like the
9 STS database or other clinical databases,
10 there is a procedure called the Norwood
11 operation, so you can quote for it. If one
12 wants to find the Norwood operation from an
13 administrative database, one would have to
14 create an amalgamation of inclusionary and
15 exclusionary criteria based on 15 different
16 ICD-9 codes, some of which are required, some
17 of which you cannot have, some of which you
18 can have.

19 It's amazing to me that based on
20 this amalgamation of 15 different codes one
21 can even identify this operation. That's one
22 example of the weakness of administrative

1 coding.

2 So I think what we've tried to do
3 through STS is create a system to stratify
4 operative complexity that can be used both in
5 clinical and administrative databases, but we
6 emphasize that we feel that it should be done
7 with administrative data -- I'm sorry, with
8 clinical data because of the flaws of coding
9 pediatric heart surgical operations with
10 administrative data.

11 I think -- I don't want to take
12 any more time right now. I think that's a
13 pretty rapid summary of the way our method is
14 -- methodology works and how we apply it.

15 CO-CHAIR TORCHIANA: Thank you,
16 Dr. Jacobs. Do we have Dr. Jenkins on the
17 phone now?

18 DR. JENKINS: Yes, this is Dr.
19 Jenkins.

20 CO-CHAIR TORCHIANA: Could you
21 speak up a little bit?

22 DR. JENKINS: Yes, I'm here. I'm

1 on the call.

2 CO-CHAIR TORCHIANA: Great. Could
3 you describe your measure, the Children's
4 Hospital measure?

5 DR. JENKINS: Sure. The measure
6 that we've proposed in this entire process is
7 known as RACS(1). It was developed a number
8 of years ago, and it's been widely used
9 recently, over the last eight years or so.

10 It's probably the most commonly
11 used measure of mortality in the United States
12 and across the globe. What we've heard
13 through this entire process is a lot of
14 sessions about what's preferable about our
15 methodology over some of the other
16 methodologies that have been put forward, and
17 let me just speak to that specifically.

18 I think it's important to say that
19 we've put forward our methodology as it was
20 originally developed and validated years ago
21 as a methodology that can be used in
22 administrative data, which has been -- there's

1 been a lot of conversation about that use, as
2 well as non-administrative data, and I think
3 that's important for the Committee to know.

4 In fact, one of the reasons that
5 we went forward with our pure RACS
6 methodology, even though there was already the
7 AHRQ methodology that had been approved
8 previously, was the fact that the prior AHRQ
9 methodology was put forward in a slightly
10 different version than the way our measures
11 had previously been developed and validated in
12 terms of the additional risk factors that were
13 incorporated for some reason that I believe
14 related to some internal AHRQ harmonization
15 but was different than the way the measure had
16 been done, and also because the original AHRQ
17 methodology only specified the use of the
18 methodology in administrative data and did not
19 incorporate the use of the methodology in non-
20 administrative data.

21 So what we've put forward is a
22 measure that includes risk categories for

1 procedural complexity, as well as additional
2 risk factors wrapped up together in a multi-
3 variate model that yields an SMR for
4 institutional performance and covers, in
5 general, roughly 85 to 92, 93 percent of an
6 entire pediatric case mix across most case
7 mixes.

8 In terms of our -- and I will say
9 something in response to the specific issue
10 that Jeff Jacobs brought up about weaknesses
11 of administrative data based on ICD-9 codes.
12 While it's definitely true that there are not
13 good ICD-9 codes to detect surgical procedure
14 for Norwood Stage 1, there is an excellent
15 ICD-9 code for the diagnosis, which is HLHS.

16 So the algorithms that have been
17 built to detect those specific procedures have
18 in general worked out pretty well, and every
19 data set that I've ever looked at using
20 RACS(1), the category for the Norwood type
21 procedures, which is the highest risk
22 category, has always had a mortality rate that

1 was distinctly higher than and distinctly
2 different than any other of the other
3 categories.

4 So I don't think there's a lot of
5 problems with identifying those procedures, at
6 least in the sense that the category is
7 finding procedures of especially high
8 mortality.

9 I would like to say something
10 about weaknesses with the five category
11 mortality rates that I believe has also been
12 proposed as part of this conversation, just so
13 the Committee is aware of them.

14 First of all, when we talk about
15 five-category mortality, whether we talk about
16 it by RACS(1) or the new STS categories or a
17 prior version of Aristotle categories, the
18 categories in general work well for the
19 procedural complexity.

20 The problem is that you take a
21 case mix which is typically around 200 or 250,
22 maybe 300 cases, and you divide it up into

1 five or six categories, and, as everyone
2 knows, what you've done then is you've
3 essentially distorted and diluted any
4 statistical power to make any meaningful
5 comparison, because the confidence limits
6 around the five-category mortality rates are
7 really rather -- are very large, even in large
8 institutions. So almost by definition from
9 statistical power alone you've diluted your
10 ability to find meaningful differences.

11 In addition, not surprisingly,
12 those categories then don't account for other
13 clinical risk factors like the age of the
14 patient and whether they have other anomalies
15 and whether the infant is premature, and so
16 the categories alone really don't account for
17 all of the variation.

18 In general, the categories will
19 give an area under the RSC curve. Some were
20 in the range of .7. You need the additional
21 risk factors to bump it up beyond that.

22 So it's a combination of the small

1 sample sizes and typical pediatric case mixes
2 and the fact that there are procedural
3 complexity variables beyond procedure that
4 make it much better to wrap up the entire
5 measure into an SMR that brings all of that
6 together and adds statistical power.

7 CO-CHAIR TORCHIANA: Okay. Dr.
8 Jenkins, could you wrap up your description?

9 DR. JENKINS: That was the end of
10 my comments.

11 CO-CHAIR TORCHIANA: Thank you so
12 much. Who will speak for AHRQ? Patrick?

13 MR. ROMANO: I will, yes. This is
14 Patrick Romano again. So this is easy for me,
15 because I think we're very clear and direct
16 that this AHRQ indicator is based on the work
17 of Kathy Jenkins and her colleagues at
18 Children's Hospital Boston, and so we defer to
19 them regarding the specific issues in the
20 application of the RACS methodology. It's
21 based on the same RACS methodology.

22 So the different -- of course, you

1 know, in terms of the process by which this
2 became an AHRQ quality indicator,
3 fundamentally AHRQ and its contractors troll
4 the field looking for quality indicators that
5 can be applied to administrative data sets.

6 Kathy Jenkins' work, of course,
7 came to the attention of AHRQ. It's in the
8 public domain, and we actually had a number of
9 conversations with Dr. Jenkins and her
10 colleagues about the specific
11 operationalization of the indicator.

12 So there are some differences
13 which are really technical differences that
14 relate to how the indicator is presented.
15 Kathy described the construction of an overall
16 SMR, a standardized mortality ratio, kind of
17 an observed-to-expected ratio.

18 The AHRQ quality indicator
19 software spits out a risk-adjusted mortality
20 rate, which is simply an SMR multiplied by
21 some overall average mortality rate, so it
22 converts it into a percentage.

1 The other differences relate to
2 the risk adjustment. Those could easily be
3 reconciled. Fundamentally, I think both
4 approaches adjust for the RACS categories that
5 Kathy has mentioned.

6 They adjust for age and birth
7 weight or prematurity. The adjusters in the
8 AHRQ are slightly different, because they come
9 out of a certain risk adjustment structure
10 that's embedded into all of the AHRQ quality
11 indicators.

12 For example, there is a specific
13 indicator for patients who are transferred in
14 in the AHRQ model to account for the fact that
15 some of those patients may be higher risk in
16 ways that aren't directly captured elsewhere
17 in the risk adjustment. So those minor
18 differences could be -- could be reconciled.

19 The final point that I want to
20 make just to the general issue is that there
21 have been -- there's been quite a bit of
22 experience, I think, with this measure, both

1 with Dr. Jenkins' team and others.

2 In fact, there was a comparative
3 study, O'Brien and Clark, that was a head-to-
4 head trial, head-to-head study that basically
5 showed that these two approaches, the STS-
6 based approach, the RACS-based approach, are
7 functionally equivalent in terms of
8 discrimination, in terms of the ability to
9 discriminate between kids who die and kids who
10 survive the hospitalization.

11 So from the statistical standpoint
12 it's very hard to discern a meaningful
13 difference in the performance. The
14 fundamental difference is that one indicator
15 is based on a registry system, which is very
16 important for quality improvement, and the
17 Children's Hospital Boston and our measure,
18 the AHRQ measure, are based on administrative
19 data.

20 CO-CHAIR TORCHIANA: Comments from
21 the Committee?

22 MEMBER HALPERN: Do you have a --

1 since we didn't get to review your measure,
2 it's clearer in the Children's Hospital
3 measure that they are looking at the low-risk
4 patients, it seems to me, because they're
5 saying RACS(1) risk category, but it's not
6 clear in yours how you discriminate between
7 severity of disease.

8 MR. ROMANO: It's the same,
9 actually. There's a -- the RACS is a five-
10 level scoring system, and so the RACS
11 categories are put into a multi-variable risk
12 adjustment model, so each of the categories
13 carries a certain additional risk that's
14 associated with it. I believe, Dr. Jenkins,
15 I believe -- is that the same approach that
16 you used?

17 DR. JENKINS: Absolutely, yes.

18 MEMBER HALPERN: So, do you report
19 it by category?

20 MR. ROMANO: The AHRQ measure
21 reports it as an overall composite in the same
22 way. It's just the only difference is that

1 the Children's Hospital Boston reports it as
2 a ratio of observed to expected, and the AHRQ
3 software translates that into a risk-adjusted
4 mortality rate.

5 Users can, of course, drill down
6 and look at the stratum-specific mortality
7 rates for each of the five RACS levels, but,
8 of course, that's more difficult for
9 consumers, purchasers, payers, other
10 stakeholders to understand, so the preferred
11 measure from the standpoint of AHRQ's
12 stakeholders is the composite measure.

13 MEMBER DILLON: What are the
14 metrics for your composite measure? What are
15 the units?

16 MR. ROMANO: It's a risk-adjusted
17 mortality percentage.

18 MEMBER DILLON: So it's -- I'm
19 sorry. That's what I'm getting at, just a
20 straight percentage.

21 MR. ROMANO: Yes. It's derived by
22 the ratio of the observed to expected

1 multiplied by the overall mean average, so it's
2 the standard approach for what we call
3 indirectly standardized mortality rates.

4 CO-CHAIR TORCHIANA: Peter, I
5 think it's a composite in that it's a
6 composite of all risk levels.

7 MEMBER DILLON: Right, because the
8 STS results in five. You've got a score for
9 each of the five levels.

10 MR. JACOBS: And the rationale for
11 that is that imagine you're a mother with a
12 child that has the highest level complexity
13 patient. You might want to be able to find
14 out how a given center performs caring for
15 patients of that level of complexity, and that
16 might not be possible if you just get an
17 overall aggregate score.

18 So it was felt that it's important
19 for patients and patients' families to be able
20 to access how a given institution performs
21 both in the low levels of complexity and in
22 the high levels of complexity.

1 MEMBER HALPERN: I guess you feel
2 that your model, your risk adjustment model
3 accounts for a case mix by its risk
4 adjustment.

5 MR. ROMANO: Well, it does account
6 for case mix. I can't argue with Dr. Jacobs'
7 point. It's just that different stakeholders
8 have different needs, and so some might prefer
9 to see a single measure that's specific to a
10 certain risk level.

11 Others will prefer to see a
12 composite measure that incorporates both low-
13 and high-risk patients and adjusts for the
14 difference, but, again, statistical
15 performance is very comparable.

16 MEMBER HALPERN: So it seems to
17 me that yours and the Children's Hospital are
18 very similar, just a different way of
19 reporting the same data, whereas the STS has
20 a distinct purpose.

21 So, to my mind, it's really
22 comparing the AHRQ and the Children's

1 Hospital, because it seems to me that the STS
2 database is reporting it in a different way.
3 They're reporting by category so people can
4 actually see by category, by risk, you know,
5 by the severity of disease.

6 MR. ROMANO: Right, and, in fact,
7 from what I understand, there is a strategy
8 both to deal with competing measures and
9 complementary measures, and it might be viewed
10 that while the AHRQ and the RACS are competing
11 measures, the STS measure could be viewed as
12 a complementary measure, because it's taking
13 a fundamentally different approach to provide
14 access to a different type of information.

15 CO-CHAIR TORCHIANA: I think
16 that's potentially a way forward, but I guess
17 I'd say this is very reminiscent of a long
18 conversation we had yesterday, with apologies
19 to the developers who weren't in that
20 conversation.

21 This is quite similar to the
22 aortic aneurism repair conversation in that

1 there is a sort of tension between adding
2 things together and getting more ability to
3 discriminate at the institutional level versus
4 splitting them up into more appropriate, more
5 homogeneous groups that thereby then lose some
6 ability to discriminate. I do think it's not
7 unreasonable to think of that as complementary
8 rather than competing.

9 Could I ask Dr. Jacobs the plans
10 or current status of the reporting this to the
11 public? If this is for families, is this
12 report to the public currently by the
13 participating STS institutions, or is that a
14 future plan?

15 MR. JACOBS: So, as some people in
16 this room probably are aware, the STS has
17 moved forward with public reporting of cardiac
18 surgical outcomes fairly aggressively in the
19 past year, and the approach we took I can
20 speak to in quite a large amount of detail,
21 because I chair the Public Reporting Task
22 Force for the Society of Thoracic Surgeons.

1 What we decided to do was
2 initially to report from the adult cardiac
3 surgery database CABG outcomes, and we've been
4 doing that for just about a year now. We
5 wanted to work out the kinks of public
6 reporting of cardiac surgical outcomes using
7 the CABG outcomes first, but that's really a
8 platform that will then be expanded in adult
9 cardiac, also to aortic valve and mitral
10 valve, and our other databases will be
11 expanded to both thoracic and congenital.

12 So our intent is to do just like
13 we do with the CABG outcomes and to publicly
14 report these outcomes, as well, using similar
15 strategies, and I think that's something
16 that's going to happen quite soon.

17 MEMBER STAFFORD: At what level
18 are you reporting those outcomes, provider
19 level, facility level, group level?

20 MR. JACOBS: So the CABG outcomes
21 are reported both at group level and facility
22 level, so one can go to the STS website and

1 see the CABG outcomes for a given hospital or
2 a given surgical group.

3 Up until now, the decision has
4 been made not to report it based on an
5 individual provider based on the concept that
6 outcomes after heart surgery are dependent on
7 so many elements of the team and not just the
8 surgeon independently. One could say heart
9 surgery is a team sport, not an individual
10 sport, and based on that so far we've reported
11 it at the group level and at the hospital
12 level.

13 MEMBER DUTTON: Can I ask a
14 question about the data? Oh, I'm sorry,
15 Terry. Go ahead. Dr. Jacobs, in the data
16 you've gathered, what does it show about
17 breaking the cases down into five different
18 categories? Do you find centers that are good
19 at simple operations and bad at hard ones --

20 MR. JACOBS: Absolutely.

21 MEMBER DUTTON: -- and vice versa?

22 MR. JACOBS: You find several

1 things. First of all, you find that this
2 methodology has the ability to identify
3 outliers, even though you've broken it into
4 five separate strata or categories. So we
5 don't need to pool all the data together to
6 identify outliers. Outliers can clearly be
7 identified in each of the five categories.

8 Second of all, we've found that
9 there are centers that don't perform surgery
10 at all in the most complex category, so there
11 are centers that don't even do Category 5
12 surgery, but instead they refer the patients
13 elsewhere.

14 If one pools all the data together
15 to create one score, then when one looks at
16 that score, it's impossible to know whether or
17 not that center is performing the high-
18 complexity surgery. So, you know, not only
19 can you identify outliers within each
20 category, but you can also with this
21 methodology identify centers that don't
22 perform the high-complexity surgery at all.

1 MEMBER ROGERS: I am speaking,
2 hopefully, for the Committee to be reminded
3 what our specific responsibility is today and
4 what the impact of that might be. That is, if
5 we were asked to make a decision, do one or
6 two of these go away, or what happens?

7 CO-CHAIR TORCHIANA: I don't think
8 we're being asked to make a decision today.

9 MEMBER ROGERS: Okay.

10 CO-CHAIR TORCHIANA: We talked
11 about that at lunch amongst this end of the
12 table. The goal is to try to have a fruitful
13 discussion to give feedback to the developers
14 and I think to identify modifications or
15 additional information that might help lead us
16 to a future decision, but the decision is not
17 to be made today.

18 MEMBER ROGERS: Thank you. Then I
19 would like to make one comment. Having played
20 in both the arena of administrative data and
21 clinically derived data, recognizing the
22 complexity of this specific issue and also

1 paying homage to the seriousness and
2 commitment of all players involved in all
3 three of these, I would have to err on the
4 side of going with a clinical database for
5 this kind of process.

6 To the extent that that kind of
7 conversation can take place between and
8 amongst, that's great. If not, then I would
9 bend on the side of the clinical database on
10 an ongoing quality measurement process.

11 MEMBER MORTON: We heard yesterday
12 the penetrance of STS for adult hospitals was
13 pretty high. It was like 95 percent. I'm
14 curious about the penetrance of STS for
15 pediatric cardiac hospitals.

16 MR. JACOBS: Right. That's an
17 excellent question. STS has done several
18 manpower surveys, and based on those manpower
19 surveys we estimate that there's 122 hospitals
20 in the United States that do pediatric
21 congenital heart surgery, and that estimate
22 has been validated through other sources of

1 data, as well.

2 Right now, STS receives data from
3 98 of those 122, and if we look at the 20
4 largest by volume, we get them all. If we
5 look at the 20 that are listed in the U.S.
6 News & World Report as the centers of
7 excellence, we get data from 19 of those, and
8 20th I think is going to start sending this
9 year.

10 So it's -- I think the penetrance
11 of the STS database is fairly high. The ones
12 that we're missing are low-volume programs,
13 and we're making every effort to encourage
14 those low-volume programs to participate, as
15 well.

16 MR. ROMANO: Could I just ask --
17 I'm sorry. What percentage have agreed to
18 public reporting of those data that are being
19 contributed?

20 MR. JACOBS: That's a good
21 question. So right now we haven't even asked
22 the congenital heart surgery database yet,

1 because that initiative hasn't started. In
2 the adult heart surgery database, last year
3 was the first year that we did public
4 reporting.

5 As most people know, it was done
6 on a voluntary basis, and in year one we had
7 20 percent of the programs participate and
8 publicly report their data. Now, in year two,
9 that number is up to 39 percent right now, so
10 going from one year to the second year we've
11 already doubled the participation,
12 essentially, and I think that it will continue
13 to climb.

14 As long as it's voluntary, I doubt
15 it's every going to get to be 100, but the
16 fact that we doubled it from year one to year
17 two tells me that more and more places will do
18 it, and if enough people do it, it becomes
19 functionally mandatory.

20 DR. JENKINS: This is Kathy
21 Jenkins. I'd just like to make one more
22 comment so people are aware that in response

1 to Patrick Romano's earlier comment about the
2 ease of harmonizing our methodology with the
3 AHRQ methodology, I had proposed that very
4 early in this process, and through the NQF
5 rules we had been told that we weren't really
6 allowed to bring things together at this
7 stage, so --

8 DR. BURSTIN: I think that
9 actually only had to do with -- this is Helen,
10 Kathy -- because this measure was in a
11 different project, but I think now that we've
12 actually sort of brought them somewhat
13 together, I think those options are completely
14 on the table.

15 DR. JENKINS: And I would just
16 like to reiterate our willingness to do that.

17 MR. JACOBS: And I think from STS'
18 point of view it seems to me that it would be,
19 first of all, very nice to see the AHRQ and
20 the Boston Children's measure harmonized.

21 I think that ultimately STS would
22 view that as a favorable move and hopefully

1 would also -- STS would also be supportive of
2 seeing a harmonized AHRQ RACS measure and the
3 STS measure ultimately both being endorsed as
4 complementary measures, because I think from
5 the discussion that we've heard today each
6 measure brings some very nice features to the
7 table. Then we could have two complementary
8 measures, a harmonized measure of AHRQ and
9 RACS and a complementary STS measure, and
10 that's something STS database would be very
11 supportive of.

12 DR. JENKINS: And that's why I
13 just went through that conversation, Jeff,
14 though, because, as I said before, our
15 methodology was originally validated in a
16 registry which is not the STS registry, but
17 the Pediatric Cardiac Care Consortium registry
18 is very similar, and so I don't see any reason
19 why an SMR using the RACS methodology even in
20 a clinical registry with STS is not also a
21 possible measure that could be useful
22 publicly.

1 MR. JACOBS: That's exactly what I
2 said. I think that I would be very supportive
3 of that happening, and I think it could be
4 viewed as a complementary measure to what STS
5 is proposing, so I think both of them together
6 are additive, rather than competitive.

7 CO-CHAIR TORCHIANA: Could I ask
8 for input from the Committee on that question,
9 the notion of having complementary registry
10 and administrative data coexisting?

11 MEMBER HALPERN: I think that's a
12 -- I think that they both bring separate
13 things together that are equally important.

14 MEMBER DILLON: The problem that
15 you have to be careful of is that we don't get
16 into -- we don't get competing or, I was going
17 to say misleading, but confusing information,
18 and I'll cite the difference between UHC and
19 NSQIP type data right now, which are 180
20 degrees opposite.

21 So the last thing you want is some
22 mother looking up, "Well, wait a minute. This

1 number says good, and this number says not so
2 good. What do I do?"

3 So the question I have is if you
4 rolled up all your STS data, what's the -- has
5 anybody looked at the correlation between a
6 unified measure of your overall STS results
7 and how it might correlate with the
8 administrative studies, the RACS study or with
9 the AHRQ?

10 MR. JACOBS: Well, I think that
11 all three of these methodologies can be
12 applied to administrative data for registries,
13 and the reason that I said that they were
14 complementary was not because administrative
15 data and clinical data is complementary but
16 because what the STS does with the STS
17 categories is somewhat different from what the
18 RACS and AHRQ methodology do.

19 I think there is value to having
20 both pieces of information. There is value to
21 having the individual outcomes of the five
22 categories at a given program, and there is

1 value to having the overall composite, and
2 that's why I think they're both complementary.
3 It's not a complementary nature of clinical or
4 administrative data, because the clinical and
5 administrative databases can function with any
6 of these three tools.

7 We have not rolled all five
8 categories into one score, because we think
9 there is value in having each of the five --
10 the information of each of the five categories
11 the way we present that. However, that's
12 something that could certainly be done if it
13 was felt that that would be a beneficial part
14 of the process, as well.

15 DR. JENKINS: And this is Kathy
16 Jenkins. I understand the point of the
17 question about confusing to the public, and
18 I've never really specifically seen that exact
19 academically done heads-up comparison that
20 you're actually looking for, but having seen
21 many, many, many reports in various ways using
22 both clinical databases as well as the

1 administrative databases, I've never seen an
2 especially confusing signal with that sort of
3 one looks up and one looks down kind of a
4 problem that you're alluding to.

5 I don't think the problem here is
6 really with the administrative versus clinical
7 signal. We're really just talking about how
8 to get the risk adjustment right so that it
9 really adjusts for complexity across such a
10 diverse case mix in a way where we can make
11 sense of the information and have enough
12 statistical confidence that there is clarity.

13 MR. ROMANO: And if I could
14 address that point, so AHRQ, I think we defer
15 to Dr. Jenkins in terms of her methodologic
16 expertise in developing this measure, but let
17 me just explain how the complementarity works
18 to some extent.

19 I think I can speak for AHRQ, even
20 though I'm a contractor, in saying that the
21 agency is very supportive of the STS registry
22 and the development of outcomes measurement

1 programs based on STS and other registries,
2 but it is the availability of alternative
3 measures based on administrative data that
4 sometimes encourages people to participate in
5 registries.

6 So within certain local markets,
7 users have the option of referring to either
8 their local administrative data set or asking
9 hospitals to join the STS, and so if it's
10 understood in a local market that purchaser
11 coalitions, for example, will produce a report
12 card based on the AHRQ measure, then what
13 often happens is that hospitals voluntarily
14 say, "Well, we'd rather release our data
15 through the STS," and that's perfect.

16 So if that alternative mechanism
17 exists, then, if anything, it tends to
18 increase participation in the registry, and in
19 the long run the goal is to get information
20 into the public domain that's useful to
21 stakeholders. So I think we're all on the
22 same page in terms of the pursuit of that

1 goal, and having complementary measures is
2 actually a way of furthering that goal.

3 MEMBER WILHOIT: And I think it's
4 really important to have the complementary
5 measures, because I just looked up STS, and
6 for Illinois we have 13 hospitals publicly
7 reporting the CABG data. Well, 13 isn't very
8 many of our hospitals that do the surgery.

9 You know, if pediatric isn't even
10 in the loop yet on public reporting, it's
11 obviously going to be a while before that
12 information is available to anybody except the
13 hospitals, so I think a measure that is
14 available on a broader scale and that can be
15 run on an administrative database, you know,
16 so that everybody has the information is
17 useful.

18 DR. BURSTIN: And one other
19 question might be going forward it would be
20 really nice to be able to see the
21 complementarity or the similarities and
22 differences between the data sources.

1 So I think it would also be very
2 useful, for example, if STS began collecting
3 as part of the registry some of that key
4 claims data so we can begin to make sense of
5 those connections, which I know has not been
6 traditionally part of the STS registry.
7 Again, anything we can do to learn more about
8 how these different resources can get us
9 complementary and/or contradictory
10 information, I think that'd be really useful.

11 MEMBER ZAMBRICKI: I had a
12 question for the surgeon from Boston
13 University Children's having to do with the
14 RACS statistical risk model. Did I hear you
15 say that that is used worldwide and it's the
16 largest risk model used in pediatrics or
17 pediatric surgery?

18 DR. JENKINS: Well, that's
19 certainly been my experience and perspective.
20 By the way, I'm not a surgeon. I'm a
21 cardiologist. I'm also the Chief Safety and
22 Quality Officer for the Children's Hospital in

1 Boston.

2 So I'm sure that Jeff and others
3 might disagree. I'm not suggesting that the
4 methodology used by STS and their sister
5 organization in Europe, the EACTS, is not also
6 widely used, but they all have required
7 participation in registries.

8 In the United States there was a
9 survey that was done by a group of pediatric
10 cardiologists about what was the preferable
11 methodology, and three-quarters of the survey
12 respondents actually chose the RACS
13 methodology in the United States. The
14 methodology has been used in South America.

15 It's being used in a large -- in a
16 very large developing world collaborative
17 which we're doing now for bench marking in
18 developing world countries, and it's been used
19 by the Children's Hospital Corporation of
20 America to generate reports internally across
21 all the large children's hospitals. So I do
22 think that the comment that it's been widely

1 used is real.

2 CO-CHAIR TORCHIANA: So, I don't
3 want to cut off any productive discussion, but
4 it seems like we've arrived at a point where
5 there seems to be pretty strong consensus that
6 these are potentially complementary measures
7 and that the -- asked that we would have
8 ultimately, I think, was just described that
9 it would be great to see, A, the STS measure
10 in the public domain as that evolves and, B,
11 that the two measures be used in a comparative
12 way on registry and clinical data or
13 administrative data to try to work out any
14 kinks or irregularities. Otherwise, I think
15 we're on pretty sound ground here, unless
16 somebody wants to raise another issue.

17 MR. JACOBS: Can I just make one
18 very brief comment about -- first of all, I
19 agree with what you said. I think that's a
20 fantastic plan moving forward, and I just
21 wanted to have the opportunity to put into the
22 record a few facts about the size and scope of

1 the measure that we're proposing and its
2 utilization.

3 So the largest congenital heart
4 surgery database in North America is the STS
5 database. The largest congenital heart
6 surgery database in Europe is the EACTS
7 database, and both of those two large-scale
8 databases have unanimously endorsed the method
9 that we're proposing.

10 Not only that, but when all of the
11 surgeons on the STS Database Task Force were
12 asked which methodology would they prefer to
13 move forward with, all of those surgeons on
14 the STS Database Task Force unanimously chose
15 to endorse the measure that we proposed as a
16 society.

17 Now, that speaks to the size,
18 scope, and support behind our measure, but I
19 do believe that these two approaches are very
20 complementary and are additive, rather than
21 competitive.

22 MEMBER DILLON: The question is

1 still going to be, though, that we still have
2 to narrow this down from three to two. Is
3 that still not the ultimate goal?

4 DR. BURSTIN: I think part of what
5 we heard is that AHRQ and Children's Hospital
6 Boston will have some ongoing discussions, and
7 I think we'll provide you the additional
8 information as that goes forward, and then
9 we'll see whether -- you know, we'll line it
10 all up for you and see if it all makes sense
11 on an upcoming conference call.

12 MS. MURPHY: So, may I just ask a
13 question of the group? Anticipating further
14 discussion on a future conference call based
15 on the fact that, one, you just got some
16 background about how to assess related,
17 competing, and you could say complementary, as
18 well, and you have first heard the discussion
19 of two of these measures, and, as has been
20 pointed out, you have not seen the
21 documentation for two of the measures that
22 you've seen of one, are there materials that

1 you would like to see to help better be
2 informed to come to a point of recommendation
3 of suggestion about how to go forward, and do
4 you have any other questions of the developers
5 that you'd want to have answers to in
6 preparation for a future discussion?

7 CO-CHAIR TORCHIANA: I guess I'd
8 answer that by saying the ideal thing to see
9 would be just a cross-comparison of the two
10 data sets on the same population with whatever
11 level of detail is available.

12 That's a pretty big project, but
13 that obviously would be the most definitive
14 contemporary way to look at the performance of
15 the two data sets and determine to what degree
16 the complement and to what degree they
17 contradict.

18 DR. JENKINS: This is Kathy
19 Jenkins. One of the -- I think the only group
20 that could really do that is probably the STS,
21 because the quoting framework that they used
22 isn't really used by anyone else.

1 MEMBER DUTTON: My request would
2 be simpler. I'd just like to see from the STS
3 the, I guess, the bin size. So, by facility,
4 by category how many cases do they have for a
5 year or two years or three years?

6 MR. JACOBS: That information has
7 actually been published by STS in the Journal
8 of Thoracic and Cardiovascular Surgery, so
9 there's a manuscript that's referenced in the
10 material that was distributed to the group
11 that publishes that exact data.

12 MEMBER DILLON: David, what you're
13 asking for, I think what we would want is, you
14 know, for whatever, a complementary or a year
15 report is for, you know, one, two, and three,
16 which would allow us to compare institution to
17 institution across the different reports. Is
18 that correct?

19 CO-CHAIR TORCHIANA: I think when
20 it comes to competing measures that would
21 obviously be as close as one can get to a gold
22 standard. Now, to what degree that actually

1 identifies the best in breed, I'm not sure,
2 but it is -- it has been done with the AHRQ
3 measures in adult heart surgery against the
4 STS measures, and it's useful information. It
5 gives you an idea of where they coincide and
6 where they diverge.

7 MEMBER DILLON: I would -- I would
8 agree. I think even if they're -- there will
9 be separate reports, but it would allow us as
10 Committee members to look at the type of or
11 how the institutions are reported out and how
12 to correlate those results.

13 CO-CHAIR TORCHIANA: I guess I'd
14 say that's a big project, depending on what
15 time line we're on, and I feel fairly
16 satisfied that these measures should be
17 approved as complementary, but that work
18 really would be very helpful.

19 MEMBER HALPERN: Do we think that
20 the AHRQ and the Children's Hospital should be
21 essentially one?

22 DR. JENKINS: I just want to

1 remind everyone that the Children's Hospital
2 measure was proposed for administrative and
3 non-administrative data, as it was originally
4 validated.

5 MR. ROMANO: There are some
6 procedures that National Quality Forum has, I
7 think, with regard to the identification of
8 measure stewards and how we would establish a
9 co-stewardship that I think would have to be
10 worked out.

11 I can't speak for the agency on
12 that particular issue, because there would
13 have to be a specific agreement by which we
14 would have joint responsibility for
15 maintaining the measure and for keeping NQF
16 up-to-date with respect to new evidence about
17 the measure and changes in the indicator
18 specification.

19 One of the disadvantages of
20 administrative database measures is that the
21 definitions have to be reexamined every year
22 as new ICD-9 CM codes are introduced or

1 removed. We're also looking forward to
2 conversion to ICD-10 CM in October 2013, so
3 all of these measures that use codes will have
4 to be respecified, and there will be a lot of
5 ongoing dialogue with NQF about that process.

6 So, in any case, we're happy to
7 work with NQF and with Dr. Jenkins and her
8 colleagues to bring these into a single
9 measure, recognizing that there may be some
10 temporal issues associated with the sort of
11 legal issues and working out the software
12 compatibility.

13 MEMBER KLEINPELL: I guess I have
14 more of a general question. It's not related
15 to these three measures specifically, but as
16 we move forward, when a measure developer is
17 submitting a new measure that may be a
18 competing measure, are they required to submit
19 a rationale for why they're submitting it?
20 Otherwise, we're just going to see a
21 proliferation, I think, of measures being
22 submitted and having to make decisions.

1 DR. BURSTIN: Yes, actually, our
2 updated measure submission form requires as a
3 condition of submission that you've looked in
4 the NQF portfolio, you have identified what
5 else there is, and, in fact, we're going to be
6 -- we're actually going to have the advantage
7 of being able to announce projects
8 significantly in advance of the due dates.

9 We will actually expect by the
10 time it's submitted to us that the developers
11 would have done the work of looking and
12 harmonizing this. As you guys know, it just
13 takes a long time, and doing it in the course
14 of a project just delays things significantly.

15 We're also going to try to, as
16 much as possible, let everybody else know
17 we're working on some pipeline things, as
18 well, so people can go, we hope, ultimately
19 somewhere to be able to say, "These are the
20 developers who are working in my space," and
21 try to, as much as possible, work
22 collaboratively.

1 MEMBER HALPERN: Is there any move
2 to make a global database that everybody can
3 access various data pieces that fulfill
4 everybody's need? Do you understand what I'm
5 saying?

6 DR. BURSTIN: I'm not sure I know
7 what data pieces are.

8 MEMBER HALPERN: Like a huge
9 registry, basically, a huge registry of data
10 that --

11 DR. BURSTIN: Of measures or of
12 data?

13 MEMBER HALPERN: That everybody
14 can, you know, use based on what everybody's
15 needs are so that, you know, everybody is --
16 because the thing that keeps coming up is that
17 everybody's data points are slightly
18 different.

19 DR. BURSTIN: There is some of
20 that work going on as part of the work NQF and
21 others have been doing on something called the
22 Quality Data Model, where they have been

1 trying to identify the key data elements that
2 would populate electronic health records in
3 particular, and we hope registries, to be able
4 to ultimately do quality measures that we know
5 we need and want.

6 Part of that will ultimately be,
7 and there is still some work being done to
8 figure out where this will reside within HHS,
9 of who would be the code set owners, which I
10 think is part of what you're trying to get at.

11 So if they're identifying these
12 procedures this way, can somebody kind of take
13 that same list the next time they're
14 developing measures so it's not this constant
15 churning of figuring that out? That's really
16 just starting.

17 There is some interesting work --
18 actually, Patrick probably knows some of this
19 -- funded through AHRQ, actually, by a group
20 called USHIK, U-S-H-I-K, which actually does
21 pull together a lot of the existing data and
22 data sets to help do that.

1 MEMBER HALPERN: So are they
2 involving the societies of the various --
3 because what keeps coming up from the
4 different societies or the different
5 specialties is that we on the clinical side
6 view things a little bit differently than
7 those on the administrative side, so, you
8 know, to blend those two sides together in
9 terms of a -- you know, again, the idea is to,
10 one, make quality better and also to be able
11 to give to the patient something that they can
12 view and understand.

13 DR. BURSTIN: Certainly on the EHR
14 side a lot of that is happening. There is
15 significant outreach to try to figure out what
16 are those data elements that would be
17 incorporated into EHRs going forward, but it's
18 just beginning.

19 MEMBER MORTON: There is a
20 movement afoot about trying to harmonize all
21 the different surgical specialties, Surgery
22 Quality Alliance, and have been meeting for I

1 think almost five years now in the hopes of
2 creating, you know, a unified surgical
3 database. Efforts have not been fruitful to
4 date in terms of getting a single data set
5 out.

6 MEMBER DUTTON: AHRQ is working on
7 a registry of patient registries right now
8 that would look like -- seriously,
9 ClinicalTrials.gov.

10 MEMBER MORTON: Department of
11 Redundancy Department?

12 MEMBER DUTTON: That would list
13 all both quality management and research
14 databases that existed. It's at the white
15 paper stage right now, so they really haven't
16 gotten very far, but the idea would be you
17 could drill into it, see what elements each
18 registry is collecting, and see what data is
19 out there.

20 DR. BURSTIN: And there are some
21 great international examples like Sweden,
22 where they actually have sort of done the

1 registry of registries that pulls it together.
2 That would be lovely.

3 MEMBER HALPERN: Sweden has that
4 massive database, and anybody can use, and
5 they have like hundreds of data elements, so
6 each society can pull from it and get whatever
7 information that they want.

8 CO-CHAIR TORCHIANA: Sure. All
9 you need is the Swedish health system with a
10 single government payer, and we're there. I
11 think we've completed that agenda topic.

12 I'd like to thank our developers,
13 and I think we can move on to the next topic
14 on the agenda. So that would be NQF
15 member/public comment if anyone is on the
16 phone. Is there anyone on the phone and
17 muted, as there was yesterday? We're a little
18 early, I guess. Okay, we'll go to Melinda for
19 next steps and time line.

20 MS. MURPHY: So, Alexis and I
21 talked a bit earlier, and what we believe is
22 that based on the fact that there is some

1 information that you wanted to have back
2 regarding some of the measures that were
3 discussed, that we need to get that collated,
4 get it out to the developers, let them provide
5 the information back, much as was done with
6 Phase I, and give you the opportunity to
7 review and react to whether or not the
8 information that's provided meets your
9 specifications, your conditions, and do that
10 as step one in a conference call and then soon
11 thereafter follow up with a second conference
12 call to have the discussion about related and
13 competing measures, related and competing
14 measures from Phase II, and we can close out
15 the discussion on the one that you've just
16 begun.

17 So we will have to get you
18 cleaned-up versions of that table with related
19 and competing that you looked at a bit
20 earlier, so that will be the second of two
21 conference calls the way that we've talked
22 about in terms of volume of material to be

1 covered to do, and we'll get out to you a
2 request about time availability to do that in
3 two calls. So that's next steps.

4 CO-CHAIR MORRIS: All right. So
5 just, in closing, I'd like to say thanks so
6 much for all of your hard work and attention.
7 I think everybody really contributed
8 substantially to the meeting, and, of course,
9 we're not really done yet, so there's more
10 coming. I'd like basically to applaud the
11 Committee for all of the hard work and also
12 the NQF staff.

13 DR. BURSTIN: And I would like to
14 thank everybody for your patience with NQF
15 processes and evolution here. We are trying
16 to make it a stronger process, and we have
17 been doing a little bit of flying it while --
18 what's that expression? Building it while
19 flying it, so thank you for your input, and
20 thanks to our Chairs for the great effort.

21 (Whereupon, the foregoing matter
22 was adjourned at 2:31 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript


In the matter of: Surgery Endorsement
Steering Committee

Before: NQF

Date: 05-05-11

Place: Washington, DC

was duly recorded and accurately transcribed under
my direction; further, that said transcript is a
true and accurate record of the proceedings.



Court Reporter

NEAL R. GROSS

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