

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

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THURSDAY
DECEMBER 15, 2011

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The Steering Committee met, at
9:30 a.m., at the National Quality Forum
Conference Center, 1030 15th Street, N.W., 9th
Floor, Washington, D.C., Pamela Cipriano and
William Conway, Co-Chairs, presiding.

PRESENT:

PAMELA CIPRIANO, PhD, RNA, NEA-BC, FAA,
Co-Chair

WILLIAM CONWAY, MD, Co-Chair

JASON ADELMAN, MD, MS, Montefiore Medical
Center

CHARLOTTE ALEXANDER, MD, Memorial Hermann
Healthcare System

JOHN CLARKE, MD, FACS, Drexel University
College of Medicine

JEAN de LEON, MD, Baylor Specialty Hospital

VALLIRE HOOPER, PhD, RN, CPAN, FAAN, Mission
Hospital

CAROL KEMPER, PhD, RN, CPHQ, Children's Mercy
Hospital

STEPHEN LAWLESS, MD, MBA, Nemours Foundation

LISA MCGIFFERT, Consumers Union

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

SUSAN MOFFATT-BRUCE, MD, PhD, The Ohio State

University

LISA MOORES, MD, Uniformed Health Services
University

PRESENT(Cont'd):

JANET NAGAMINE, MD, BSN, Permanente Medical
Group (via phone)

LOUISE PROBST, MBA, BSN, St. Louis Area
Business Health Coalition

PATRICIA QUIGLEY, PhD, MPH, ARNP, FAAN,
Department of Veterans Affairs

MARY SIEGGREEN, MSN, APRN, Detroit Medical
Center

JIM SMITH, PT, DPT, Utica College

IONA THRAEN, MSW, Utah Department of Health

TRACY WANG, MPH, Wellpoint, Inc.

SAUL WEINGART, MD, PhD, MPP, Dana-Farber
Cancer Institute

RICHARD WHITE, MD, University of California
Davis

NQF STAFF:

HEIDI BOSSLEY, MSN, MBA, Vice President,
Performance Measures

AKINLUWA DEMEHIN

KAREN JOHNSON

JESSE PINES, MD, MBA, MSCE

ANDREW LYZENGA

JESSICA WEBER

ALSO PRESENT:

DAWN ALAYON, NCQA

JOHN BOTT, Agency for Healthcare Research
and Quality

DALE BRATZLER, The Joint Commission

JEFFREY GEPPERT, Agency for Healthcare
Research and Quality

ERIN GIOVANNETTI, NCQA

JEREMY GOTTLICH, NCQA

EMILY GRAHAM, American College of Emergency
Physicians

DENISE KRUSENOSKI, The Joint Commission

BOB REHM, NCQA

GARY REZEK, Quality Insights of Pennsylvania

PATRICK ROMANO, Agency for Healthcare

Research and Quality

KORYN RUBIN, American Association of
Neurological Surgeons

ALSO PRESENT(Cont'd):

DAVID SHAPIRO, ASC Quality Collaboration

DONNA SLOSBURG, ASC Quality Collaboration

HEATHER SMITH, American Physical Therapy

Association

ARJUN VENKATESH, American College of

Emergency Physicians

ANN WATT, The Joint Commission

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

8:38 a.m.

CO-CHAIR CONWAY: (presiding) Why don't we start with a round of introductions?

I am Bill Conway.

In the introduction, just give some description of what you do and say something interesting about yourself.

(Laughter.)

So, I am the Chief Quality Officer for the Henry Ford Health System. I'm a physician.

I have five daughters and have spent a fortune on shoes.

(Laughter.)

CO-CHAIR CIPRIANO: Good morning. It is a real pleasure to be here with all of you.

I am Pam Cipriano. I am currently on faculty at the University of Virginia School of Nursing, having just completed a year at the Institute of Medicine as the Nurse

1 Scholar-in-Residence, working primarily on
2 health information technology and safety and
3 quality measures at the Office of the National
4 Coordinator for Health IT.

5 I don't know if I can top the
6 shoes, but probably my passion in life has
7 nothing to do with healthcare -- well, sort of
8 maybe indirectly -- but I love to cook and
9 have always spent many, many days in the
10 kitchen, have always cooked for my family, but
11 learned most of that from my immigrant
12 grandmother, who lived with us when I was
13 young. So, I have been able to carry on a lot
14 of the Italian traditions in my family.

15 MEMBER LAWLESS: I am Steve
16 Lawless. I am the Vice President of Quality
17 and Safety for the Nemours Foundation, a not-
18 for-profit pediatric multi-specialty group.
19 My venue is risk management, infection
20 control, quality, risk, and other things as
21 assigned.

22 I guess my interesting facet is I

1 am a diehard Yankee fan, and I still can't to
2 this day believe that Albert Pujols got past
3 the Steinbrenners.

4 (Laughter.)

5 MEMBER WEINGART: I'm Saul
6 Weingart. I am an internist, and I am Vice
7 President of Quality and Patient Safety at
8 Dana-Farber Cancer Institute in Boston.

9 I don't have many interesting
10 things to report. I have to reach pretty
11 deep. I did play the tuba for a brief period
12 toward the end of high school, but not since.

13 (Laughter.)

14 MEMBER ADELMAN: Jason Adelman. I
15 am the Patient Safety Officer at Montefiore
16 Medical Center in the Bronx, right down the
17 block from the Yankees. I am physician,
18 internal medicine.

19 Thank you.

20 MEMBER SIEGGREEN: My name is Mary
21 Sieggreen. I am an Advanced Practice Nurse at
22 the Detroit Medical Center, just a short walk

1 away from Henry Ford, and I am a Board member
2 of the National Pressure Ulcer Advisory Panel.

3 I don't have a whole lot of things
4 that would be interesting to you. My favorite
5 things, I guess, are my family. I have two
6 daughters. One is an automotive engineer.
7 What else from Detroit, right? And the other
8 one is a curator at the Detroit Zoo.

9 MEMBER MICHALEK: Good morning,
10 everybody.

11 I'm Chris Michalek. I work with
12 the Institute for Safe Medication Practices,
13 where I am a Medication Safety Specialist. I
14 am a pharmacist by background. I have worked
15 with ISMP for many years, just recently coming
16 over full-time with them. And prior to that,
17 I was Director of Pharmacy at Lehigh Valley
18 Health Network in Pennsylvania.

19 An interesting fact about me is I
20 am a big sports fan of any sports team that
21 plays in Philadelphia, which is hard to do
22 right now.

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(Laughter.)

MEMBER PROBST: I'm Louise Probst, the Executive Director of the St. Louis Area Business Health Coalition. Like other coalitions, we work with employers on issues of quality and affordability of healthcare.

I am a nurse by training. My favorite as a nurse was the Administrator of the Medical Services in Yellowstone, where I got to live for seven years, do pre-hospital care.

MEMBER MCGIFFERT: Hi. I'm Lisa McGiffert with Consumers Union Safe Patient Project. We work with grassroots individuals and organizations around the country to try to improve patient safety.

Just a couple of months ago, I documented my trip across Greece by doing tai chi in all the major places, like the Parthenon and Meteora, where there are monasteries, and the islands.

MEMBER WHITE: I'm Rich White.

1 I'm from UC-Davis. I'm the Chief of General
2 Medicine, and I direct the Anticoagulation
3 Service at UC-Davis. So, I am involved in
4 anticoagulation in a hospital and out in the
5 clinics. We are working now with other UCs to
6 institute means of monitoring prophylaxis
7 using downloaded reports out of the electronic
8 medical record.

9 My claim to fame is I frequently
10 call in very sick whenever it is snowing up in
11 the mountains. I invariably get this disease
12 called "the runs" and can't make it to work.

13 (Laughter.)

14 MEMBER MOORES: Hi. My name is
15 Lisa Moores. I am a pulmonary and critical
16 care doc in the Army at the new Walter Reed
17 National Military Medical Center here in town.

18 My real day job currently, though,
19 is I am the Assistant Dean for Clinical
20 Sciences. I manage all the third- and fourth-
21 year students at the Uniformed Services
22 University.

1 You might tell from my uniform I
2 am an Army fan. So, this weekend was a bit
3 frustrating. My son is a second-year cadet at
4 West Point. So, at least I got to spend the
5 day with him. I'll take that.

6 MEMBER CLARKE: Hi. My name is
7 John Clarke. I am a Professor of Surgery at
8 Drexel University in Philadelphia, and I am
9 the Clinical Director of the Pennsylvania
10 Patient Safety Reporting System, which
11 collects about a thousand reports of medical
12 errors every day. We have about 1.5 to 2
13 million reports in our database, including a
14 large number of complications.

15 And as far as interesting facts, I
16 am writing a novel for my 11-year-old
17 daughter.

18 MEMBER WANG: Hi. Good morning,
19 everyone.

20 I am Tracy Wang. I am Clinical
21 Research Manager with WellPoint. I am in the
22 public health policy area. I lead patient

1 safety efforts throughout the enterprise and
2 have been working pretty closely with the
3 Statewide Patient Safety Collaborative in
4 California.

5 I am a worship leader at church.
6 So, sometimes I do fill in as a drummer and
7 pianist as well.

8 MEMBER QUIGLEY: Thank you.

9 Good morning, everyone.

10 I'm Pat Quigley, and I am a nurse
11 scientist and a nurse practitioner with the
12 Department of Veterans Affairs from Tampa,
13 Florida. We have a Patient Safety Center
14 there in a Research Center of Excellence for
15 Rehabilitation Outcomes. And I am here on
16 behalf of the American Nurses Association, who
17 put my name forward, I am just honored to say.

18 And to share with you, my husband
19 and I have three adopted boys, and our three
20 adopted boys are rescue basset hounds.

21 (Laughter.)

22 So, we are absolutely engaged in

1 rescue basset hounds in the Suncoast Basset
2 Rescue. So, through them, we have three
3 orphans who found a home forever.

4 MEMBER HOOPER: Hi. I'm Vallire
5 Hooper. I am the Manager of Nursing Research
6 for Mission Health Systems in Asheville, North
7 Carolina. And I am a perianesthesia nurse by
8 trade.

9 And probably the most interesting
10 thing about me, which freaks my husband out,
11 is when I was a junior and senior in high
12 school, I drove a school bus. Because if you
13 had good grades in high school, you could
14 actually drive a school bus, which always
15 freaks my husband out.

16 (Laughter.)

17 But, anyway, I used to drive a
18 school bus.

19 MEMBER KEMPER: Hi. I am Carol
20 Kemper from Kansas City, Missouri. I am a
21 nurse by background and work at the Children's
22 Hospital there, Children's Mercy in Kansas

1 City. And I am the Senior Director for
2 Quality and Safety in the Center for Clinical
3 Effectiveness. And so, we are focusing on
4 evidence-based practice and health outcomes
5 and quality and patient safety throughout the
6 organization.

7 And an interesting thing is I just
8 got back from China, and it was just thrilling
9 today to not have to boil water before I
10 brushed my teeth.

11 (Laughter.)

12 MEMBER SMITH: Good morning.

13 I am Jim Smith. I am a Professor
14 of Physical Therapy at Utica College in
15 Upstate New York. And the American Physical
16 Therapy Association has specialty sections.
17 We have an Acute Care Section. I am the
18 president of that organization.

19 And my interesting fact is,
20 similar in some ways to Dr. White, except when
21 that snow melts, I get on it as whitewater.
22 I am hoping on our June trip to have more

1 flexibility in my schedule coming in because
2 between Upstate New York and here there's lots
3 of whitewater; I can go paddle and have some
4 fun. I say "June trip" only because I saw the
5 tentative schedule for a future meeting.

6 (Laughter.)

7 MEMBER ALEXANDER: Good morning.

8 I'm Charlotte Alexander. I'm from
9 Houston, Texas. I'm an orthopedic hand
10 surgeon, and I chair the Quality Committee for
11 the Memorial Hermann Healthcare System, which
12 is a large system we have in Houston.

13 I have four children. Only one is
14 a doc. She is pediatric EMT. The youngest
15 one has no fear; just finished a year in
16 Mongolia, has moved to Beijing. Doesn't have
17 a job yet, is looking for one.

18 (Laughter.)

19 And hopefully, he will be off the
20 payroll pretty soon.

21 MEMBER MOFFATT-BRUCE: Good
22 morning.

1 I'm Susan Moffatt-Bruce. I'm a
2 cardiothoracic surgeon. I practice at the
3 Ohio State University. And about 18 months
4 ago, I was anointed as the Chief Quality and
5 Patient Safety Officer for the Healthcare
6 System.

7 At that time, I also took up
8 marathon running because it is somewhat akin
9 to my current responsibilities and enjoy that
10 very much.

11 MEMBER THRAEN: Good morning.

12 My name is Iona Thraen, and I am
13 impressed by the brain power and the quality
14 of folks sitting in this room. I am a lowly
15 MSW.

16 However, I will say that, as of
17 this month, I am finishing a Ph.D. in
18 biomedical informatics at the U. So, I feel
19 like I am catching up; I'm a slow bloomer --
20 what do you call it? -- a late bloomer.

21 And my daughter came down from New
22 York City last night, and I got to see her all

1 of about two hours last night when she came in
2 and is off to Virginia for a job-related
3 event. So, I am here to travel up to New York
4 City on Friday to see her and spend the
5 weekend for Christmas.

6 Thank you.

7 MS. WEBER: I'm Jessica Weber.
8 I'm a Project Analyst in the Performance
9 Measures Department at NQF.

10 Okay. My interesting fact will be
11 I went to Thailand in September for a week,
12 and, yes, it was a great vacation, really
13 interesting.

14 MS. BOSSLEY: I'm Heidi Bossley,
15 Vice President of Performance Measures,
16 filling in as the Senior Director until Jesse
17 Pines actually joins us. Well, Jesse will
18 introduce himself as well.

19 My interesting fact is I am a
20 twin. So, there is another one of me out
21 there, for better or for worse.

22 (Laughter.)

1 MR. LYZENGA: Hi. I'm Andrew
2 Lyzenga. I am a Project Manager in
3 Performance Measures at NQF.

4 I'll just play off Jessica's trip.
5 I just went to Vietnam pretty recently as a
6 honeymoon. I also just got married a few
7 months ago.

8 CO-CHAIR CIPRIANO: Janet, can you
9 introduce yourself?

10 MEMBER NAGAMINE: Sure. Good
11 morning, everyone.

12 I'm Janet Nagamine. I am trained
13 as both a nurse and a physician. I started
14 out as an ICU nurse and went back to medical
15 school. I am currently a practicing
16 hospitalist at Kaiser Santa Clara in
17 California. And within Kaiser, I have done
18 patient safety work, both at the local and
19 regional, I guess as well as some of the
20 national programs.

21 And I am a Board member for the
22 Society of Hospital Medicine and actively

1 involved in their National Quality and Safety
2 Initiatives as well.

3 Interesting facts: like John, I
4 am working on documenting for my 8-year-old
5 daughter. I am working on a documentary about
6 my father, or her grandfather, and he was a
7 lost soldier in China.

8 So, Charlotte, I want to hire your
9 daughter to start doing some research for me
10 in China.

11 DR. PINES: Hi. I'm Jesse Pines.
12 I'm an emergency physician and health services
13 researcher at George Washington University,
14 right in town here. I am also the Director of
15 the Center for Healthcare Quality and very
16 excited to be coming on, on a part-time
17 capacity, starting next month. I am going to
18 be working on this project specifically.

19 An interesting fact: that we have
20 two very small children at home, 3 and 1 and
21 a half, and a third on the way. So, we are
22 very busy.

1 (Laughter.)

2 DR. VENKATESH: Hi. I'm Arjun
3 Venkatesh, down from Boston from Brigham and
4 Women's and Mass General. I am here on behalf
5 of the American College of Emergency
6 Physicians.

7 MS. SLOSBURG: Good morning.

8 I'm Donna Slosburg with the ASC
9 Quality Collaboration.

10 Do you want interesting facts
11 about us? I love to scuba dive.

12 MS. KRUSENOSKI: Good morning.

13 I am Denise Krusenoski, a nurse
14 with the Joint Commission.

15 My interesting fact is I once swam
16 in shark-infested water.

17 DR. BRATZLER: Hi. Dale Bratzler.
18 I am a professor at the University of Oklahoma
19 Health Sciences Center.

20 I used to drive a fire truck.

21 MS. WATT: I'm Ann Watt -- good
22 morning -- from the Joint Commission.

1 I don't really think there is
2 anything particularly interesting about me.

3 MR. BOTT: John Bott. I work
4 under contract with the AHRQ. I just got back
5 from the Galapagos, and swimming with the sea
6 lions was the highlight, I think.

7 DR. ROMANO: I am Patrick Romano
8 from the University of California, Davis, in
9 Sacramento. I am here on behalf of AHRQ.

10 MS. SMITH: Heather Smith. I'm
11 with the American Physical Therapy
12 Association.

13 MR. REHM: Hi. I'm Bob Rehm. I'm
14 the Assistant Vice President for Performance
15 Measures at NCQA.

16 And I'm sorry I'm late, but
17 between my scooter and the Metro, I didn't
18 quite get here quickly enough.

19 Interesting thing: I used to be a
20 whale and dolphin trainer.

21 MR. GOTTLICH: I'm Jeremy
22 Gottlich, a Senior Analyst at NCQA.

1 I guess the first sport I ever
2 learned to play was cricket.

3 DR. GIOVANNETTI: Erin
4 Giovannetti, a research scientist in geriatric
5 performance measures at NCQA. And this is my
6 second week of work.

7 MS. ALAYON: I'm Dawn Alayon. I
8 am a Senior Healthcare Analyst at NCQA. I,
9 too, am from Florida, but I am a strange
10 Floridian who never liked the beach.

11 MS. BOSSLEY: So, this is always
12 the fun part of the day. We are going to ask
13 you to do some disclosure, just for the
14 Committee members.

15 Just a reminder, you are here as
16 an individual. You may have been nominated by
17 an organization, but, again, you are here for
18 your expertise in methodology, et cetera. We
19 would ask you to disclose anything that you
20 think would be relevant to the work of this
21 Committee. It doesn't necessarily have to be
22 financial in nature.

1 You may not have anything, and
2 that is perfectly fine if you say you don't
3 have anything. But anything that you did
4 disclose perhaps on the form that you think
5 should be at least known to your Committee
6 member, we would ask that you do that now.

7 So, should we start with the
8 Chairs? Yes.

9 CO-CHAIR CONWAY: I have none to
10 report.

11 CO-CHAIR CIPRIANO: I have none to
12 report.

13 MEMBER LAWLESS: None to report.

14 MEMBER WEINGART: I'm on a Board
15 of Governors with the National Patient Safety
16 Foundation. It is a non-fiduciary role.

17 MEMBER ADELMAN: None to report.

18 MEMBER SIEGGREEN: I have nothing
19 to report.

20 MEMBER MICHALEK: Nothing to
21 report.

22 MEMBER PROBST: Nothing to report.

1 MEMBER MCGIFFERT: Nothing to
2 report except that I am a shameless advocate
3 for consumers. That will become evident.

4 (Laughter.)

5 MEMBER WHITE: I have no relevant
6 disclosures.

7 MEMBER MOORES: I have no
8 financial. I will say I am the immediate past
9 Chair of the Quality Improvement Committee at
10 the American College of Chest Physicians.

11 MEMBER CLARKE: I receive funding
12 for running the State Patient Safety Program,
13 and I sit on numerous advisory committees for
14 WHO, AHRQ, et cetera.

15 MEMBER WANG: I have nothing to
16 report.

17 MEMBER QUIGLEY: I have nothing to
18 report.

19 MEMBER HOOPER: I have no
20 financial report, but I am the editor for the
21 Journal of PeriAnesthesia Nursing.

22 MEMBER KEMPER: I have nothing to

1 report.

2 MEMBER SMITH: Nothing to report.

3 MEMBER ADELMAN: Nothing to
4 report.

5 MEMBER MOFFATT-BRUCE: I have
6 nothing to report.

7 MEMBER THRAEN: Nothing here.

8 MS. BOSSLEY: Janet?

9 MEMBER NAGAMINE: No disclosures.

10 MS. BOSSLEY: Okay. We ask this
11 every time. Is there anything that your other
12 members have said that you would like to
13 discuss further?

14 (No response.)

15 Usually it's no. That's fine.

16 Okay. Thank you.

17 Okay. So, why don't we run
18 through, I think, quickly -- Andrew, oh, you
19 do have it up. Okay.

20 You went through an orientation
21 previously, and the Workgroups have been
22 meeting. So, we are not going to spend a lot

1 of time. But I just wanted to give you a
2 sense of what we will do today.

3 First, we will ask the developers
4 to provide any context on their measures.
5 During that initial discussion, we will give
6 them roughly five minutes, if they would like
7 to explain it.

8 Then, we will turn it over to the
9 individual who was assigned the measure to
10 provide a brief overall summary of how you
11 believe the measure did or did not meet the
12 criteria.

13 The Workgroups went through the
14 individual subcriteria. So, for importance,
15 you discuss the impact, the opportunity for
16 improvement, and the evidence. Here, we are
17 going to ask you to summarize that briefly.
18 Then, we will open it up for discussion across
19 the Committee.

20 But when it comes to voting, we
21 will actually just ask you to vote on the
22 overall criteria. So, you will do yes/no on

1 importance; yes/no on scientific
2 acceptability, usability, and feasibility.

3 Just a reminder of the criteria,
4 the first one is importance. That is, again,
5 high impact, opportunity for improvement, and,
6 also, evidence. And the evidence piece,
7 again, depending on whether it is an outcome
8 or a process measure, we will walk you through
9 that as a reminder.

10 But outcomes, we are looking for
11 rationale. For process, we are looking for
12 information on the quality, quantity, and
13 consistency of the evidence. So, again, all
14 three of those subcriteria must be met in
15 order to pass importance.

16 If the measure then passes
17 importance, you move on to scientific
18 acceptability, which is, again, is the measure
19 precisely specified so that anyone who really
20 wants to use the measure has the information
21 they need to be able to do that. Is it
22 reliable and valid?

1 And then, usability again, is it
2 useful for quality improvement and
3 accountability? And then, last, but not least
4 is the feasibility piece.

5 So, again, I am not going to go
6 through it specifically because you have been
7 through it a few times, but are there any
8 questions or anything you want to talk about
9 specifically related to the criteria? We can
10 also do it as we are going through the
11 measures.

12 (No response.)

13 Okay. Normally, we don't have
14 Workgroups meet before, so we spend more time
15 on the criteria, but I don't think we need to
16 this time. Okay.

17 All right. Would we like to start
18 on the first measure set? Okay.

19 CO-CHAIR CIPRIANO: Okay. So, we
20 are going to start with the VTE measures.

21 And, Heidi, I think what you said, we would
22 first ask our measure developer?

1 MS. BOSSLEY: Yes.

2 CO-CHAIR CIPRIANO: Okay. So,
3 these first four measures are Joint Commission
4 measures. And so, we would ask if there is
5 any comment that the measure developer would
6 like to make.

7 Maybe we will start with No. 0371.

8 Before you start, let me just ask,
9 for the members on this Workgroup, since Mark
10 is not here, does anyone who was on that
11 Workgroup have information specifically about
12 it? Was there any discussion about who might
13 present on behalf of the Workgroup?

14 (No response.)

15 Okay. We won't worry about that.

16 All right, go ahead, please.

17 DR. BRATZLER: Good morning.

18 Dale Bratzler. I am representing
19 the Joint Commission today on these measures.

20 Just a very brief background, I
21 had the pleasure of co-chairing the Technical
22 Advisory Committee along with Joe Caprini back

1 when these measures were originally developed,
2 actually, an NQF project at that time.

3 So, venous thromboembolic disease
4 is still far too common, still far too common
5 in hospitalized patients, and is a known
6 complication of hospital care. Indeed, when
7 you look at patients who die of pulmonary
8 embolism, the vast majority of those patients
9 have been hospitalized in the recent past.

10 So, we think the measure set is
11 very important and the datasets demonstrate
12 that there is remaining opportunity for
13 improvement. DVT prophylaxis is
14 underutilized. And we also know from data
15 that we have from hospitals that treatment
16 protocols are not consistently followed.

17 So, that is a very brief
18 background on the measures. And so, this is
19 a comprehensive measure set of six measures
20 that focus on both prevention and treatment of
21 venous thromboembolic disease. And I will
22 certainly be happy, as we move along through

1 the individual measures, to help provide the
2 rationale from the conversations of both the
3 Technical Advisory Panel and the Steering
4 Committee that endorsed these measures a
5 number of years ago.

6 CO-CHAIR CIPRIANO: Okay. Thank
7 you.

8 So, we will go measure-by-measure.
9 And like I said, what we would typically do is
10 have our subgroup person speak to the
11 different criteria. But maybe if we move to
12 0371, and are we trying to put that on the
13 screen?

14 All of a sudden, mine is blank, my
15 file. Do you have the same thing? Yes, mine
16 is blank. Is yours blank? That's what I
17 downloaded.

18 Lisa, would you be comfortable
19 walking through this measure, in addition to
20 0373?

21 MEMBER MCGIFFERT: Who me?

22 CO-CHAIR CIPRIANO: No.

1 You can take a quick look at it is
2 as we are pulling it up. Lisa Moores?

3 MEMBER THRAEN: I have a question
4 about protocol. In terms of having questions
5 about it, do you want to wait until the full
6 walk-through or during, or how do you want to
7 handle that, if you have clarification
8 questions?

9 CO-CHAIR CIPRIANO: I think we
10 will have each person present one measure.
11 And then, after they have done their summary,
12 then we will take questions.

13 MEMBER McGIFFERT: And is there a
14 way that we could have sort of a large
15 discussion of these before we would start.

16 CO-CHAIR CIPRIANO: Of this group
17 of measures?

18 MEMBER McGIFFERT: Yes.

19 CO-CHAIR CIPRIANO: The six
20 measures?

21 MEMBER McGIFFERT: All the groups.
22 I think all of these are being reevaluated,

1 right? And they are endorsed. I don't know.
2 Maybe not all of them, but most of them have
3 been?

4 CO-CHAIR CIPRIANO: Yes, those are
5 maintenance measures.

6 MEMBER McGIFFERT: And my
7 understanding is that we are evaluating these
8 for the purposes of public reporting. I may
9 be wrong about that. There may be other
10 purposes. But, generally, I think that is why
11 we are looking at it.

12 I think that we should have a
13 discussion about the value of process measures
14 in public reporting. We basically feel that
15 we should be focusing on outcome measures.
16 However, I think there is some definite value
17 of endorsing the specifics of measures for
18 providers to use internally to improve care.
19 But for public reporting, I think it might be
20 a good to have a conversation about whether we
21 want to keep going down this path of focusing
22 on process measures.

1 MS. BOSSLEY: I will give a little
2 context from the NQF perspective perhaps, and
3 then I think it is a worth you all having a
4 conversation about this.

5 The ultimate goal is, I think for
6 the most part, to have measures that are
7 publicly reported, but there is a continuum on
8 heading toward that, I think. And so, when we
9 view it, we look to see if a measure is useful
10 for, first of all, quality improvement and
11 also for accountability. Again, I will find
12 a slide, if I can, and project it at some
13 point to give you a sense of what we are
14 thinking.

15 So, we are looking at anywhere
16 from quality improvement with benchmarking,
17 perhaps maintenance of certification used for
18 accreditation, to the point of used for
19 payment programs and then, ultimately, public
20 reporting. And a measure could actually be
21 anywhere within that continuum. So, that is
22 the first thing, I think, because, Lisa, you

1 started talking, really addressing the
2 usability.

3 The other piece, though, too, is
4 we have not said that we don't want to endorse
5 process measures. Our preference, I think, is
6 to outcome measures. But if we do endorse a
7 process measure, it should be closely proximal
8 to the outcome. So, you don't want the
9 measures that are more distal, perhaps
10 something that looks at -- I think a good
11 example one of our committees looked at was
12 prophylaxis ordered. You want to at least
13 look at prophylaxis provided.

14 And so, that is what I think you
15 want to take a look at, the measures you have
16 under consideration. You may give preference
17 to the outcome measures. You may actually see
18 that there is need and there is use for the
19 process measures as well.

20 So, again, I think it is we have a
21 preference perhaps, but not necessarily
22 something that says one over the other. But

1 I think that is part of what you need to look
2 at here. Many of these measures are under
3 maintenance. They have been out in use for
4 quite a while. Is there still need for them?
5 Are you better with the outcome or is there
6 still need for the process measures? I think
7 those are the things that you need to weigh
8 today.

9 CO-CHAIR CIPRIANO: Maybe if I
10 could add to that, I sit on the Consensus
11 Standards Approval Committee. And so, a very
12 similar discussion has occurred at that
13 Committee.

14 I think that, given where we are
15 with the number of measures that exist today
16 and, as you very clearly stated, many, many of
17 them are process measures, not inclusive of
18 the kinds of outcomes that we would like to
19 measure.

20 So, I think we are in a transition
21 phase where we are dealing with a universe of
22 measures that are so relevant, but perhaps

1 there continues to be a pretty high degree of
2 desire that more outcome-based measures get
3 developed, and including the composite
4 measures we have, but, then, also, new
5 measures.

6 So, some of those measures are
7 under development through contracts from CMS.
8 And so, we anticipate more measures coming
9 forward in the next year. As you know, the
10 timeline for measure development with
11 different groups is pretty lengthy.

12 So, right now, we are staying true
13 to the process of measure maintenance. And
14 then, as these measures work their way
15 forward, I mean, some groups, not so much the
16 Patient Safety, but some of the other more
17 specialty-focused groups, we are seeing more
18 and more measures being retired.

19 So, I think you can have
20 confidence that, again, other groups are
21 having a similar discussion about, if we have
22 reached complete saturation with no more

1 opportunity for improvement or perceive very,
2 very little opportunity, then those measures
3 are being retired.

4 So, again, I would sense that we
5 are pretty much in a transition. There has
6 been a stated expectation that measures be
7 much more outcome-oriented in the future.

8 MS. BOSSLEY: If you would put
9 your name card up like this when you would
10 like to speak, and then, this way, we can
11 clearly identify you and try to keep track of
12 the order.

13 MEMBER WHITE: So, for the process
14 measurement for venous thrombosis prophylaxis,
15 I think a problem some of us have is it is
16 easy enough if something is given, but the
17 definition is variable from hospital to
18 hospital as to what constitutes, quote,
19 "effective prophylaxis", and different
20 guidelines come up with different suggestions
21 as to what is effective prophylaxis. So,
22 really, you don't have a measure that is

1 comparable between hospitals.

2 I could create a risk model that
3 said 85 percent of my patients do not need
4 prophylaxis. I will follow the ACP guidelines
5 that just came out that say the doctors can
6 make that judgment on their own and
7 prophylaxis is only required in high-risk
8 patients.

9 So, you've got a nice measures,
10 yes; I put them on prophylaxis or not, but it
11 varies amongst every institution according to
12 what is deemed to be appropriate prophylaxis.
13 One person may put on mechanical. Another one
14 may say, "I don't like those. I like foot
15 pumps." And somebody else says, "I don't like
16 foot pumps. I just like heparin."

17 You know, that's the problem, I
18 think, is that the process measure isn't
19 uniform in terms of the quality and the type
20 of prophylaxis that may be administered.

21 CO-CHAIR CIPRIANO: John?

22 MEMBER CLARKE: When I looked at

1 the process measures, I am not enthusiastic
2 about process measures that are authority-
3 based or opinion-based, consensus-based. But
4 if a process measure has an evidence-based
5 relationship with an outcome, I think it is
6 perfectly valid to have a process measure.

7 And in fact, I would argue that in some
8 instances where the outcomes, presumably, if
9 they follow practice are negligible, I mean,
10 that is, there is no adverse events, then you
11 really only have the process measures as an
12 indication of whether people, in fact, are
13 providing best practice or just being lucky.

14 So, I think I evaluated these in
15 terms of, is this process measure just
16 something off the top of someone's head or is
17 this process measure based on something that
18 we know is valid.

19 And DVT is an excellent example.
20 If the processes are being done in a way which
21 we know is valid, I think they are perfectly
22 good process measures. But if they are being

1 done the way Richard described them, they are
2 totally arbitrary and worthless.

3 MEMBER NAGAMINE: Heidi, this is
4 Janet. Can I make a comment?

5 MS. BOSSLEY: Yes. Please go
6 ahead.

7 MEMBER NAGAMINE: Yes. So, I
8 would want to tag onto the conversation about
9 process measures. I would say that there are
10 many things that are good ideas, but is there
11 evidence that it impacts outcome is the
12 question.

13 And then, I just wanted to add
14 that, if we are going to look at process
15 measures, I think we move more towards
16 prospective audits where like, for example,
17 the prophylaxis, we are looking at it when the
18 patient is in the hospital. And we can still
19 audit our performance: did they or did they
20 not have prophylaxis? Did they or did they
21 not have adequate prophylaxis? And then, have
22 a mechanism, if they didn't have prophylaxis,

1 make it that they get it. So, that you are
2 impacting care rather than retrospectively
3 saying, "We didn't perform very well."

4 Thank you.

5 CO-CHAIR CIPRIANO: Okay. Thank
6 you.

7 In the back, from the Joint
8 Commission.

9 DR. BRATZLER: Thank you.

10 I realize I am not a member of the
11 panel. So, I certainly defer to the panel.

12 So, I have been involved in both
13 the development of process and outcome
14 measures now for quite a number of years. I
15 think, as we talk about measures today, we can
16 take other examples. The vast majority of the
17 measures that are submitted have an evidence
18 base behind them that suggests that, if you do
19 these things correctly, you will get better
20 outcomes.

21 I think one thing that has
22 happened recently that we are starting to look

1 at very carefully now is that there have been
2 a lot of these papers that have been published
3 trying to take data off of things like
4 Hospital Compare on how individual hospitals
5 are performing on process care measures. And
6 they haven't been able to predict patient
7 outcomes in a variety of studies. You have
8 seen it for AMI, heart failure, pneumonia,
9 surgical care.

10 I think you have to be very, very
11 cautious looking at those papers because there
12 are some fundamental problems with many of
13 those studies that have been done, the big one
14 being that recognize that, when you create a
15 process measure, by definition, you have to
16 define a population that is eligible for that
17 measure. But many of these papers that are
18 looking at patient outcomes are looking at
19 all-cause events or the entire population of
20 patients and not accounting for all of the
21 patients who aren't eligible for the
22 performance measure.

1 So, we have looked at numerous
2 topics now, surgery, AMI, heart failure. We
3 find that patients who aren't eligible for
4 these process-of-care measures have much, much
5 worse outcomes very consistently across all of
6 the topics we have looked at.

7 So, you just have to be cautious
8 in interpreting some of it. There has been a
9 lot of press lately about the current process
10 measurement system not defining outcomes for
11 patients or you can't predict hospital
12 outcomes. But we just have to be cautious
13 looking at that data because that is not what
14 these process-of-care measures were designed
15 to do, to predict outcomes at the level of the
16 hospital.

17 And to the points that Rich made,
18 I understand the point about the adequacy of
19 prophylaxis or the appropriateness. We have
20 talked about those things when we had the
21 technical -- so, let's just take VTE-1, which
22 is prevention of, VTE prophylaxis,

1 essentially, for hospitalized patients. We do
2 have some limited parameters of minimum
3 effectiveness. So, in other words, we know
4 there was gaming of measures in the past. And
5 so, we won't capture a dose of a
6 unfractionated heparin of less than 5,000
7 units. We define some of that in the
8 specifications for the actual performance
9 measure.

10 But if I try from afar, as a
11 process-of-care measure developer, to define
12 what the clinician does at the bedside,
13 recognizing the patient may have multiple
14 medical problems, chronic renal insufficiency,
15 I can't define dosing and stuff without
16 capturing a lot of data that makes the data
17 collection completely unreasonable.

18 Now I just looked at data. So, I
19 am going to use VTE-1 as an example.
20 Recognizing volunteer groups of hospitals
21 report this measure -- it is not nationally
22 reported yet -- CMS has defined it, has

1 suggested that it would be reported starting
2 in January 2013. But a volunteer group of
3 hospitals that have been submitting it had a
4 rate of performance on the measure of 68
5 percent at baseline. And I suspect that
6 nationally, when it gets rolled out by CMS,
7 assuming it is re-endorsed, rates of
8 performance are going to be much, much lower.

9 So, while I will agree that we may
10 not look necessarily at adequacy of
11 prophylaxis, there's a lot of patients that
12 aren't getting anything or aren't being
13 assessed for their risk at all. I think that
14 is primarily what we decided to focus on with
15 this particular performance measure. Is
16 somebody thinking about risk of VTE when a
17 patient comes into the hospital? Recognize
18 that lots of patients in the hospital are at
19 risk of these events.

20 So, this measure is not perfect.
21 None of our measures are perfect. But that is
22 the focus, is somebody thinking about risk,

1 somebody assessing the patient, and if they
2 are at risk, are they giving them prophylaxis,
3 some form of prophylaxis, recognizing we don't
4 have a perfect measure?

5 CO-CHAIR CIPRIANO: Iona?

6 MEMBER THRAEN: This is going to
7 be a shift in topic. So, I want to make sure
8 everybody is done before I make a comment.

9 CO-CHAIR CIPRIANO: Okay.

10 MEMBER THRAEN: Okay. And this is
11 maybe for future reference, but I just want to
12 bring it out now. Under the data source that
13 has been identified for these particular
14 measures, and it is common across all of the
15 measures, I would ask that either NQF or the
16 vendors consider identifying the specific
17 code, national codes, that they are
18 recommending associated with their particular
19 measure. So that, as we move forward into
20 Meaningful Use, either the ICD-9 codes that
21 they are recommending be used for data sources
22 or the laboratory LOINC codes or the SNOMED

1 codes, whatever it is that is associated with
2 capturing the data associated with those
3 measures, that they begin to include that
4 moving forward.

5 CO-CHAIR CIPRIANO: Okay. So, I
6 think what you are suggesting is that measure
7 developers put forward the electronically-
8 tooled measures.

9 And, Heidi, I guess I would ask if
10 there has been discussion that might guide
11 that. That is almost like a whole other
12 measurement development activity.

13 There is a limited number that has
14 been electronically-retooled by NQF, about 116
15 measures. And as new measures are being
16 developed, many are being developed
17 exclusively as electronically-retooled
18 measures.

19 Maybe, Heidi, if you could comment
20 on any discussion about expectations of
21 measure developers that has occurred?

22 MS. BOSSLEY: Right. So, first of

1 all, as you evaluate the measures, if it is
2 specified for a data source that would require
3 codes, like ICD-9, LOINC, et cetera, they
4 should be provided to you. And if not, we
5 have either not included it in here or we need
6 to get it from the developers. So, that is
7 the first thing.

8 But we do not yet have a
9 requirement that all measures that come
10 forward or the vast majority of measures be
11 specified for electronic health records yet.
12 There's several things that need to occur
13 before we can get to that point.

14 We have had several measures, and
15 I think some of the ones that are before you
16 have been what we are calling retooled. So,
17 they were measures that were previously for
18 paper medical records. They have actually now
19 been respecified to be used in electronic
20 health records.

21 In that instance, again, if we are
22 missing it, we will get it to you. But you

1 should be provided the e-measure, which
2 includes kind of the clinical logic of how you
3 would calculate that measure electronically.
4 It should include the code sets mapped to the
5 quality data model. So, again, giving greater
6 detail on how you would pull that information,
7 where it should be stored in the electronic
8 record, and then pulled out. And then,
9 actually, the fun thing that I can still read,
10 the XML format.

11 So, that should be provided if it
12 has been retooled to date. Developers are
13 also providing that to us from time to time
14 when they are ready. And they are bringing it
15 forward. But we are not yet to the point
16 where we can say that anything that, for
17 example, is paper medical records should come
18 forward with electronic health record
19 specifications.

20 MEMBER THRAEN: The only reason I
21 raised that is because this is a three-year
22 endorsement process. Some of these measures

1 are already being required, preventable
2 conditions, et cetera, et cetera; ICD-9 codes
3 are already being put out there.

4 So, if we approve it in its
5 current form, it is going to be another three
6 years before --

7 MS. BOSSLEY: Perhaps, but
8 probably not. So, what will happen as well is
9 we have an annual update process. So, anytime
10 a measure is not within maintenance, we ask
11 the developers to provide updates on coding,
12 specifications, et cetera. If at that point,
13 for example, if it was used for Meaningful Use
14 or something, we would actually ask them to
15 bring in that e-measure specification to us.
16 We would review it, probably would not require
17 a full review.

18 But there's no reason to say that
19 it would take three years to get that in. It
20 might, but for the most part I would say for
21 a lot of these measures I expect it may happen
22 faster.

1 CO-CHAIR CIPRIANO: Yes, Iona, I
2 would say that I think we definitely
3 appreciate the recommendation because right
4 now it does limit the universe of measures
5 that can be selected for programs like
6 Meaningful Use.

7 So, are there any additional
8 general comments about the six measures? We
9 have got four right ahead of us, but there was
10 a total of six in the VTE prophylaxis group.
11 Are there any additional comments of the
12 Workgroup on general terms about the
13 discussion about the process that you went
14 through before we move, then, to each
15 individual measure?

16 (No response.)

17 Okay. So, are we ready to start
18 with Measure 0371? And if you have electronic
19 spreadsheet that was sent around last night,
20 right -- that's the one we should be using --
21 which has the composite of your votes, then we
22 can quickly look across the tally for each of

1 the criteria. I said for this first measure
2 we don't have a specific spokesperson, but we
3 can look at the individual ratings and decide
4 whether or not the group is ready to support
5 an action on this particular measure.

6 So, maybe if we just walk through
7 this first one as a group -- and is there
8 anyone having difficulty getting the numbers?
9 If your eyes are good to see the screen, they
10 are posted on the screen over there.

11 All right. So, under the measures
12 of importance, it is almost all "H's", so
13 high, in terms of those criteria.

14 Is there evidence to support?

15 Yes.

16 I have to switch back and forth
17 here.

18 As we look at usability, again,
19 almost exclusively "H's" except for 4b. Let
20 me see what 4b is. Scroll down.

21 Okay. Are the data elements
22 needed for the measure as specified available

1 electronically?

2 And 4c is "Susceptibility to
3 inaccuracy, errors, or unintended consequences
4 of the measurement identified during testing
5 and/or operational use and strategies to
6 prevent, minimize, or detect...."

7 So, there is a little variability
8 in that section.

9 And if we look at the last two
10 columns, again, a fairly high consensus in
11 terms of feasibility, and then on suitability
12 all but one vote.

13 Richard?

14 MEMBER WHITE: So, how does the
15 Joint Commission, when they look at this, what
16 do they use for their guidelines for the use
17 in a specific hospital? I mean, does the
18 hospital have to provide a risk model and say
19 I have low risk, intermediate risk, high risk,
20 and did they get what they term the
21 appropriate prophylaxis? Or using some
22 national guidelines?

1 Again, to my way of looking at it,
2 it is a question of validity. I might have a
3 very easy risk model and just put everyone on
4 mechanical prophylaxis and say, as far as I am
5 concerned, that is the way the literature
6 goes. And it would be out of level of
7 acceptance for most of the hospitals, and
8 other ones may be very aggressive.

9 So, I would like a little
10 clarification.

11 DR. BRATZLER: So, the way the
12 performance measure is structured, we had
13 many, many conversations about the need for
14 risk assessment. As you know, my Co-Chair has
15 been a proponent of risk assessment for VTE,
16 Joe Caprini, for many years.

17 But at the time that we developed
18 the performance measure, and I actually would
19 argue that even today there are not well-
20 validated risk-adjustment models out there to
21 determine whether or not does a person with 10
22 points versus 5 points have a greater risk of

1 VTE. It has just not been clinically-
2 validated.

3 So, we developed the performance
4 measure that basically to either prophylaxis
5 or documentation of why the patient did not
6 get prophylaxis. Now if you look in the
7 details of the specification, the details of
8 the specification actually allow the hospital
9 to use a developed risk assessment form to
10 make that determination of whether or not the
11 patient needs prophylaxis.

12 So, if they have a form that they
13 use and the physician -- or we also allow
14 documentation by the nurse, the APN, the
15 advanced practice nurse, PA, or the
16 pharmacist -- if they use some type of a
17 standard protocol and they determine that the
18 patient is at low risk and doesn't need
19 prophylaxis, that passes the performance
20 measure.

21 Again, here the primary focus was
22 to make the hospital think about VTE at the

1 time that a patient is admitted. They either
2 give prophylaxis or they document in the
3 medical record why the patient doesn't need
4 prophylaxis, and that can be through risk
5 assessment. But we don't specify what that is
6 because I am not sure what I would recommend.

7 I think Greg Maynard's work is an
8 example of something that has worked well and
9 is simple, and I really promote it a lot. But
10 is it clinically-valid? I don't know yet.

11 MEMBER WHITE: So, that is the
12 problem. In the stroke study in England, they
13 put on graded compression stockings and they
14 had actually worse outcomes, more skin
15 breakdown, et cetera. And ACP now advises
16 against the use of graded compression
17 stockings.

18 But, then, experts could say,
19 "Well, they put on TED hose and they don't
20 have a measure gradient, and there might have
21 been too high of pressure at the knee and not
22 enough at the ankle, and that is what caused

1 the problem." So, now we are down to the
2 brand and the type, and none of these are
3 specified really.

4 I mean, to me, that is the real
5 issue. It is kind of a little game. I mean,
6 you could put down that you could put some
7 kind of foot pump on everybody and say you've
8 got a risk model and that's what it is, and
9 someone else in another hospital says, "In my
10 opinion, that is ineffective," in that you
11 score well with the process measure because it
12 fit your risk model.

13 So, that is my only problem with
14 this whole thing, that we don't have those
15 validated risk-assessment tools --

16 DR. BRATZLER: That's true.

17 MEMBER WHITE: -- and the
18 elucidated best, optimal prophylaxis, and yet
19 we are measuring it in everyone.

20 DR. BRATZLER: Right. So, I would
21 agree, we don't have validated risk
22 assessment. And that is why this is actually

1 a measure set. Because as we get to the end
2 of the measure set, the potentially
3 preventable, then we start looking at, okay,
4 who was a patient that developed the VTE in
5 the hospital and wasn't present on admission?
6 Here the goal is to have a little rate, and
7 you would assume that, if the patient is at
8 higher risk, the hospitals are thinking about
9 the use of adequate prophylaxis.

10 And so, that is actually one of
11 the reasons we paired these measures, because
12 the last measure, VTE-6, looks at, is the risk
13 assessment that the hospital is using
14 sufficient? Are they identifying the high-
15 risk patients that are more likely to need
16 prophylaxis and giving it?

17 So, I completely agree. But,
18 again, Rich, I think the fundamental problem
19 is still in U.S. hospitals, and you probably
20 know well as me that a lot of patients don't
21 get anything or aren't assessed at all.
22 People just don't think about it.

1 And there is some good work out
2 there where people have done it, but, like I
3 say, a group of hospitals that volunteered,
4 you know, 35-36 percent of the patients had no
5 assessment of risk and did not get prophylaxis
6 at all.

7 MEMBER WHITE: Well, let's just do
8 one acid test. So, let's say in my hospital
9 I say that aspirin is effective and I write it
10 in my guidelines, and everyone gets aspirin.
11 And no one else in the United States believes
12 it is effective. Do I have a good performance
13 measure? Is that allowable?

14 DR. BRATZLER: It would fail
15 because we actually exclude the aspirin. It
16 is not acceptable in the performance measure
17 specifications.

18 So, we look at either mechanical
19 prophylaxis or pharmacologic prophylaxis, and
20 it has to be unfractionated heparin, one of
21 the low molecular weights or one of the
22 thrombin inhibitors on the paranox or

1 warfarin. But we do not, the specifications
2 do not allow aspirin.

3 MEMBER WHITE: Is that list in our
4 specifications here of acceptable prophylaxis?
5 I must have missed it.

6 DR. BRATZLER: We could pull up
7 the specific data element, but aspirin is
8 explicitly excluded.

9 CO-CHAIR CIPRIANO: Okay, let me
10 go ahead. We have got a number of speakers
11 lined up. We have Pat, Lisa, Jason, and
12 Vallire.

13 So, Pat, let me go ahead with you.

14 MEMBER QUIGLEY: Thank you, Pam.

15 My comments are very different
16 than the clinical relevance and
17 appropriateness. So, Pam, my comments are
18 related to my rating of scientific
19 acceptability of the measure. So, it was a
20 different section, and I just needed a little
21 bit of clarification.

22 I actually had rated this as

1 medium because there were some very good staff
2 comments. I apologize at the document that I
3 have here that I downloaded because Andrew
4 gave me the flash drive, so I don't have the
5 staff comments on them. I have them actually
6 on my files at work. I can access through
7 VPN.

8 But my question is, how very
9 specific do the actual measurement criteria
10 have to be? Because there were questions that
11 staff had raised about, was all the
12 measurement information relayed there in terms
13 of defining of episode of care -- I think it
14 was -- and the age criteria, other kinds of
15 things?

16 Even like, you know, for the
17 denominator, it says all discharged patients,
18 but in other sections it says all discharged
19 patients but with a whole series of exclusion
20 criteria.

21 So, in terms of a performance
22 measure, I think the staff input has just been

1 invaluable as they reviewed this for us, but
2 I just didn't know how clear this really has
3 to be.

4 So, my comments and my questions
5 are really very different than the clinical
6 relevance of the measure. So, I apologize if
7 I was out of context.

8 CO-CHAIR CIPRIANO: Let me ask if
9 Heidi or Andrew have a --

10 MR. LYZENGA: I don't have a copy
11 that I can pull up right now.

12 MEMBER QUIGLEY: Well, those
13 comments were raised in several of the
14 indicators that we received.

15 CO-CHAIR CIPRIANO: And Pat and
16 others in the Workgroup, then, do you feel
17 that the composite ratings that we have,
18 though, have taken into consideration your
19 previous deliberations from the Workgroup
20 discussion?

21 MEMBER QUIGLEY: Yes.

22 CO-CHAIR CIPRIANO: Okay.

1 MEMBER QUIGLEY: But my question
2 was really related to the clarity, once this
3 really gets adopted, you know, the clarity of
4 the measure that is used by everybody.

5 So, thank you.

6 CO-CHAIR CIPRIANO: And again, I
7 think NQF staff typically will provide
8 interpretation and clarity for anyone trying
9 to use the measure, and they give feedback to
10 the measure developer.

11 MEMBER QUIGLEY: Thank you.

12 CO-CHAIR CIPRIANO: Okay. Lisa?

13 MEMBER MCGIFFERT: Well, I was
14 wondering if there's information in here -- I
15 couldn't find it in most of them about, these
16 have all been used for quite some time. In
17 the introduction, there was some discussion
18 about do we need to maintain them or have we
19 already reached the point where everybody is
20 doing this. I think that is what was said.
21 At least, that is what I heard.

22 And so, I am wondering if we have

1 any information about is this being measured
2 -- let's see, I saw somewhere where it has
3 been used. The requirement of participation
4 in the ORYX Initiative, but I think this
5 measure is out there. Is it on Hospital
6 Compare?

7 DR. BRATZLER: No, it's not.

8 MEMBER McGIFFERT: No, it's not?

9 DR. BRATZLER: No, it's not.

10 MEMBER McGIFFERT: Okay.

11 DR. BRATZLER: And so far, it has
12 only been used voluntarily by --

13 MEMBER McGIFFERT: Okay.

14 DR. BRATZLER: -- Joint-
15 Commission-accredited hospitals that have
16 wanted to use it through their ORYX
17 Initiative. But CMS has defined this measure
18 set for national implementation for January
19 2013 discharges, where it then would go on
20 Hospital Compare. But it has not been used
21 nationally.

22 MEMBER McGIFFERT: Okay.

1 DR. BRATZLER: So, we think there
2 this is still a great opportunity for
3 improvement.

4 CO-CHAIR CIPRIANO: Okay. Jason?
5 I'm sorry, Jason (referring to the Operator),
6 we have a Jason Committee member. So, this is
7 Jason Adelman.

8 MEMBER ADELMAN: Thanks.

9 I wanted to weigh-in on the
10 earlier conversation about the difference
11 between the accuracy and appropriateness of
12 the DVT prophylaxis and just the fact that it
13 is addressed.

14 But I have seen the issue
15 clinically at my own institution about the
16 lack of DVT prophylaxis being addressed. It
17 was mentioned in one of the references I
18 mentioned, the ENDORSE survey, where there was
19 also a major gap.

20 And I see an analogy of simple
21 immunization, where the appropriateness is not
22 really an issue. It is just it often doesn't

1 get done. And so, I do see the value in
2 simply keeping track if DVT prophylaxis is
3 addressed and not getting into the clinical
4 appropriateness. I mean, we are far away, I
5 think, from looking at the appropriateness of
6 antibiotics and other treatments in any sort
7 of real way, but I do think we can push the
8 point of addressing something as simple and I
9 believe, and it was shown, often overlooked as
10 DVT prophylaxis.

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

13 Vallire?

14 MEMBER HOOPER: In listening to
15 the conversations, I guess it seems that there
16 is much consensus regarding the need for risk
17 assessment. And of course, we want to move
18 toward outcome.

19 But I agree that there just seems
20 to be a lot of issues with what is appropriate
21 prophylaxis. I will preface with this is not
22 my area of expertise, but it seems that the

1 evidence is mixed regarding what is
2 appropriate prophylaxis. So that, in and of
3 itself, seems to be problematic from a quality
4 measurement perspective.

5 I agree that it seems that there
6 is great consensus that there needs to be risk
7 assessment. And then, if we have a measure of
8 the actual outcome, does unintended VTE occur,
9 it seems that what we do for prophylaxis at
10 this point the evidence seems quite mixed.
11 And so, I would think it would be difficult to
12 measure.

13 Thank you.

14 CO-CHAIR CIPRIANO: Again, I guess
15 I would ask, Dale, if you have any comment to
16 that?

17 DR. BRATZLER: Well, so our
18 Committee, when we were meeting, talked a
19 great deal about the whole risk assessment.
20 So, I am going to push back a bit and say that
21 some people believe that, if you are in the
22 hospital, you are at risk. Because, frankly,

1 look around hospitals today. We don't admit
2 very many fully ambulatory, healthy people
3 anymore. They are all managed in the
4 outpatient setting. Most people in the
5 hospital are at risk.

6 And so, some centers have
7 addressed VTE prophylaxis by exception. You
8 know, it is the rule unless the patient can
9 clearly be defined as somebody that doesn't
10 need prophylaxis. And that is somewhat of the
11 approach the Committee took, was that the
12 majority of patients that are sick enough to
13 be hospitalized today probably need to be on
14 some form of VTE prophylaxis, though I can't
15 define what is best, and I certainly can't
16 define at the bedside, recognizing there are
17 many nuances that will make the clinician at
18 the bedside decide mechanical prophylaxis
19 versus various forms of pharmacologic
20 prophylaxis and all the other decisionmaking
21 points.

22 So, we took the position that

1 either the patient should be on prophylaxis or
2 there should be some form of a risk assessment
3 or documentation by the physician that it is
4 not needed. But we weren't going to put
5 ourselves between the clinician and the
6 patient and the bedside. And that is the way
7 we defined the metric.

8 CO-CHAIR CIPRIANO: Okay. Thank
9 you.

10 Jason Adelman again.

11 MEMBER ADELMAN: Sorry. I just
12 wanted one other thing. The idea of the
13 evidence around DVT prophylaxis, you know, I
14 think Dr. White, really this is his expertise.
15 But my understanding, Dr. Clarke made a point
16 earlier that the better process measures are
17 ones where there is really good evidence
18 behind them.

19 As far as DVT prophylaxis, there
20 is the ACCP guidelines, which I have looked at
21 extensively. There's like 700 references.
22 They have recommendations for many, many

1 different kinds of diseases. If somebody
2 comes in and they fracture their hip versus an
3 elective hip replacement, and then each
4 recommendation is graded based on those 700
5 references. Some of them would meet Dr.
6 Clarke's criteria of really well-evidence-
7 based and randomized controlled trials and
8 others lean more towards expert opinion.

9 But it is not like we have no idea
10 what we are doing. There are lots of pretty
11 good guidelines out there with a lot of
12 evidence. We are not just starting from
13 scratch.

14 MEMBER NAGAMINE: Heidi, this is
15 Janet. I would like to comment when you're
16 ready.

17 CO-CHAIR CIPRIANO: Janet, go
18 ahead.

19 MEMBER NAGAMINE: All right. So,
20 I just wanted to summarize a few thoughts. I
21 have spoken at great length with Greg Maynard
22 about this. This prophylaxis measure, does it

1 make sense to keep track of how we are doing?

2 Absolutely.

3 And just a few points or comments
4 that may help strengthen the measure. In the
5 absence of a validated risk tool, I think
6 measuring adequacy of prophylaxis is going to
7 be difficult. That said, it is one of the
8 sort of criticisms of this measure.

9 But it all depends on how high you
10 want to set the bar. And my feeling is you
11 have got to start somewhere, and especially
12 until we come up with a validated risk tool
13 that looks specifically at the risk of
14 bleeding, because that is what we don't
15 want -- we don't want everyone to be
16 prophylaxed and bleed. That happens in
17 specific populations, the renal patients, the
18 older patients. So, we don't want to cause
19 harm by trying to prevent a VTE, either.

20 The other thing is that the ACP
21 guidelines that just came out November 1st
22 definitely lean, it sort of it pulls back

1 saying that you've really got to assess risk
2 before you prophylax. And we also have the
3 ACCP-9 guidelines that are anticipated to come
4 out in February of 2012.

5 So, does it make sense or in this
6 process is it possible to hold off on this
7 measure until the new guidelines come out, is
8 one question.

9 And then, the other point was what
10 I made earlier about encouraging real-time
11 assessment of prophylaxis while patients are
12 in the hospital, so that we can intervene of
13 they are getting prophylaxis.

14 So, those were our big comments on
15 this.

16 CO-CHAIR CIPRIANO: Okay. Thank
17 you.

18 Richard? And then Lisa.

19 MEMBER WHITE: I will second that,
20 the last set of comments. I think we should
21 be spending as much time looking at the list
22 of acceptable modalities of prophylaxis as we

1 are whether or not someone gets it.

2 Lisa just brought up the list.

3 And it is acceptable just to pull on a set of
4 TED hose, and you are giving acceptable
5 prophylaxis, even to your high-risk patient,
6 which, to my way of looking at it, there is no
7 evidence.

8 So, again, I think we need a match
9 between the level of prophylaxis given and the
10 risk. And again, we don't have those risk
11 models.

12 And we have this problem of the
13 ACP now saying, really, if you are low-risk,
14 you are actually putting the patient at risk
15 for bleeding if you put them on prophylaxis.

16 So, just somehow this measure
17 ought to incorporate or add on some kind of
18 risk model with a set of recommended
19 modalities. I mean, at UC-Davis we put
20 everyone on prophylaxis. So, don't get me
21 wrong; I am not a non-believer. Everybody
22 gets it. But that is easy to measure. But in

1 other places I don't know what their risk-
2 assessment tool is and what they are putting
3 the patient on.

4 CO-CHAIR CIPRIANO: Lisa?

5 MEMBER MOORES: So, Dale, I guess
6 the thing that I am struggling with is I heard
7 you say that you are pairing VTE-1 and -6.
8 So, some way to look at whether, whatever my
9 interpretation of risk assessment or adequate
10 prophylaxis is, does it translate to the
11 number of preventable VTEs? I think there are
12 some issues with that measure that we will get
13 to. But I understand that process, and that
14 sort of makes sense to me.

15 But stepping back from that, I am
16 still grappling with what Rich is saying. I
17 am a big proponent as well. As you know, I
18 sort of had to debate against Joe about
19 whether we should do risk assessment, and I
20 took the stance not to because it is just
21 validated. I think AT-9 is going to confuse
22 this even further.

1 And so, I just don't know whether
2 the process measure means something to me
3 across -- like we said, what does it really
4 mean unless it is absolutely every time looked
5 at in the same light as the number of
6 potentially preventable VTEs that you had,
7 because, otherwise, it means nothing, except
8 for the fact that, as we have all said, we
9 agree there's a gap.

10 I mean, if you look across any
11 type of study and any type of national look or
12 international, we are just pitiful in terms of
13 looking at the risk and giving prophylaxis of
14 any type. So, I agree that there is a gap,
15 but I just don't know if this process measure
16 is going to address that gap as much as maybe
17 focusing on VTE-6 alone.

18 DR. BRATZLER: So, I mean, I
19 understand all those points and they were all
20 discussed at length. If I knew, Rich, how to
21 design data collection that, if we had
22 validated risk assessment so I could say,

1 "Yes, Clinician, on that particular patient,
2 you should always use low molecular weight
3 heparin for prophylaxis," then we could. But
4 the data collection was simply unreasonable.

5 And again, it inserts us, as a
6 major developer, in between the clinician at
7 the bedside and their patients. We have had
8 to be very careful about that.

9 Clearly, this measure addresses
10 prophylaxis risk assessment. That is what
11 this measure addresses. Are we taking the
12 first step? Is somebody in the hospital, when
13 a patient is admitted to the hospital,
14 thinking about the risk of VTE? And we know
15 that many places are not.

16 So, again, I highlighted upfront
17 it is not a perfect performance measure
18 because we don't look at the adequacy of the
19 prophylaxis they may give.

20 I would actually argue that I
21 don't personally like graduated compression
22 stockings or TED hose as a form of

1 prophylaxis, but there actually is some
2 placebo-controlled data, particularly in
3 surgical populations, not necessarily medical
4 populations, that they have reduced some
5 venographic events. So, I think intermittent
6 pneumatic compression is clearly better than
7 stockings.

8 But, again, I don't know how, as a
9 major developer from afar, to define that for
10 the clinician at the bedside. We think every
11 hospital ought to develop their own protocols
12 and their own risk assessment and their
13 protocols or appropriateness.

14 And in fact, there were two
15 companion documents. I don't know if you
16 remember when NQF did the project there was a
17 policies and best practices document and then
18 there was the performance measures document.
19 And in the policies and best practices, we
20 clearly recommended that every hospital
21 address VTE prophylaxis for all their
22 hospitalized patients by developing

1 standardized policies, as you have done at UC-
2 Davis. We just don't have a performance
3 measure that measures whether you have a
4 policy or not at this point.

5 So, I tell people all the time
6 performance measures are not perfect.
7 Measured perfect performance is not feasible
8 with most performance measures, but we think
9 there is a big gap between the number of
10 patients that come into the hospital that have
11 risk factors and aren't assessed and don't get
12 anything. And that is what the measure
13 addresses.

14 CO-CHAIR CIPRIANO: Okay. We have
15 Saul and Carol, and then I am going to try to
16 summarize where I think we are on this one.

17 MEMBER WEINGART: Thanks.

18 So, I think this is a very
19 valuable conversation because it highlights
20 issues that are going to come up for each of
21 these, each of the next several measures. So,
22 I think it is good that we air that now.

1 I think there are some really
2 critical issues around risk assessment and
3 about what makes adequate thromboprophylaxis.

4 My own take on this, though, is
5 that the perfect is always going to be the
6 enemy of the good, and that we will always be
7 able to make suggestions and recommendations
8 for coming up with a better measure.

9 At the same time, I take this
10 point that there is an enormous performance
11 gap out in the world. My own view is that,
12 given the high ratings on virtually all the
13 criteria, that we ought to just call the
14 question on this in a minute or two and move
15 on, with the proviso that the Committee make
16 a recommendation to the Joint Commission that
17 some of the items discussed in today's
18 deliberations, including the adequacy of
19 thromboprophylaxis with some of the more iffy
20 mechanisms be kind of taken back and reviewed
21 periodically.

22 My understanding is that it is not

1 part of the measure specification and the
2 material we are provided, although the tools
3 are outlined in one of the PDFs that is
4 attached. So, my sense is that that could be
5 periodically updated.

6 Is that correct?

7 DR. BRATZLER: I meant to make
8 that point. Actually, we meet and update all
9 the performance metrics used by the Joint
10 Commission/CMS every six months. And any
11 substantive changes, we always discuss with
12 NQF, but there are constant updates. We are
13 waiting for ACCP-9 before we make any big
14 changes to anything, honestly.

15 MS. BOSSLEY: Can I just add
16 something, too. So, the PDF that is provided
17 to you of the specifications, that is
18 considered part of the measure that is being
19 endorsed. So, that is part, if there are
20 comments/comments on that, but that is what
21 will always be provided if we are asked for
22 it.

1 The other thing I think that may
2 be helpful, we have had the issue before with
3 our Cardiovascular Committee. We are waiting
4 for JNC to come out with their next set of
5 recommendations.

6 Our timing, we can never get it
7 quite perfect. So, what we anticipate with
8 that is, when that comes out, we will actually
9 work with the developers to make sure that the
10 measures that are endorsed are current with
11 the new evidence. We will do the same thing
12 with the ACCP guidelines when they come out.

13 So, it will take a little time
14 because the developers will need to go back
15 and look and see, are there now
16 inconsistencies between what you see from ACP
17 and ACCP? We don't know. But that will be
18 something that we will build into the process.
19 We can do an ad hoc review, if needed.

20 So, just keep that in mind.
21 There's always a process in place to ensure
22 currency. So, you work with what you have

1 now, and we will figure out what to do next
2 when we get there.

3 CO-CHAIR CIPRIANO: Carol?

4 MEMBER KEMPER: I can see from the
5 discussion it seems like there's a lot of
6 value in this type of a measure and just
7 evaluating whether we are recognizing and
8 looking at patients and assessing them and
9 then implementing some type of prophylaxis.

10 And so, I think there is value in
11 knowing how we are doing as an organization.
12 However, I am concerned about with the
13 discussion about the variability and how we
14 are defining prophylaxis and even the
15 population, that if we are going to use this
16 as a comparative measure or for public
17 reporting, how meaningful that is going to be.
18 I think it could be very confusing for
19 patients and families if they are using this
20 to evaluate care. And I worry about how some
21 groups publish this sort of information and
22 compare all of us against each other.

1 CO-CHAIR CIPRIANO: Okay. All
2 right, Lisa?

3 MEMBER MOORES: Just a procedural
4 question because listening to Carol just
5 brought up the issue of I think all of us
6 would agree with this process measure as a
7 quality improvement indicator, absolutely, but
8 as a public reporting? And so, is that
9 something we are voting on today? I mean, are
10 we saying at what level this is appropriate?

11 CO-CHAIR CIPRIANO: No. Our
12 responsibility is just to approve or not
13 approve the measure to continue to exist as an
14 NQF-approved measure.

15 MS. BOSSLEY: Right, but to add,
16 too, you are endorsing this for use beyond
17 quality improvement. We don't endorse
18 measures just for quality improvement. So, it
19 would have to fall within that accountability
20 spectrum. It may not be public reporting,
21 but, again, it would be for use for
22 accountability.

1 MEMBER MOORES: So, what is the
2 mechanism, then, if you endorse a measure that
3 you think has value at some point in the
4 spectrum, but not for comparative public
5 reporting?

6 MS. BOSSLEY: Right. So, we have
7 not, to date, classified the endorsement for
8 what use it should be. I don't think there is
9 any plan to do that.

10 The expectation is that we have a
11 Usability Task Force looking at this right
12 now. So, that is part of, I think -- you are
13 looking at older criteria that, hopefully,
14 will be updated to explain this further.

15 But I think you should feel
16 comfortable that the measure you put forward
17 could be used throughout that accountability
18 spectrum all the way to public reporting.
19 Because when it is out there, we are not the
20 ones responsible for how it is used in that
21 way. You are endorsing it to be appropriate
22 for accountability all the way through public

1 reporting.

2 Am I answering your question?

3 MEMBER MOORES: You are.

4 MS. BOSSLEY: Yes.

5 CO-CHAIR CIPRIANO: Yes, I think,
6 again, we cannot specify use. So, we have a
7 responsibility to have evaluated critically
8 the measure to say it is appropriate for use
9 throughout the spectrum.

10 Lisa, is yours a clarifying
11 question?

12 MEMBER McGIFFERT: Just quick,
13 because there were a couple of comments that
14 mentioned pairing this. We have talked about
15 pairing it with outcome measures. Is there an
16 outcome measure that this is paired with or
17 could be paired with or is related to that is
18 going to maybe make it more meaningful?

19 DR. BRATZLER: The Joint
20 Commission does not have an outcome measure on
21 VTE prophylaxis. This measure, Ann reminded
22 me, is publicly reported for those hospitals

1 that voluntarily submit this data already.

2 And again, the baseline average
3 rate was 68 percent on the measure. I don't
4 know what the range of performance was. If it
5 was at Rich's institution, it is probably 100
6 percent, but that tells me there are
7 institutions that probably had very, very low
8 rates of assessment of the patients for VTE.

9 CO-CHAIR CONWAY: If you notice,
10 we do have a couple of, when we get down to
11 these, 0376 and 0450 look like they would
12 address your issue. They look like they
13 are --

14 MEMBER MICHALEK: Which numbers?

15 CO-CHAIR CONWAY: They are 0376
16 and 0450.

17 CO-CHAIR CIPRIANO: Okay. Louise,
18 is it a comment or question?

19 MEMBER PROBST: I guess it is a
20 comment. I would just like to say that I
21 think, when you get to public reporting, it is
22 very unlikely that a consumer is going to use

1 this measure to really choose the facility, a
2 discrete measure such as that.

3 But public reporting has
4 additional values, and we do know that what
5 gets reported publicly gets improved. And
6 these measures have been out there for a long
7 time, and they are not moving farther fast
8 enough.

9 And so, I would like to say that
10 there's a lot of folks like my group in
11 communities where we sit with hospitals and
12 others and look at these measures and talk
13 about what are the opportunities for
14 improvement across hospitals and across the
15 community.

16 So, I would hate to see us move to
17 not -- I mean, I think NQF's position of not
18 differentiating how the measures are used is
19 really important.

20 CO-CHAIR CIPRIANO: Okay. Iona,
21 and then I would like to see if we can
22 summarize it.

1 MEMBER THRAEN: Actually, it is
2 pretty much the same. I was just going to
3 make the case that by keeping this measure, it
4 keeps the measure on the radar screen. And
5 given the performance gap that has already
6 been identified, that means we get to come
7 back or somebody gets to come back and revisit
8 this in the future to continue to improve the
9 measure itself as the culture begins to adapt
10 and adopt the practice. So, I think that
11 there is value in keeping it on the radar
12 screen.

13 CO-CHAIR CIPRIANO: Okay. Thank
14 you.

15 I am going to take the prerogative
16 of the Chair. We have to at least understand
17 whether or not we are close to making a
18 decision or if there are any other really key
19 things that we have to explore.

20 MEMBER QUIGLEY: A point of
21 information?

22 CO-CHAIR CIPRIANO: Go ahead.

1 MEMBER QUIGLEY: May I ask a
2 question?

3 CO-CHAIR CIPRIANO: Microphone,
4 please.

5 MEMBER QUIGLEY: Thank you, Madam
6 Chair, for that privilege.

7 But it is a point of information.
8 My question is, before we summarize, is this
9 really a process measure or not? You know, it
10 is were they treated or were they not, were
11 they prophylaxed or were they not. It is not
12 if they were assessed, which is process.

13 So, could you just clarify that
14 one in the summary of the comments? Because
15 the numerator was were they treated or were
16 they not.

17 Thank you.

18 CO-CHAIR CIPRIANO: And I guess I
19 am not sure that I can actually make that
20 determination. I mean, we try not to
21 pigeonhole a measure with that kind of
22 descriptor. It is a subjective assessment of

1 the committees that review the measures.

2 So, I think you are absolutely
3 right, there are parts of it that indicate
4 that a particular process was achieved, but it
5 is a yes/no measure of specific intervention.

6 MS. BOSSLEY: Right. I think we
7 would typically call it a process measure
8 because it is not looking at a patient
9 outcome. So, it is not looking at the outcome
10 of care, whether they did have VTE. I would
11 say your outcome measures are more the
12 incidence, 0376, and the 450, looking at
13 whether they actually did develop a VTE or
14 not.

15 This is more the process steps
16 along the continuum to get to the outcome,
17 measuring the outcome. So, there's kind of
18 just the steps. You would assess, then you
19 would treat, et cetera. And we would say this
20 would be process. And I think the Joint
21 Commission has put it forward as a process
22 measure.

1 CO-CHAIR CIPRIANO: Okay. There
2 would appear to be two major issues. One was
3 starting with the discussion about clinical
4 relevance, which I believe led to some very
5 robust discussion about the lack of
6 specificity relative to what the evidence-
7 based interventions ought to be. And I think
8 we understand and recognize that that is not
9 part of this measure because of the
10 variability and because of the need for clear
11 assessment, risk assessment, and assignment,
12 which we have deemed as left up to the care
13 provider in the organization, for however they
14 have defined their approaches to VTE
15 prophylaxis.

16 So, the measure, though, does
17 reinforce the fact that it is a necessary
18 process, but, again, stops short of measuring
19 specific interventions as a preferred set of
20 evidence-based activities.

21 And I think Saul did a nice job of
22 kind of summarizing, as did several others of

1 you, the fact that while there might be a
2 little bit of risk in having this measure out
3 there, if we are thinking about public
4 interpretation of what does it mean, that
5 there is benefit of maintaining a high degree
6 of acknowledgment that it is important that we
7 are, in fact, recognizing that VTE prophylaxis
8 is a very important part of the process of
9 care for a variety of diagnoses and treatment
10 plans.

11 And so, I think the sense that I
12 am getting from the commentary is that, while
13 there are concerns about the potential use of
14 the measure, that there perhaps is a majority
15 of support for saying that we would keep the
16 measure because it reinforces within this set
17 of six that there is a starting point.

18 I think we could also -- and
19 again, I will ask Heidi for her guidance --
20 I think we can also, if we were to approve it,
21 give guidance to the measure developer that we
22 believe that it is important that within the

1 scientific community that there be aggressive
2 work done. And maybe some of this is coming
3 forward in the work that you have mentioned is
4 slated to come out next year, that may, in
5 fact, create measures that are more related to
6 specific interventions, which would, then, at
7 some point render this more generic approach
8 less relevant.

9 So, that being said, again, I am
10 hearing a little bit more consensus on the
11 side of approving it, but that will be
12 determined by your final vote. But I am not
13 sure that there is any other big outstanding
14 issues. Yes, there was a little bit on
15 specifications, which I think the group
16 identified would only come if we had very
17 specific interventions included in the
18 measure.

19 So, were there any other issues
20 that the group wanted to bring forward?

21 Steve?

22 MEMBER LAWLESS: You may have

1 mentioned this or not. Can we re-endorse it,
2 endorse it also as a paired measure with the
3 incidence?

4 MS. BOSSLEY: Yes. So, what you
5 can do -- and I think I need to clarify with
6 Joint Commission -- if you put it forward,
7 then we would have to have the developer agree
8 to this. But you can endorse measures to be
9 paired, where we recommend that they be used
10 together all the time, reported together,
11 separate rates, but used together all the
12 time.

13 So, Ann looks like she wants to
14 say something.

15 MS. WATT: How could you tell?

16 (Laughter.)

17 Hi. I'm Ann from the Joint
18 Commission.

19 As Dr. Bratzler mentioned, this is
20 one of a set of six measures. In Joint
21 Commission's world, hospitals don't have a
22 choice. If they report to us on the VTE

1 measure sets, they report to us on all six of
2 these measures. So, there is no question.
3 Because that is the way we develop measures.

4 We liken it to a jigsaw puzzle,
5 where each one of the measures is a piece of
6 the puzzle, with the hope that you get enough
7 of them together; you take a look at it. The
8 ultimate picture becomes clear. That is our
9 measure development philosophy. You would
10 never see this measure reported in the absence
11 of the other five.

12 CO-CHAIR CIPRIANO: Okay. Any
13 other questions or comments on Measure 0371,
14 which would be part of the measure set? Or do
15 we need a specific recommendation? Okay.

16 (No response.)

17 Okay. Seeing none, I would ask
18 Jessica to instruct us on the voting.

19 MS. WEBER: All right. So,
20 everyone should have an electronic control
21 right now. For the voting, we will have the
22 numbers displayed as 1 equals yes, 2 equals

1 no. For the completely/partially/minimally,
2 it will be up there as numbers as well.

3 You hit the number of your
4 response and press Send. Make sure you point
5 it towards this computer because this is
6 actually where the device is hooked up.

7 There will be a live tally. So,
8 we can stop as soon as we have 20 votes. And
9 you may have to enter your vote more than
10 once, and it should be 60 seconds. So, we can
11 continue.

12 Point it here at the voting.

13 CO-CHAIR CIPRIANO: Jessica, we
14 are going to do a test vote first, is that
15 correct?

16 MS. WEBER: Yes, we will do a
17 test.

18 CO-CHAIR CIPRIANO: And, Janet, we
19 will ask you every time for your vote, and you
20 will just tell us over the phone.

21 MEMBER NAGAMINE: Okay. Thanks.

22 MS. WEBER: All right. So, let's

1 go ahead and try this.

2 Point it towards me and hit the
3 number of your response.

4 CO-CHAIR CIPRIANO: This is just a
5 test one.

6 MS. WEBER: It is just a test.

7 CO-CHAIR CIPRIANO: This is a test
8 one. We won't hold you to this at all.

9 (Whereupon, a test vote was
10 taken.)

11 So, if your green button has gone
12 off, does that mean your vote has been
13 transmitted?

14 MS. WEBER: Yes. And we have 20
15 votes. So, then, we will see a graph of our
16 vote.

17 CO-CHAIR CIPRIANO: Does that make
18 sense to everyone? It's always fun.

19 Okay. So, now we are going to
20 start the actual votes.

21 So, the first one will be on
22 importance. And again, we are going to go

1 through each of the criteria, and then you
2 will have an overall recommendation for the
3 measure.

4 So, give Jessica just a second on
5 this.

6 For those who were on the last
7 Safety Committee, you may have remembered you
8 were the guinea pigs the first time. It
9 didn't work. This is much better, we promise.

10 MS. WEBER: All right. Let's give
11 it a shot.

12 All right. So, we have divided up
13 into subcriteria.

14 For this vote, this will be the
15 importance to measure and report. Are all
16 three subcriteria met, 1a, high impact; 1b,
17 performance gap; 1c, evidence?

18 CO-CHAIR CIPRIANO: So, everyone
19 should be casting their vote.

20 (Whereupon, a vote was taken.)

21 MS. WEBER: We need one more vote.

22 Hit Send.

1 Okay. We have 20.

2 CO-CHAIR CIPRIANO: Janet?

3 MEMBER NAGAMINE: Yes.

4 MS. WEBER: Okay. So, the summary
5 of votes is 20 yes, 1 no.

6 Scientific acceptability, 2a,
7 reliability; 2b, validity.

8 (Whereupon, a vote was taken.)

9 CO-CHAIR CIPRIANO: And Janet,
10 it's yes or no.

11 MEMBER NAGAMINE: Yes.

12 MS. WEBER: Go ahead and cast your
13 votes again. It won't count it twice.

14 The summary of votes is 17 yes, 4
15 no.

16 Usability?

17 MS. BOSSLEY: And this one is the
18 high, moderate, low, insufficient. So, it is
19 not the must-pass. So, it is 1 through 4: 1,
20 high; 2, moderate; 3, low; 4, insufficient
21 information.

22 (Whereupon, a vote was taken.)

1 MS. WEBER: Janet?

2 MEMBER NAGAMINE: I would say mod.

3 MS. WEBER: Okay. Try casting
4 your votes again. We have two more votes.

5 The summary of votes is 3 high, 14
6 moderate, 4 low.

7 Feasibility, 1; high; 2, moderate;
8 3, low; 4, insufficient.

9 (Whereupon, a vote was taken.)

10 MS. BOSSLEY: Janet?

11 MEMBER NAGAMINE: Mod.

12 MS. WEBER: All right. Let's try
13 casting your votes one more time.

14 All right. The summary of votes
15 is 8 high, 10 moderate, 3 low.

16 Overall suitability for
17 endorsement. Does the measure meet all the
18 NQF criteria for endorsement?

19 (Whereupon, a vote was taken.)

20 MS. BOSSLEY: Janet?

21 MEMBER NAGAMINE: Yes.

22 MS. WEBER: Okay. Try casting

1 your votes again. Three more votes needed.

2 Okay. Seventeen yes, 4 no.

3 CO-CHAIR CIPRIANO: Okay. Thank
4 you very much. Pat yourselves on the back.
5 We made it through the first one.

6 (Laughter.)

7 And again, I think very rich
8 discussion. And I think, as was also
9 previously stated, this will, I believe, help
10 us as we look at the remaining measures in
11 this set. I think a number of the issues are
12 relevant.

13 Just for your information, as the
14 recommendations of this group and all of the
15 other subject matter expert groups come
16 forward to the Consensus Standards Approval
17 Committee, all of these individual numbers
18 appear on the information that is seen. So,
19 the CSAC will see that there was not unanimity
20 in every single rating.

21 And so, as the report is
22 presented, there will be questions back to the

1 Chairs saying, "Well, help us understand what
2 that discussion was" or "If you were really
3 mixed on this particular item, help us
4 understand why." So, the details of the
5 information do get look at again and
6 scrutinized by the CSAC before it gets finally
7 approved by them and, then, gets sent forward
8 for final endorsement to the Board.

9 All right.

10 MEMBER NAGAMINE: Heidi, this
11 is --

12 CO-CHAIR CIPRIANO: Is that Janet?

13 MEMBER NAGAMINE: I have a
14 question about deep in the discussion will be
15 incorporated and whether the developer at this
16 time anticipates any modifications to the
17 measure.

18 CO-CHAIR CIPRIANO: Again, we
19 provide guidance back, but there is not an
20 expectation that there is a specific revision
21 to the measure.

22 MEMBER NAGAMINE: Okay. Thank

1 you.

2 CO-CHAIR CIPRIANO: And I guess
3 just to clarify, if we had a major revision,
4 then it would probably mean that we would not
5 be approving the measure. If we had something
6 very minor, it is possible the measure
7 developer could agree to make that minor
8 modification and go forward. But in this
9 case, there is no change that will occur with
10 this first measure.

11 MEMBER NAGAMINE: All right.
12 Thanks.

13 CO-CHAIR CIPRIANO: Sure. Thank
14 you.

15 Okay, Richard, we have Measure
16 0372, intensive care unit VTE prophylaxis.
17 And if you would walk us through the group
18 discussion on that, please?

19 MEMBER WHITE: Well, this is
20 essentially identical to Measure 1, only
21 advocating the assessment of risk or the
22 institution of prophylaxis in patients

1 admitted to an intensive care unit. And
2 there, I think the level of evidence is very
3 high that these patients are at very high risk
4 for developing venous thromboembolism. In our
5 own research, half of all hospital-acquired
6 venous thrombotic events in medical patients
7 are in people who have seen the ICU at
8 sometime during their stay. They also are a
9 group that have higher risk for bleeding. So,
10 it is certainly prudent to risk-assess, but
11 also to institute prophylaxis.

12 Again, I would ask the Joint
13 Commission to refine their list of what
14 constitutes appropriate prophylaxis
15 continuously. But if we were all in agreement
16 on the first, I can't imagine there's any real
17 question about this second measure where we
18 are in a very high-risk population.

19 One issue I have that I didn't
20 bring up with VTE-1 that is interrelated is we
21 have seen a gap in our own hospital of people
22 coming out of the intensive care unit and not

1 getting orders for prophylaxis. So that, for
2 VTE-1 we might also include any admission or
3 transfer to a medical ward, not just hospital
4 admission, because in this measure every time
5 they go to the ICU they have to satisfy this
6 measure, but there's no measure for transfer
7 back to the ward. And it is a gap. We have
8 picked it up at our own institution by virtue
9 of the way the house staff copy orders.

10 So, it is not precisely having to
11 do with this measure, but I will just bring up
12 the problem of transfer out of the ICU may be
13 almost more problematic than transfer into the
14 ICU.

15 I didn't have much more to say. I
16 think, otherwise, the measure is pretty much
17 the same.

18 CO-CHAIR CIPRIANO: Lisa?

19 MEMBER MOORES: So, the question I
20 have -- and maybe Dale or someone can clarify
21 for me, and this is a discussion we have had
22 at the QIC, at the ACCP, a lot as well -- is

1 I am not sure we are tracking why you want to
2 separate out this population and why that
3 wouldn't automatically be covered in VTE-1.

4 DR. BRATZLER: Yes. So, actually,
5 a very good point. So, this measure actually
6 tracks a patient that goes into the ICU at any
7 point during the hospital stay.

8 So, the background for this
9 particular measure was -- most of you may be
10 aware of that NQF has a safe practice that
11 actually calls for hospitalized patients to be
12 periodically reassessed for their risk of VTE
13 events. And so, we had long conversations
14 about how we define this periodic reassessment
15 because there was an interest in developing a
16 measure around this periodic reassessment.

17 And we couldn't really come up
18 with anything except, as Rich pointed out,
19 there was complete agreement if the patient
20 during the stay became sick enough to go to
21 the intensive care unit, that they should be
22 reassessed for their risk, because, as Rich

1 pointed out, the risk is very great in that
2 population. So, that was the genesis of the
3 measure.

4 So, a patient could be eligible
5 for VTE-1 at admission and perhaps made the
6 decision that they didn't need VTE
7 prophylaxis, but, then, four days into the
8 stay, transferred to the ICU. The measure
9 simply says, is the patient reassessed at the
10 time of transfer? I think Rich's point about
11 transfer out of the ICU back to the medical
12 ward is legitimate and one that we will
13 certainly talk about in the future.

14 But that was this whole concept of
15 looking at the periodic reassessment. And
16 this was a population of patients where
17 everybody agreed the risk was high and that,
18 if they are going to the ICU, somebody ought
19 to be thinking about it again.

20 CO-CHAIR CIPRIANO: Any others?
21 Steve?

22 MEMBER LAWLESS: When you are

1 reporting them from the Joint Commission and
2 you are putting these measures together, do
3 you get partial credit? If you have been on
4 prophylaxis at any time, is that a yes or does
5 it have to be continuous?

6 MS. WATT: I'm not sure that I
7 understand.

8 MEMBER LAWLESS: The patient has
9 been on prophylaxis on the floor, goes to the
10 ICU, is taken off, or whatever, and then put
11 back on, or back onto the floor, or assessed
12 for it, or during the ICU stay has been on for
13 a short period of time and then off.

14 MS. WATT: Measure 1 or the one
15 that we just discussed looked at patients on
16 the day of admission or the day after
17 admission. This measure looks at patients on
18 the day of admission to ICU or on the day
19 after, and those are the only times that are
20 looked at.

21 If I am understanding you
22 correctly, do we say did they meet the one and

1 not the ICU?

2 MEMBER LAWLESS: But on the day of
3 admission --

4 MS. WATT: Yes?

5 MEMBER LAWLESS: -- were they on
6 it? So, then, on the second day, so on the
7 day of admission coming from somewhere else.
8 Does it give the full sense that the ICU
9 doctors weren't necessarily up-to-speed by
10 using prophylaxis whereas they were still in
11 the 24-hour assessment stage versus it was two
12 days later they used the prophylaxis?

13 MS. WATT: It is the day of or the
14 day after admission to the ICU. That is what
15 this measure addresses.

16 CO-CHAIR CIPRIANO: Okay. And I
17 think, Richard, as you aptly stated, too,
18 perhaps we have been through the issues with
19 the first measure, that that discussion would
20 be germane to your deliberation and thinking
21 about approving each of the sub-items for this
22 particular measure.

1 Are we ready to do the voting on
2 0372 then?

3 Okay. Jessica, will you walk us
4 through, please?

5 MS. WEBER: Importance to measure
6 and report. Are all the subcriteria met, high
7 impact, performance gap, evidence?

8 (Whereupon, a vote was taken.)

9 Janet?

10 MEMBER NAGAMINE: Yes.

11 MS. WEBER: We need one more vote.
12 Go ahead and try it again.

13 Okay. Twenty-one yes.

14 Scientific acceptability of
15 measure properties, 2a, reliability; 2b,
16 validity.

17 (Whereupon, a vote was taken.)

18 Janet?

19 MEMBER NAGAMINE: Yes.

20 MS. WEBER: Twenty-one yes.

21 Usability?

22 (Whereupon, a vote was taken.)

1 MS. BOSSLEY: Janet, this one is
2 high, moderate, low, insufficient.

3 MEMBER NAGAMINE: Mod.

4 MS. WEBER: Ten say high; 11 say
5 moderate.

6 Feasibility?

7 (Whereupon, a vote was taken.)

8 MS. BOSSLEY: Janet, this one,
9 again, is the high, moderate, low --

10 MEMBER NAGAMINE: Mod.

11 MS. BOSSLEY: Okay.

12 MS. WEBER: Twelve high, 8
13 moderate, 1 low.

14 Overall suitability for
15 endorsement. Does the measure meet all the
16 NQF criteria for endorsement?

17 (Whereupon, a vote was taken.)

18 MS. BOSSLEY: Janet?

19 MEMBER NAGAMINE: Yes.

20 And then, I would just want to add
21 a comment regarding the question that was
22 about that one point in time and then not

1 getting prophylaxis after leaving the ICU. Is
2 there any way we can incorporate a comment
3 about that?

4 CO-CHAIR CIPRIANO: Again, we can
5 make that as the recommendation.

6 DR. BRATZLER: Yes, I will tell
7 you that we have heard it and we will
8 certainly, as these measures are continuously
9 updated, we will certainly incorporate those
10 comments and think about that.

11 MEMBER NAGAMINE: All right.
12 Thanks.

13 CO-CHAIR CIPRIANO: And, Dale, I
14 guess I would ask you, as Joint Commission and
15 certainly other groups are thinking about the
16 development of more longitudinal measures with
17 multiple points in time for measurement, I
18 mean, does this kind of fit into your thinking
19 or would you see this as more discrete, that
20 it would be as there are transitions in care
21 within an institution?

22 MS. WATT: I can tell you that we

1 are looking very closely at transitions of
2 care and looking at measurements of
3 transitions of care. And so, yes, absolutely,
4 we know that this is an area of importance.

5 CO-CHAIR CIPRIANO: Great. Thank
6 you very much.

7 Okay. Lisa, I think we are up to
8 you on 0373, VTE in patients with
9 anticoagulant overlap therapy.

10 MEMBER MOORES: Okay. So, VTE-3
11 is looking at treatment of patients with acute
12 VTE, and it is based on the recommendations
13 from multiple guidelines, primarily the ACCP,
14 that you initiate heparin therapy as quickly
15 as possible and get the patients
16 anticoagulated quickly, that that shows
17 reduced recurrent events, and that when the
18 warfarin is initiated, that you overlap that
19 therapy for five days to reduce the risk of
20 increased hypercoagulability during that
21 timeframe.

22 And so, the measure looks at

1 patients that get appropriate overlap therapy
2 or, if they are discharged prior to that
3 period of time, that they are discharged on
4 both medications or there is some reason that
5 those were not indicated.

6 And I think in terms of the
7 evidence behind it, that there is certainly a
8 good body of evidence that that process makes
9 sense. And you can see up on the screen in
10 terms of the Subcommittee the majority of
11 people felt that it did meet a high level of
12 importance, that there is some evidence in the
13 literature of a performance gap, and that not
14 everybody is doing this and not everybody is
15 monitoring anticoagulation therapy as well as
16 they could be.

17 From a usability standpoint,
18 again, most people felt that that made sense.

19 And the issue really more, I
20 think, where there was a lot of discussion
21 came in feasibility, in defining these and
22 trying to capture that data, and looking at

1 what is 24 hours and is it two consecutive
2 days, and just problems there in terms of
3 gathering the data. So, there was some
4 concern about feasibility.

5 CO-CHAIR CIPRIANO: Thank you very
6 much.

7 Questions for Lisa or comments or
8 clarifications from the group?

9 Richard?

10 DR. BRATZLER: Excuse me. I will
11 make just one point, and that is there has
12 been tremendous pressure on shortening length
13 of stay. We actually had found in past
14 studies that we published that a lot of
15 patients were being discharged completely
16 inadequately anticoagulated. So, we commonly
17 saw people that had their heparin stopped, had
18 a non-therapeutic INR, and were being
19 discharged from the hospital only on warfarin.

20 And so, with the pressures and,
21 again, here the baseline performance was in
22 the sixties again on this particular

1 performance measure also.

2 CO-CHAIR CIPRIANO: Richard?

3 MEMBER WHITE: The concern I think
4 we had in the phone conversation -- and I just
5 wanted some clarification -- had to do with a
6 very little nitpicking kind of part of this
7 measure, which is you had to go five days on
8 heparin. If you went four and you had a
9 therapeutic INR and you stopped heparin, that
10 was felt to not be appropriate. You have to
11 go five days.

12 And then, I want to make it clear
13 that one INR in the therapeutic range after
14 day five says you made it or do you have to
15 have 24 hours of therapeutic INR to meet the
16 measure? Because in one, the American College
17 of Cardiology, they say for 24 hours, and
18 another one gets there. And, of course, what
19 we see in practice is on day five we've got an
20 INR of 2.1. We stop the heparin, and the next
21 day it is 1.9. But we walked away feeling
22 great because we made the measure.

1 So, you know, this is the problem
2 with this measure. There are so many parts to
3 it, it may be kind of hard to measure, when
4 what we really want to do is make sure you use
5 heparin followed by warfarin and you
6 eventually get there. It is just a tough
7 measure to actually get at it.

8 DR. BRATZLER: So, I would
9 actually argue we don't want to just see
10 heparin followed by warfarin because that is
11 actually common. We want to see overlap.
12 That is really the focus here.

13 Because we know, we have seen
14 multiple examples of patients that go home on
15 day two on warfarin alone or day three. I
16 mean short lengths of stay for VTE treatment
17 are actually becoming quite common; in fact,
18 directly out of the emergency department, not
19 uncommon anymore.

20 So, the performance measure looks
21 at give calendar days of overlap, and, yes,
22 you are correct that if one of the INRs is

1 greater than 2.0, the case will pass, right,
2 again, because of the feasibility of data
3 collection.

4 So, would it be ideal to look at
5 24 hours post-discontinuation of the
6 parenteral? Sure. But, again, we are looking
7 at feasibility of the performance measure.
8 The focus here is to get people thinking about
9 the fact that a couple of days of parenteral
10 anticoagulation just because the INR is
11 prolonged doesn't mean that a patient is
12 safely anticoagulated.

13 MEMBER NAGAMINE: This is Janet.

14 The reason for five or more days,
15 I know that that overlap therapy is from old
16 literature, but in current literature I am not
17 aware of studies that look at the overlap in
18 conjunction with the risk of bleeding.

19 And the reason I ask is I have
20 done a study within Kaiser on a fairly large
21 number of participants. I haven't published
22 it. But bleeding events on warfarin were

1 rather predictable on day three of therapy in
2 the elderly population and renal patients.
3 So, that was my concern about specifying five
4 days of overlap in a particularly high-risk
5 population.

6 MEMBER WHITE: Well, yes, you're
7 right. I mean, there's no data. The only
8 data we have is Brandeis in 1992, where if it
9 was warfarin alone, they had a high risk of
10 recurrence. If you had heparin followed by
11 warfarin, it was a 7 percent recurrence in
12 three months. So, yes, we don't have any
13 data, and there will be a higher risk for
14 bleeding during that overlap time period.

15 And here's a little question I
16 have of the Joint Commission: we want to get
17 expert, well-done transition of care at every
18 hospital. So, shouldn't they be tracking all
19 the ones they discharged on low molecular
20 weight heparin and ensuring that they are
21 getting overlap with warfarin? I mean,
22 exactly what we are talking about on the

1 inpatient side is not being looked at on the
2 outpatient side, when that is critical. You
3 don't want just sent out on warfarin and not
4 any low molecular weight heparin. It would be
5 nice to see that the hospital ensured that
6 that overlap did occur.

7 DR. BRATZLER: Yes, indeed, that
8 is actually what the measure does. I mean, we
9 look at, if they go home in less than five
10 days, which is quite common, then they have to
11 be to pass the measure discharged on the
12 combination of parenteral plus warfarin.

13 MEMBER WHITE: But you don't have
14 an INR measurement? You don't have them
15 document --

16 DR. BRATZLER: No, we don't have
17 an INR because, once the patient leaves the
18 hospital -- this is a hospital performance
19 measure, and we have no way to track them once
20 they leave.

21 MEMBER NAGAMINE: What if they are
22 on day five and their INR is 5? As you know,

1 it is so variable, the rate of rise of INR.

2 DR. BRATZLER: So, I have seen
3 that happen on day two in a small elderly
4 female. So, I guess I am not sure what the
5 point is. We recognize that.

6 You know, again, the performance
7 measure is primarily addressing -- and I
8 actually think there is still a lack of
9 knowledge on this issue of the need to overlap
10 therapy. I think there is still a knowledge
11 gap here.

12 Again, in multiple audits that we
13 have done over the years, we just find the
14 patients go home early, warfarin alone,
15 oftentimes with a subtherapeutic INR. It is
16 much more common in our experience of chart
17 reviews.

18 CO-CHAIR CIPRIANO: Okay. Lisa?
19 And then, Saul, did you want to say something?

20 So, any other comments on
21 therapeutic issues? Vallire and then Saul.

22 MEMBER NAGAMINE: I wanted to add

1 that in a study that we did the bleeding
2 occurred in elderly patients on day three even
3 with the subtherapeutic INR. So, that was my
4 main concern, is that while you don't want
5 thromboembolic events because they are
6 inadequately anticoagulated, I am not sure
7 what the risk/benefit ratio would be. If you
8 specify five days, then you are not sure where
9 the INR is.

10 MEMBER WEINGART: So, and the
11 clotters probably know this better than I, but
12 my understanding for the rationale of overlap
13 is that the INR goes up faster than the
14 depletion of the factors. And so, my
15 understanding was that one of the main reasons
16 for the overlap was to ensure that the heparin
17 wasn't discontinued prematurely, even though
18 the INR was therapeutic.

19 So, I think there is a risk of
20 bleeding, but my understanding is this
21 practice was originally instituted more to
22 prevent premature thrombosis.

1 MEMBER WHITE: Denise just
2 reminded me that this particular measure
3 actually does give the clinician the ability
4 to formally document an explicit reason for
5 not discharging on overlap. So, if you had
6 that patient with an INR of 5, we do allow the
7 clinician to explicitly document the reason
8 for not doing it. So, there is that clinician
9 input that is allowed in the performance
10 measure.

11 CO-CHAIR CIPRIANO: Okay.
12 Vallire, was yours specific to this part of
13 the issue? Please go ahead.

14 MEMBER HOOPER: I just have a
15 question as to, do we have any data as to how
16 many patients are sent home prior to that
17 five-day mark where we are not capturing that
18 INR? And I wonder if perhaps what is missing
19 from this set is a measure that captures
20 patients that are readmitted for complications
21 related to anticoagulant therapy.

22 Because I am a bit concerned about

1 the fact that we have rapid discharge and we
2 are sending patients home. And I understand
3 it is difficult to monitor and capture that
4 measure. But how many patients are we sending
5 home prior to that five-day mark?

6 DR. BRATZLER: So, I will comment
7 briefly that that's part of what Measure No.
8 5 addresses, is how good/adequate the
9 discharge instructions are for patients who go
10 home on warfarin.

11 It doesn't capture complications,
12 but there is no way to do it in a hospital-
13 specific performance measure because there is
14 no guarantee that they will come back to the
15 same hospital even. So, we don't have any way
16 of capturing that, at least from the
17 standpoint of this performance measure, but we
18 do address it in recognizing that patients
19 that go home on warfarin need explicit
20 discharge instructions on followup monitoring
21 and other things.

22 CO-CHAIR CIPRIANO: Okay. So, we

1 are saying there is also potentially a measure
2 gap as the window for length of stay keeps
3 shrinking, which again is sort of, have we
4 managed the episode of care in such a way that
5 we actually have information about therapeutic
6 range, whether it is overlap or not, which is,
7 again, not part of the measure because this is
8 only going to measure the five-day overlap.

9 Okay. Lisa, do you want to come
10 back in at this point?

11 MEMBER MCGIFFERT: Yes, I do.

12 CO-CHAIR CIPRIANO: Okay.

13 MEMBER MCGIFFERT: I will just say
14 to that, that I would rather see a readmission
15 measure than this because I think that gets to
16 what is happening, what is really happening to
17 the patients. And the hospital might have to
18 do things to figure out how to make that not
19 happen, but that is a more meaningful measure,
20 in my opinion.

21 I was just going to ask, I see
22 that as the Joint Commission uses this, and

1 you mentioned before that you use it in
2 combination as a bundle, but once this measure
3 is out there, there is no bundling requirement
4 at all with the measure that we are endorsing,
5 right? We are endorsing each measure
6 individually. Even though the Joint
7 Commission says they are using it as a bundle,
8 that doesn't mean that someone else is going
9 to use it as a bundle in the future. Am I
10 correct on that?

11 CO-CHAIR CIPRIANO: Well, we can
12 recommend that it be paired, so that it is
13 always used as a paired measure.

14 MEMBER MCGIFFERT: I mean, it
15 seems like that is what they are recommending,
16 but it is not really clear, as we are voting,
17 that that is what we are voting for.

18 CO-CHAIR CIPRIANO: That could be
19 a separate deliberation of the group, once we
20 have made it through the six.

21 MEMBER MCGIFFERT: Okay. Great.
22 Thanks.

1 DR. BRATZLER: And the only thing
2 I would say is bundle versus measure set, I
3 think the Joint Commission defines it as a
4 measure set, and CMS has defined it as a
5 measure set that would be implemented for all
6 hospitals in January of 2013 as a set.

7 Bundling, to me, has the whole
8 connotation of rolling up performance measure
9 rates and creating some type of a composite.
10 And that is certainly feasible, but you have
11 to have multiple measures to do that.

12 MEMBER MCGIFFERT: Can I just ask
13 a followup? You have mentioned this before,
14 Dale. So, CMS is planning to use this measure
15 and the other two that we have done so far in
16 2013?

17 DR. BRATZLER: Yes. They, in the
18 final inpatient prospective payment system
19 rule, linked --

20 MEMBER MCGIFFERT: That was in
21 there?

22 DR. BRATZLER: -- public reporting

1 to the VTE measure set.

2 MEMBER McGIFFERT: So, they have
3 already -- okay.

4 CO-CHAIR CIPRIANO: Richard,
5 please.

6 MEMBER WHITE: Just two comments.
7 One, VTE patients bleed a lot. A lot of them
8 are elderly, and when you put them on
9 anticoagulant therapy, what happens, I think,
10 is that they have a bleeding site and then it
11 bleeds. I am not certain we are exactly
12 causing it. We are kind of unmasking this
13 underlying risk.

14 Second, at least in California,
15 recently, half of all DVT cases are diagnosed
16 and sent out of the ER rather than being
17 admitted. So, they don't even get in the
18 hospital.

19 So, if you really want to get out
20 and see if they are getting proper overlap
21 therapy, et cetera, you would have to tap into
22 the emergency room situations, where not

1 uncommonly they are even picked up in the
2 clinic, sent down to the ER, started on low
3 molecular weight heparin and sent home. So,
4 there is a whole area we are missing on that.

5 CO-CHAIR CIPRIANO: Steve? Sorry.

6 MEMBER LAWLESS: This will help me
7 with feasibility and reliability.

8 When your Joint Commission is
9 looking at all the measures, all these seven
10 together, do you have an idea or have looked
11 at how many patients who actually qualified
12 actually have had all the measures done? So,
13 if you have had patients prophylaxed, went to
14 the ICU, got their prophylaxis there, got
15 their overlap there. They got the
16 instructions. I mean everything was
17 completely done by the book. What percent of
18 the patients are there who have that done?

19 By the gap, it is 60 percent is
20 here, and 30 percent had it and 50 percent --
21 you put them all together like a Bayes
22 theorem, it turns out to be, it looks like,

1 maybe like 5 percent of patients have actually
2 been properly handled.

3 MS. WATT: We don't track that.
4 We have individual measure rates, of course,
5 for each one of the measures or we know the
6 individual measure rates for each one of the
7 measures. We don't track like a perfect
8 patient or a perfectly-managed patient.

9 MEMBER LAWLESS: Okay.

10 CO-CHAIR CIPRIANO: Okay. Any
11 other questions or clarifications?

12 (No response.)

13 I think the summary at this point
14 is that there is probably still a population
15 of hospitalized patients for which this
16 measure does cover what is believed to be
17 appropriate overlap therapy. At the same
18 time, we have heard several recommendations of
19 what might be either new measures or the
20 potential to have measures that are instituted
21 at readmission or in some way as measures
22 begin to migrate across settings, again, these

1 continuity-of-care measures could be
2 incorporated. But our decision will be
3 whether or not to retain this measure as one
4 for the population that will meet these
5 criteria in the hospital and that will satisfy
6 the five-day requirement for overlap therapy.

7 Any other comments/questions
8 before we vote?

9 (No response.)

10 Okay. Jessica, please.

11 MS. WEBER: All right. Importance
12 to measure and report, 1a, high impact; 1b,
13 performance gap; 1c, evidence.

14 (Whereupon, a vote was taken.)

15 MS. BOSSLEY: Janet?

16 MEMBER NAGAMINE: Moderate.

17 MS. BOSSLEY: Oh, I'm sorry, this
18 one is yes/no.

19 MEMBER NAGAMINE: Oh, I'm sorry.

20 MS. BOSSLEY: On importance.

21 MEMBER NAGAMINE: I would say yes.

22 MS. BOSSLEY: Okay.

1 MS. WEBER: Twenty yes, 1 no.

2 Scientific acceptability of
3 measure properties, 2a, reliability; 2b,
4 validity.

5 (Whereupon, a vote was taken.)

6 MS. BOSSLEY: And this one is a
7 yes/no as well, Janet.

8 MEMBER NAGAMINE: I would say no.

9 MS. BOSSLEY: Okay.

10 MS. WEBER: Two more votes. There
11 we go.

12 Eighteen yes, 3 no.

13 Usability? This is a high,
14 moderate, low, insufficient.

15 (Whereupon, a vote was taken.)

16 MS. BOSSLEY: And Janet?

17 MEMBER NAGAMINE: I would say low.

18 MS. WEBER: Seven high, 9
19 moderate, 5 low.

20 Feasibility. This is a high,
21 moderate, low, insufficient.

22 (Whereupon, a vote was taken.)

1 Janet?

2 MEMBER NAGAMINE: Low.

3 MS. WEBER: Six high, 9 moderate,
4 6 low.

5 Overall suitability for
6 endorsement. Does the measure meet all of the
7 NQF criteria for endorsement?

8 (Whereupon, a vote was taken.)

9 Janet?

10 MEMBER NAGAMINE: No.

11 MS. WEBER: Eighteen yes, 3 no.

12 CO-CHAIR CIPRIANO: Okay. Thank
13 you very much.

14 Let me ask the group, we were
15 scheduled for a break about 10 minutes ago.
16 We are just a little bit behind schedule.
17 Would you like to go ahead and take a 15-
18 minute break?

19 I see a lot of heads nodding.
20 Okay. So, if you would be back and ready to
21 go about five minutes of? Thank you.

22 (Whereupon, the foregoing matter

1 went off the record at 10:43 a.m. and resumed
2 at 10:58 a.m.)

3 CO-CHAIR CONWAY: Okay. We are on
4 Measure 0374, venous thromboembolism, patients
5 receiving heparin with a platelet count
6 monitoring.

7 The primary reviewer for Workgroup
8 B is not with us today. Is there a volunteer
9 in Workgroup B that would like to briefly
10 summarize the Workgroup's action on this?

11 (No response.)

12 If we don't have a volunteer, we
13 might appoint someone.

14 (Laughter.)

15 Come on.

16 MEMBER MOORES: I don't mind
17 speaking to it, although I wasn't on the call.
18 So, I might ask Rich or someone else to chime
19 in on some of the --

20 CO-CHAIR CONWAY: Okay. Thank
21 you, Lisa.

22 MEMBER MOORES: -- discussions

1 that you had.

2 But this measure is one that gets
3 at the bottom line, patients that are on
4 heparin for prophylaxis, and the risk for
5 heparin-induced thrombocytopenia is one part
6 of the measure, and the other one was making
7 sure that you get them into the therapeutic
8 range very quickly. Because we have good
9 data, again, that if you don't get them into
10 the range, that the recurrent rates, both
11 short-term and long-term, are higher.

12 So, you can see again the ratings
13 are up there. The group agreed that both of
14 these issues, both quick therapeutic
15 anticoagulation and reduction of HIT are
16 important. So, well, you are kind of
17 scattered over a little bit, so you can't see
18 those right now. But there we go.

19 All right. So, in terms of the
20 evidence, people felt there was a good body of
21 evidence behind that. The scientific
22 acceptability was a little bit lower.

1 And I think, again, I wasn't on
2 the call, but some of that may stem from the
3 fact that there is a considerable amount of
4 controversy around the usefulness of platelet
5 monitoring for prevention of HIT. I know, for
6 me, that is an issue with this measure. And
7 so, grouping them together was somewhat
8 problematic.

9 Usability for both public and QI
10 was high among the group. And then,
11 feasibility, mostly high. So, again, not a
12 problem there. So, if you look across, there
13 was pretty good consensus.

14 I will speak to the fact that my
15 own issues with this measure are the pairing
16 of the two processes, and I think that there
17 is very, very good evidence that we should be
18 using a nomogram and then making sure that we
19 are getting patients in the therapeutic range.

20 However, the platelet-monitoring
21 evidence is not nearly as strong and, in fact,
22 some evidence that it may be harmful if it is

1 looked at in every patient. I think the
2 guidelines as to who should have platelet
3 monitoring and who shouldn't are a moving
4 target. We will probably change again.

5 And in addition, a lot of evidence
6 that when the platelet counts are monitored,
7 that oftentimes nothing is done about it
8 anyway. People monitor the platelets, but
9 they either don't look for HIT or they look
10 but don't do anything with that information.
11 They don't change the heparin to a direct
12 thrombin inhibitor or some appropriate
13 alternate agent.

14 So, I would prefer to see these,
15 even if we are going to look at a HIT measure,
16 it being separated from the nomogram. But
17 that is just my comment.

18 CO-CHAIR CONWAY: Thank you for
19 teeing that up.

20 Do we have a comment from the
21 Joint Commission?

22 DR. BRATZLER: Of course, the

1 measure was based on ACCP-8, which did
2 recommend routine platelet count monitoring,
3 both at baseline and then subsequent during
4 therapy, particularly looking for a dropping
5 platelet count, and that is where the
6 performance measure.

7 And I think just one general
8 comment about this measure, we have had a
9 bigger concern and discussed a lot, even two
10 to three years ago, that the use of
11 unfractionated heparin for treatment of VTE
12 events has dropped, though it hasn't gone
13 away, particularly for patients that are being
14 bridged for surgery.

15 So, we recognized the denominator
16 nationally probably has dropped. We don't
17 have strong numbers about how many still were
18 treated by unfractionated heparin. But that
19 has been one concern.

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

22 And any questions from the panel?

1 Richard, you can go first.

2 MEMBER WHITE: So, my problem with
3 this measure, it is a surrogate for what you
4 just said is the aim. The aim is to get the
5 patient in the therapeutic range, but the
6 measure is did you use a nomogram.

7 So, we just did, one of the
8 pharmacy residents at UC-Davis did a project,
9 and he looked at everyone in the hospital and
10 saw how well we were doing. And we were 100
11 percent compliant. We always used a nomogram.
12 But only 45 percent got in the therapeutic
13 range using the nomogram. And you say, how
14 can that be?

15 Well, I mean, the nurses had to
16 turn it up a certain amount every time it was
17 low. You had to get those measures back. If
18 you put in ideal body weight, it doesn't
19 work. You have to use total body weight.

20 I mean, so we have a nomogram in
21 place, and we would get an A+, if we were to
22 be measured on this performance measure. And

1 yet, we did an absolutely horrible job.

2 And then, you have to satisfy your
3 logic. You also have to do the platelet
4 count, and it probably should be separated,
5 just because you could do one really well and
6 not the other, and you would get a bad rate
7 overall. So, it doesn't make a lot of sense.

8 So, I am just pointing out it is
9 not measuring looking at what we are really
10 interested in, which is getting therapeutic
11 APTTs.

12 CO-CHAIR CONWAY: Okay. Thank
13 you.

14 Jason? And then Iona.

15 MEMBER ADELMAN: So, I have a
16 question for the Joint Commission. First,
17 just exactly how this would be monitored. I
18 mean, we have very bright residents at my
19 institution who can keep the nomogram in their
20 head. And so, for someone to see if they
21 followed the nomogram, they would have to sort
22 of reproduce it every time there is a lab

1 value and then a change in dosing.

2 And second is there is another
3 measure coming up that is not a Joint
4 Commission measure about starting heparin in
5 ER. And I pulled an article from Chest from
6 2010. And they talked about incredibly-
7 improved outcomes when there is a therapeutic
8 PTT reached within 24 hours.

9 And I was wondering why not, I
10 think to Dr. White's point, why not have a
11 measure of time from order until time you
12 reach therapeutic PTT, or what percentage gets
13 to a therapeutic PTT within 24 hours? That
14 showed to be, in this one article that they
15 referred to in the measure coming up, an
16 incredible predictor for decreased mortality.
17 It is therapeutic PTT within 24 hours.

18 DR. BRATZLER: As I recall, that
19 goes way back to Russ Hall's work years and
20 years and years ago about the timeliness. So,
21 I don't know whether that has ever been
22 completely reproduced. Perhaps you guys know

1 better than I.

2 The performance measure is looking
3 at whether or not a protocol is being used by
4 the hospital system when they are giving IV
5 infusions of unfractionated heparin. It is
6 absolutely correct that we don't look at
7 appropriately whether or not they achieved a
8 therapeutic level or not.

9 I am just looking to see what the
10 baseline rates were. Eighty percent. So,
11 about 80 percent. Twenty percent of the cases
12 that were reported did not have a nomogram or
13 a protocol documented that was being used to
14 monitor or manage unfractionated heparin.

15 So, again, it is measure looking
16 at the first step. Was a protocol in place or
17 a nomogram used?

18 MEMBER ADELMAN: So, it is not at
19 the patient level or the provider level? It
20 is just at the institution level is there a
21 nomogram or not?

22 DR. BRATZLER: No, all the cases

1 are measured at the patient level.

2 MEMBER ADELMAN: So, then, you
3 would have to look at each decision made.
4 Some reviewer, right, if the PTT was 40 and
5 the weight was 100 kilograms?

6 DR. BRATZLER: No, no, there has
7 to be some documentation that there is actual
8 like formal protocol on the medical record,
9 either a paper-based form or through the
10 electronic medical record, there are some
11 decision support tool, some nomogram or some
12 protocol. There has to be some physical
13 evidence of a protocol that is documented in
14 the medical record.

15 CO-CHAIR CONWAY: Iona?

16 MEMBER THRAEN: So, based on the
17 conversation, this one sounds like if you were
18 just looking at the therapeutic range
19 question, that it would lend itself really
20 well to electronic reporting. So, lab
21 results, pharmacy, medication orders, et
22 cetera, as opposed to whether or not there are

1 documents on the chart or there is decision
2 support in a particular EMR or some of the
3 other pieces that you were talking about.

4 And based on the conversation,
5 wouldn't this be a nice opportunity to retool,
6 quote, "retool" this particular measure
7 towards that end?

8 DR. BRATZLER: So, I will agree
9 that some of these measures are going to lend
10 themselves very, very well to use in
11 electronic medical records, and it is not
12 really a part of our conversation today, but
13 those activities are happening in the
14 background, that these measures are set up for
15 electronic medical records, which then allows
16 you to look at electronic laboratory output
17 and others to see whether or not, as Rich is
18 pointing out, the patient achieves a
19 therapeutic level. But this is the first
20 iteration of the measures that we will use to
21 build this.

22 MEMBER THRAEN: Well, I guess,

1 again, I am using the three-year window where
2 Meaningful Use is supposed to be in place, the
3 staging that is going on with the EMR
4 implementation. I really wonder whether or
5 not this one ought to be evaluated from that
6 perspective, that there is a better way to
7 capture this information to get to the
8 endpoint that you are trying to get to.

9 And rather than accept it in its
10 current form, that that be reconsidered. It
11 sounds like, and this would fall under the
12 feasibility of data collection, I think, to a
13 certain extent, but it also sort of shifts the
14 paradigm of the focus back more towards the
15 outcome range and away from the process
16 measures, the process approach that we are
17 taking in terms of really looking at how
18 patients are benefitting from any kind of
19 process that might be in place.

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

22 Christina?

1 DR. BRATZLER: I will just say
2 that is happening. But that is a whole
3 separate NQF process.

4 MEMBER THRAEN: All right. So,
5 does that mean that if this group endorses the
6 measure's current format, which doesn't have
7 the requirement for the electronic dataset,
8 that this other process he is referencing,
9 this measure would go over into that other
10 process? And would getting the lab results
11 and the medication orders, et cetera, actually
12 fulfill meeting this need or does this measure
13 have to be reframed to an outcome approach as
14 opposed to this process approach?

15 MS. BOSSLEY: The question about
16 whether it is better to be looking at the
17 outcome, the levels, et cetera, rather than
18 that, I think is the question that the
19 Committee needs to consider now.

20 If the measure is retooled or
21 respecified for EHRs, we will take a look at
22 it. Often, right now, we are seeing it being

1 more of a one-to-one. So, you achieve it
2 through the paper record. They are really
3 doing the same translation to the electronic
4 health record.

5 I do believe what you would like
6 to see is an advancement into the future of
7 getting more toward getting values, et cetera.
8 I don't know if that is what is going to
9 happen with this measure or not, but I think
10 you need to talk about whether that is the
11 measure you want to see, yes.

12 MS. WATT: Could I just say
13 something, just in the interest of full
14 disclosure and transparency? This measure, as
15 well as all of the other VTE measures, all are
16 six of the fifteen that have been retooled by
17 the Healthcare Information Technology
18 Standards Panel and are clinical quality
19 measures for Meaningful Use. So, this has
20 been done for this measure actually twice. We
21 just finished the second revision of the HITSP
22 specifications, and they are due up to be re-,

1 re-, retooled in using the QDM format.

2 So, this work has been done. It
3 is continuing to be done for this measure, as
4 I said, and for all the others in the set.

5 MEMBER THRAEN: So, given that,
6 again, this focuses at whether or not there is
7 a protocol in place, there is decision support
8 in place, and the nomogram that was mentioned,
9 which is different than collecting lab
10 information and pharmacy information.

11 So, in that process that you just
12 described, has that reframe taken place and
13 moved over into the lab and medication order
14 arena or is still at the protocol decision
15 support level?

16 MS. WATT: As Heidi indicated, the
17 work of the HITSP Task Force and the
18 continuing work is basically to translate the
19 measure as it exists into e-specifications.
20 And to the extent that this measure does
21 require platelet monitoring, that is included
22 in the retooling.

1 MEMBER THRAEN: All right. So, it
2 sounds like to me like in its current
3 framework you are collecting metadata on the
4 electronic medical record system that is in
5 place as to whether or not there is a decision
6 support algorithm that addresses this issue.

7 MS. WATT: I think that the
8 e-specifications, I don't know that I would
9 classify it as metadata, to be honest with
10 you. So, what the e-specifications are doing
11 is, again, for every patient who is admitted
12 and has the VTE, that the treatment be
13 directed by a protocol or a nomogram. That is
14 what the measure says and that the platelets
15 are monitored.

16 CO-CHAIR CONWAY: Okay.
17 Christina?

18 MEMBER MICHALEK: Having heard
19 what everybody is saying, looking back to what
20 was presented to us, from the organizations
21 that are actually sending their data to the
22 Joint Commission, it looks like they are at 94

1 percent performance rate. So, I am just
2 questioning, is there value in continuing? Or
3 am I missing something?

4 DR. BRATZLER: I will address
5 that. So, first, this is purely voluntary.
6 So, it is a very biased group of hospitals
7 that submit the data because it is not
8 required nationally. The baseline rates of
9 performance for these biased group of
10 hospitals was 80 percent.

11 Also, as I understand it, the
12 number of reporting hospitals for some of
13 these measures has actually declined over
14 time. It is purely a voluntary activity.

15 So, my bet is that, if it were
16 rolled out nationally, we are going to see
17 rates of performance that are lower than the
18 80 percent baseline that we saw. I don't have
19 any national dataset, though.

20 CO-CHAIR CONWAY: Okay. Richard,
21 Pam, and then Vallire.

22 MEMBER WHITE: My question to the

1 Joint Commission is, are all your performance
2 measures patient-based? So, you have to have
3 a numerator and denominator for patients. Or
4 could it be a hospital measure?

5 For example, the measure is at UC-
6 Davis you have to sample 50 patients a year to
7 see if your nomogram is working. In other
8 words, it is kind of like a SCIP measure. You
9 sample certain patients, and how many were in
10 the therapeutic range at 24 hours? I mean,
11 that is really what we want to do. If we
12 hadn't gone back and done this, we wouldn't
13 have realized our nomogram wasn't really
14 working.

15 So, can you have a performance
16 measure where the hospital has to show you
17 that they validated their nomogram?

18 DR. BRATZLER: So, I actually
19 think it is a completely different measure.
20 I mean, it may be a very valid measure that we
21 ought to focus on with the Technical Panel
22 moving forward, that the measure isn't about

1 whether you just used the nomogram, but did
2 you achieve whatever we define as a
3 therapeutic partial thromboplast in time? So,
4 I mean, I think that is a consideration for a
5 completely different measure.

6 Right now, the measure simply
7 looks to see whether or not -- and it is
8 collected at the patient level, but aggregated
9 at the hospital reporting. So, what
10 proportion of the patients treated for DVT or
11 pulmonary embolism actually had use of the
12 nomogram, if they were receiving
13 unfractionated heparin?

14 MEMBER WHITE: But the effect of
15 the other measure would probably get you what
16 you want. If the hospital suddenly knew, oh,
17 gosh, I've got to sample my patients and see
18 if the nomogram worked and how many got in the
19 fair therapeutic range, they would institute
20 not only the nomogram, but a better nomogram
21 that worked, right, because they are being
22 watched?

1 CO-CHAIR CIPRIANO: I think, just
2 going back to the previous discussion about
3 does this measure go far enough to collect the
4 data that will tell us about the therapeutic
5 impact of using the nomogram, again, I think
6 we can be consistently tempted to want to make
7 changes to these measures, but we are really
8 limited, if you will, to saying, can this
9 measure go forward as it is and continue to be
10 a measure? And if we believe that it needs to
11 move into more outcome measurement, then I
12 think that needs to be a specific
13 recommendation that is a separate action from
14 what we will do with the measure today. If we
15 don't believe that the measure is an
16 appropriate measure to continue, then we
17 wouldn't approve it.

18 MEMBER HOOPER: I just wanted to
19 reflect on the previous comment about
20 performance gap. I know that when I was
21 reading the evidence supporting the
22 performance gap, it was outdated. So, I guess

1 I would defer to the VTE experts to comment as
2 to, is there a performance gap supporting the
3 worthiness of this measure?

4 MEMBER WHITE: We certainly have a
5 gap with our nomogram, but we get an A+ for
6 using it. So, yes, there is a big gap, but it
7 is not what is being measured. We look
8 terrific, but we are not getting where we want
9 to go.

10 DR. BRATZLER: So, I would say
11 that Richard White is a biased sample, though,
12 in terms of whether or not nomograms or
13 protocols are in use -- (laughter) -- because
14 you have highly-performing patient safety
15 experts, quality experts in the room. I think
16 when you go down into a lot of community
17 hospitals, smaller other hospitals,
18 performance rates are very different than you
19 might see amongst the group of institutions
20 represented here.

21 CO-CHAIR CONWAY: Lisa?

22 MEMBER MOORES: Yes, I would say

1 this, again, is just somewhat more anecdotal,
2 experiential. But when I go out and talk to
3 community hospitals and we talk about
4 treatment of VTE, they are always surprised
5 when I say, "Well, if you are going to still
6 use unfractionated heparin, use a nomogram."
7 And they look at me like, what's a nomogram?
8 So, I think probably there is a knowledge gap
9 there.

10 There is good data that using a
11 nomogram gets a larger percentage of patients
12 to a therapeutic goal within a certain period
13 of time. But I think it is interesting that
14 in Rich's institution that even doing that
15 still isn't getting us where we want to go.
16 So, I agree with Dale that it is probably,
17 there is evidence that that is a good first
18 step, but I wonder if we shouldn't be looking
19 more toward further down in the process. As
20 you said, that is a different measure, but I
21 think that might be more useful.

22 And I was just wondering, Dale, if

1 you could kind of clarify for us why these two
2 are linked. I recognize they are both part of
3 if you are going to use unfractionated
4 heparin, but you are getting at two different
5 things. And if it is one measure and, as Rich
6 said, you may be very good at one and not good
7 at the other, and vice versa. And why were
8 they put into a single?

9 DR. BRATZLER: So, as I recall,
10 the conversation was, we actually had a
11 conversation about two separate measures, both
12 focusing on therapy with unfractionated
13 heparin. And the decision was made to combine
14 them into a single measure with, again, the
15 limited denominator, patients that were
16 receiving IV unfractionated heparin,
17 monitoring the platelet count, looking for HIT
18 syndrome, and using a nomogram to adjust it.

19 And I think, at least
20 historically, we will not get the most
21 nomograms. Most of them actually have 112036.

22 CO-CHAIR CONWAY: So, since it has

1 come up several times, would the Joint
2 Commission be interested in splitting those
3 measures? And you don't have to answer that
4 right away. You can think about it for a
5 little bit before we vote.

6 You're back now?

7 MEMBER WEINGART: Yes. My
8 comments were already, I think, reflected by
9 the group. I mean, I think this is a pretty
10 low bar. Twelve years ago, people were
11 arguing about whether a nomogram was necessary
12 or valuable. So, I think this is a pretty low
13 bar for most organizations, but there is a
14 small number of places that are really behind
15 the times and for whom this is an important
16 improvement initiative.

17 CO-CHAIR CONWAY: Christina?

18 MEMBER MICHALEK: I just had a
19 question. On the use of a nomogram, you are
20 just looking to see that a nomogram exists?
21 If, for some reason, there was a variation to
22 it, like, for example, they picked the

1 nomogram, but there was no bolus that was
2 given, which is part of the nomogram, and no
3 initial bolus or half initial bolus, like you
4 are not looking at that at all? Just that
5 they are ordering based on a nomogram?

6 CO-CHAIR CONWAY: Janet, were you
7 trying to say something?

8 MEMBER NAGAMINE: Yes.

9 CO-CHAIR CONWAY: Yes.

10 MEMBER NAGAMINE: I just wanted to
11 point out that they (telephonic interference).

12 MEMBER McGIFFERT: You are cutting
13 out. Is there something that you could do to
14 get closer to the phone or something?

15 MEMBER NAGAMINE: I'm sorry. The
16 power went out. So, I am now on my cell
17 phone. I got disconnected and had to start
18 back in. So, I apologize.

19 What I had said is that only 10 to
20 15 percent of patients are on unfractionated
21 heparin. And so, it is a small population
22 that we are talking about here.

1 And so, combining with the issue
2 of the nomogram being combined with the
3 platelet counts, and the fact that this only
4 applies to maybe 10 or 15 percent of
5 inpatient, I am just raising the question of
6 the value or the yield of this measure.

7 CO-CHAIR CONWAY: Thank you.

8 Have you had a chance to think
9 about splitting the measures?

10 DR. BRATZLER: Well, I don't know.
11 All of the measures of the Joint Commission,
12 I mean there would be a Technical Expert Panel
13 that sits down and reevaluates evidence. We
14 are certainly, as I mentioned earlier,
15 anticipating ACCP-9 because that may perhaps
16 lead to something that will have information
17 about platelet counts that we would have to
18 incorporate into a measure or consider
19 splitting it out completely.

20 But, yes, these measures undergo
21 continuous revision and updates. That is part
22 of the process.

1 CO-CHAIR CONWAY: So, the answer
2 is not for right now?

3 (Laughter.)

4 Is that correct?

5 DR. BRATZLER: Yes. Well, I --

6 CO-CHAIR CONWAY: That's okay.

7 DR. BRATZLER: I can't make the
8 changes right now without the Expert Panel
9 input.

10 CO-CHAIR CONWAY: Okay. Hearing
11 no other comments, shall we move on to voting
12 on this measure? All right.

13 MS. WEBER: All right. Importance
14 to measure and report, is it high impact, a
15 performance gap, and evidence? It is a yes/no
16 question.

17 (Whereupon, a vote was taken.)

18 Janet?

19 MEMBER NAGAMINE: (Telephonic
20 interference).

21 MS. BOSSLEY: Janet, did you say
22 yes or no?

1 MEMBER NAGAMINE: No.

2 MS. BOSSLEY: Thank you. You
3 answered the question, because we were split
4 in the room.

5 MS. WEBER: Ten yes, 11 no.

6 MS. BOSSLEY: So, let's talk
7 first, just a minute --

8 CO-CHAIR CONWAY: So, that sort of
9 holds the --

10 MS. BOSSLEY: Right. So, this is
11 one of the must-pass criterion. You were
12 really close, 10 to 11. At this point, I
13 would actually think it is worthwhile to keep
14 going. We will have additional discussion on
15 importance.

16 MEMBER CLARKE: Why don't we see
17 what they score on the other excluding
18 criteria first?

19 MS. BOSSLEY: Do you mean the
20 scientific acceptability? Yes.

21 MEMBER CLARKE: So, for instance,
22 if the next one is no, too, then it is a

1 slamdunk.

2 MS. BOSSLEY: Yes. I think it
3 would be helpful. I think it will also help
4 the Joint Commission get a sense of
5 everything.

6 So, if everyone agrees, let's
7 continue on to scientific acceptability, see
8 what the vote is on that, and then see where
9 we are.

10 MS. WEBER: All right. Scientific
11 acceptability. Are both reliability and
12 validity rated moderate or high? It is a
13 yes/no question.

14 (Whereupon, a vote was taken.)

15 Janet?

16 MEMBER NAGAMINE: No.

17 MS. WEBER: Seven yes, 14 no.

18 MS. BOSSLEY: These are always the
19 fun ones.

20 I think, if you are willing, maybe
21 we should just continue this through. It is
22 just three more votes. And, again, I think it

1 will be informative to the public as this goes
2 out for comment, and then, also, to the CSAC.

3 MS. WEBER: Usability? It is
4 high, moderate, low, insufficient.

5 (Whereupon, a vote was taken.)

6 Janet?

7 MEMBER NAGAMINE: I would say low.

8 MS. WEBER: It is high, moderate,
9 low. Sorry, did you say low?

10 MEMBER NAGAMINE: Low.

11 MS. WEBER: Okay. Thank you.

12 Two high, 5 moderate, 13 low, 1
13 insufficient.

14 Feasibility?

15 (Whereupon, a vote was taken.)

16 Janet?

17 MEMBER NAGAMINE: Low.

18 MS. WEBER: Three high, 8
19 moderate, 10 low.

20 Overall suitability for
21 endorsement. Does the measure meet all the
22 NQF criteria for endorsement?

1 (Whereupon, a vote was taken.)

2 Janet?

3 MEMBER NAGAMINE: No.

4 MS. WEBER: Four yes, 17 no.

5 CO-CHAIR CONWAY: Okay. Thank
6 you.

7 Moving on to 0375, this is venous
8 thromboembolism warfarin therapy discharge
9 instructions.

10 Could we hear from, 0375 --

11 MEMBER SIEGGREEN: Me.

12 CO-CHAIR CONWAY: Mary? Yes.

13 MEMBER SIEGGREEN: Yes. This
14 measure assesses the number of patients
15 diagnosed with confirmed VTE that are
16 discharged on warfarin, and that there is
17 documentation that they were given written
18 discharge instructions or other educational
19 material covering these four components:
20 compliance issues, dietary advice, followup
21 monitoring, and potential for adverse drug
22 reactions and interactions.

1 And this is in terms of
2 importance, it is a high, and there is a high
3 gap. Usability and suitability I think is
4 high. And reliability and validity, that was
5 high.

6 Now, in our conversations in our
7 small group, first of all, I think the
8 overarching goal in this was a patient safety
9 goal from the Joint Commission that was to
10 reduce patient harm. And that is why the
11 education was introduced in the first place.

12 And this is a process, not an
13 outcome. So, there is a knowledge deficit
14 identified with the patient population, and
15 they need to be given written information.

16 It also supports face-to-face
17 interaction between the knowledgeable person,
18 which is a clinical caregiver, and the patient
19 or the patient family member, whoever is going
20 to be responsible for this.

21 Now in our discussions we
22 identified that there is a huge unknown here,

1 and that is the quality of education. The
2 measure itself is just like a checkoff sheet.
3 Did you get the written information that has
4 these four components to it? It doesn't
5 identify what the patient's value system is
6 for health belief. It doesn't identify the
7 patient's ability to comprehend it or how that
8 was evaluated, which is a big component of
9 patient education.

10 So, between the identification of
11 the science, that patients need to know this
12 and patients in general may benefit from this,
13 to go through the patient education, the
14 patient's ability to learn, and the patient's
15 willingness to implement the knowledge into
16 actually behavior changes, there is a big
17 process there that is really unaccounted for
18 in this because it only identifies the
19 documenting that you did -- "you" being us --
20 did give the patient this written information.

21 Now a big recommendation that came
22 from our small group is that, if this measure

1 is endorsed, that a component be added that
2 the patient is given information in his or her
3 own language, which is not specified in here
4 at all. And that would be a big component of
5 patient education.

6 Otherwise, this is very similar to
7 the nomogram. Is it there or isn't it there
8 in terms of a document? It has nothing to do
9 with the outcome it would eventually be.

10 CO-CHAIR CONWAY: Okay. Any
11 comments from the measure developer?

12 DR. BRATZLER: So, I think that is
13 a fair assessment. And as you know, there is
14 a whole science now of measurement of post-
15 discharge knowledge acquisition for patients.
16 It is clearly important.

17 I would argue that this measure
18 remains incredibly important, though, clearly,
19 the implementation also is very important,
20 which I think you are getting to the
21 implementation issue.

22 CDC just released their report

1 within the past or so, the last month or so,
2 that of all adverse drug events that come into
3 emergency departments, warfarin is still No.
4 1. It is still the most common medication
5 associated with emergency department visits
6 for adverse drug events.

7 So, I think there is tremendous
8 need here. And I was shocked at this measure
9 when the biased group of volunteer hospitals
10 had a 40 percent rate of performance on this
11 measure at the outset. And even after months
12 now collecting and reporting the data, still
13 25 percent of the patients aren't getting
14 information about these components of care.

15 So, again, I agree with all of
16 your comments about culturally-appropriate
17 training, and the real need is to figure out
18 what they actually remember when they got
19 home. And again, that is beyond the level of
20 a hospital performance measure, but I think it
21 is really important, and this medication was
22 singled out because we know so many adverse

1 drug events occur because of this one
2 medication.

3 MEMBER SIEGGREEN: One more
4 comment from our small group. We did look at
5 this maybe -- we thought it was important,
6 also, and we thought of it maybe being the
7 first step and other things to come, as we
8 progress through the months and through the
9 years, or whatever. But that it was a first
10 step, and we have to start somewhere.

11 CO-CHAIR CONWAY: So, Patricia and
12 then Vallire.

13 MEMBER QUIGLEY: Excuse me. Thank
14 you, but I do believe Vallire had hers up
15 first.

16 CO-CHAIR CONWAY: We can just move
17 around the table this way.

18 MEMBER QUIGLEY: Oh, thank you so
19 much.

20 I would also say that I rated this
21 with my moderate concern, but really would
22 rather rate it low. As a nurse and practicing

1 in the VA and running fall prevention clinics,
2 I did view this just as a checklist. And if
3 this was to be a proper process measure in the
4 hospitals, and it should be education that is
5 provided during the episode of care for
6 patients who are receiving this kind of
7 treatment, and it should be interdisciplinary
8 because this discharge education is going to
9 be done by nurses as a checklist.

10 And there's plenty of evidence
11 that education alone does not make a
12 difference, that we need to be able to do
13 coaching and mentoring, and we have to involve
14 the patient. So, even in the numerator it
15 says the patient or caregiver, and it should
16 be "and".

17 So, I really was not in favor that
18 this linked to patient safety, that it did not
19 inform the healthcare community. It did not
20 inform patient safety, and it did not inform
21 the consumer whether education was done or
22 not. That is not enough to change behavior.

1 Thank you.

2 MEMBER HOOPER: And I concur with
3 Patricia.

4 I remember in earlier
5 conversations with some of the earlier
6 measures, Dale, it seemed that there was
7 somewhat of an implication of, well, this is
8 somewhat of a proxy for an outcome measure for
9 return with complications. Because if
10 education is done, then the patient is less
11 likely to return to the healthcare setting
12 with a complication related to anticoagulant
13 therapy.

14 And I just think that is a very
15 broad leap that is based on faith as opposed
16 to evidence. There are too many confounding
17 factors other than education that impact these
18 patients returning to the ED with bleeding.
19 Did they have transportation to get their INR?
20 Education does impact outcome, but what we are
21 seeing in postop education is that capacity to
22 absorb the knowledge and retention of the

1 knowledge, even with a written instruction, is
2 very low.

3 And so, I really question that the
4 general response, if your performance on this
5 is low, is, "Well, we are doing it, but we are
6 not documenting it." So, let's find a way to
7 trigger the documentation.

8 So, I think this measure is a
9 reflection of a checklist, and not actually
10 impacting, reflecting actual process and
11 quality process, nor is it reflecting an
12 impact on outcome.

13 MEMBER THRAEN: This goes back to
14 the vendor. So, this particular measure in
15 its current form has been in place for three
16 years, and you have had reporting in on it.
17 Is there a reason why, based on what people
18 are saying and the advance of the science, et
19 cetera, that this measure hasn't been
20 reformulated to accommodate the language
21 issues, to accommodate some of the other
22 issues that have been discussed? Why is it

1 being asked to be maintained in its current
2 form?

3 DR. BRATZLER: So, I will tell you
4 that this is the first time there has been any
5 reevaluation of the measure. So, the comments
6 about language, I mean I think that may be
7 appropriate, but that has never been discussed
8 before.

9 Even as the measure exists -- and
10 Denise has been pointing out to me that you
11 have to dig down into the specifications. It
12 is more than a checklist, this particular
13 measure.

14 So, as an example, she highlighted
15 for me that there is a requirement, for
16 instance, that there has to be documentation
17 that the name, the phone number, the health
18 professional, the clinic monitoring, the
19 anticoagulation clinic, the next date for PT
20 and INR must be given to the patient to pass
21 the performance.

22 So, it is more than just checking

1 a list. You've got to give very explicit
2 information to pass it. It is, in part, why
3 some of these hospitals, even after three
4 years of capturing this data, are still 25
5 percent of the time failing the measure,
6 because the specifications for the measure are
7 fairly explicit about what has to be provided
8 to the patient to ensure that they at least
9 got that information when they walked out the
10 door.

11 I really understand the whole
12 issue of care transitions and patient
13 knowledge of discharge instructions. It is a
14 tough time to teach patients when they are at
15 the end of an acute care stay, but that is not
16 what this measure addresses. It doesn't look
17 at post-discharge care.

18 And I would also argue that,
19 again, around the table we often have a
20 somewhat biased group. Out in the area in the
21 community hospital and the small rural
22 hospitals around the country, there aren't

1 teams of people doing this education in most
2 institutions. It may be a pharmacist. It may
3 be a nurse.

4 So, we set out in the
5 specifications of the measure very explicit
6 documentation that must be there, that must be
7 given to the patient at the time they leave
8 the hospital.

9 And there are still gaps, big
10 gaps.

11 MEMBER THRAEN: But again, given
12 its current form, do we know what this
13 effectiveness is? So, I understand you are
14 saying there is a performance gap, but for
15 those who are actually doing it, do we have
16 any effectiveness data to say that -- because
17 all of the conversation is basically saying,
18 in the way that we are doing it, it is not
19 working. Even if we are doing it, it is not
20 necessarily working because we are still
21 seeing the ER visits; we are still seeing the
22 problems.

1 So, do we know if this measure has
2 any effectiveness associated with it?

3 DR. BRATZLER: No, I don't know of
4 any studies evaluating the effectiveness at
5 the patient level on things such as
6 readmissions. I don't know of any data that
7 has done that.

8 And again, this measure has only
9 been used by a select group of hospitals that
10 volunteered to report it. It has not been
11 nationally required.

12 So, I believe that the data will
13 look much worse on a national basis.

14 MEMBER NAGAMINE: Iona, I'm sorry.
15 This is Janet. I do have some sort of thought
16 on that question when you are ready.

17 MEMBER THRAEN: Go ahead.

18 CO-CHAIR CONWAY: Go ahead, Janet.

19 MEMBER NAGAMINE: Yes. As far as
20 the effectiveness of education, our group
21 really had robust discussion on this because,
22 on the one hand, you have got to start

1 somewhere. You have got to educate them. You
2 have got to make sure that they have followup.

3 But, that said, we have a very
4 robust inpatient and outpatient anticoag team
5 in Kaiser. And I have studied how we have
6 done in terms of our education. And it was
7 rather disappointing that, knowing that it had
8 been done, knowing that they had been referred
9 to the anticoag clinic, they have been calling
10 them, we still have gaps in terms of what the
11 patient understood.

12 And so, I think some education is
13 better than none. But how effective it is I
14 am not sure. It is so complicated.

15 MEMBER THRAEN: Okay. And one
16 last thing, just a point of clarification.
17 So, if this measure is voted down or not
18 endorsed, what are the options following that?

19 So, if we say that based on the
20 fact that it doesn't address the issues that
21 we have talked about, and we don't endorse it,
22 does the sponsor still have the opportunity to

1 go back, retool it, bring it back? What is
2 that process?

3 MS. BOSSLEY: Yes. So, if any
4 measures, I think, that are not recommended
5 here or as new measures are developed, we have
6 periodic calls for measures. So, they would
7 be able to bring them in for consideration.
8 As to when that would be, it does vary right
9 now. We are working on a process that would
10 make it a little more open to allow it to come
11 back in more periodically, but, for sure, in
12 three years.

13 DR. BRATZLER: But through this
14 conversation, so far I have only heard a
15 couple of things that were feasible for a
16 hospital to implement. So, language-based
17 instructions, I think that is certainly
18 feasible to look at that.

19 But most of what I am hearing you
20 talk about is this whole concept of patients
21 grasping the knowledge that they are given at
22 the time of discharge, which is a post-

1 discharge assessment and not within the
2 control of this particular performance
3 measure.

4 Now Eric Coleman has a very nice
5 care transitions measure that is NQF-endorsed,
6 that is used by many centers, that does assess
7 the effectiveness of the discharge instruction
8 process. That is a separate NQF-endorsed
9 measure.

10 But this measure focuses on what
11 happens when they are still at the hospital at
12 the time of discharge. Is somebody telling
13 them to follow up, to be seen, to watch out
14 for drug interactions, and those things?

15 So, I recognize that just giving a
16 list, education, showing them the DVD may not
17 be enough. I understand that. But I can tell
18 you that, for a whole lot of patients, that is
19 not even happening.

20 CO-CHAIR CONWAY: I don't usually
21 like to address things as the Chair, but on
22 this one I can't help myself.

1 We have got now a several-year
2 history of checklists like this in the
3 healthcare industry. I mean, look at the
4 failure of heart failure discharge
5 instructions. Come on. And that is a multi-
6 component list of things that are supposed to
7 be done, and there is no evidence that we are
8 helping patients understand how to manage that
9 disease. The staff are just checking things
10 off.

11 We have got to find a new way to
12 hold people accountable for this type of
13 patient education, but this is the not the way
14 to go.

15 MEMBER ADELMAN: I just want to
16 point out -- and I believe I am right about
17 this -- that although we may not endorse this
18 as a measure, I believe that we all are
19 required to educate all of our -- there is a
20 patient safety goal about educating everybody
21 on discharge on anticoagulation. And then,
22 there is the Joint Commission standards about

1 the proper way to educate in the right
2 language.

3 So, regardless of how we vote
4 today, I think this is something we all are
5 required to do. Am I correct about that?

6 MEMBER SIEGGREEN: I think this
7 whole thing is very confounding because
8 education is the big issue here. And for
9 most of us who have been in healthcare, we
10 didn't go through an education process, and we
11 don't know how to educate. And I think that
12 is a big problem. Because I have told you
13 doesn't mean you have learned.

14 And I think in order to mandate
15 that we get the outcomes by educating the
16 patients, then we have to mandate that the
17 people learn how to educate. So, I think it
18 gets so complex that we have to start out with
19 something. And if is a checklist, it is a
20 checklist. And if we then do research on how
21 the checklist failed -- like with heart
22 failure, now we have some changes in the way

1 we deal with heart failure within our
2 institutions. We are going to have to have
3 some changes in the way we deal with education
4 regarding this as well.

5 MEMBER WHITE: I have a
6 procedural. So, if we like the idea of
7 educating people, but we are demanding they
8 have to do it in their language to where they
9 can understand, how does one go about voting
10 on this? So, you vote down what is currently,
11 and then we just make a comment? Or we say,
12 yes, education is good, but we would add this?
13 What are we doing?

14 MS. BOSSLEY: So, I think we
15 should first on importance because I think
16 that is what all of you are kind of struggling
17 with. Then, the next question would be on
18 scientific acceptability. If it passes
19 importance, I think the question would be, is
20 Joint Commission willing to add in some
21 specifications that would require it be
22 provided to them in their own language, which

1 I think is a doable thing for them to do.
2 But, again, let's first, if everyone is ready,
3 vote on importance. And then, that question
4 I think we can just ask when we get to
5 scientific acceptability. I think that is a
6 very easy request for them to build into the
7 measure.

8 CO-CHAIR CONWAY: Okay. Why don't
9 we come up this side of the table and then we
10 will swing over here? John?

11 MEMBER CLARKE: I see this as part
12 of the general problem of health literacy.
13 And so, the outcome measure is that the
14 patient understands. It is a very complex
15 issue, and I think we are very far from it.

16 So, backing up, the process
17 measure is that we communicate effectively to
18 the patient in a way that an average patient
19 should be able to understand. But I think
20 this measure really touches at something that
21 is even further upstream, which is you have to
22 talk to the patient. And I think the problem

1 here is that we are trying to capture is we
2 don't even talk to the patient. We don't even
3 tell them they are on a blood thinner. We
4 just say, "Take the pink pill."

5 And I think measure adequately
6 captures that very first step, which is a
7 requirement that you actually do something in
8 the way of communicating with the patient.
9 Then, I think we can proceed to the second
10 step. As Mary, I think it was, said, how do
11 you do that effectively when you see that it
12 is not getting the traction that you want?
13 And maybe sometime in a decade or two, get
14 into the health literacy issue.

15 CO-CHAIR CONWAY: Vallire?

16 MEMBER HOOPER: I would still go
17 back. You know, when we are looking at a
18 measure that is not an outcome measure, then
19 we are asked to evaluate the evidence related
20 to the process and its relationship to the
21 outcome.

22 And in this measure, I have yet to

1 see the direct connection of the process of
2 written instructions, John -- this is written
3 instructions; it does not even include that
4 you have to talk to patients technically; it
5 is written instructions -- to the outcome of
6 complications related to anticoagulation
7 therapy.

8 And I think while the patient must
9 also be at the center, we also have to be
10 aware of the resources that it takes, various
11 healthcare facilities must dedicate to
12 gathering this data. And for Joint
13 Commission, once it becomes a Joint Commission
14 measure, that is not an option. That is a
15 requirement.

16 And to ask an institution to
17 gather data that is not shown by the evidence
18 to improve the patient outcome is, in my
19 opinion, being somewhat irresponsible.

20 And so, again, I would just ask to
21 consider the relationship of a written
22 instruction sheet to patient outcome. I would

1 much rather see a new measure developed
2 related to how many patients do we have coming
3 back to the hospital facility with
4 complications related to anticoagulant therapy
5 and start to research what is the root cause
6 of those complications.

7 CO-CHAIR CONWAY: Steve and then
8 Saul.

9 MEMBER NAGAMINE: This is Janet.

10 I just want to second that because
11 we did do that. I do think that there are
12 local specifics about how you do the education
13 that aren't necessarily generalizable to all
14 populations. So, I do think that would be
15 meaningful.

16 MEMBER LAWLESS: I have a little
17 bit of a problem with it, only because we have
18 had measures in the past that talk about you
19 have to have discharge summary instructions,
20 medication reconciliation, and educational
21 materials sent. But now we really mean it
22 about warfarin. So, it looks like you are

1 subpopulating that really now we are serious
2 with those, which they should be al included
3 with it.

4 (Laughter.)

5 The other piece, I would say, is
6 not just language. With the new guidelines on
7 communication with the Office of Minority
8 Health, I guess as it is called, or whatever,
9 that it is not just language; it is also
10 degree of how well you speak English. So
11 that, it is not just language; that also gets
12 included. So, that is going to open up a
13 whole new field of things.

14 So, I echo the comments that the
15 Chairman has made. I think that this is
16 something that looks bad that you are not
17 endorsing it, but the reason you are not
18 endorsing it is because it is not really
19 hitting the point.

20 MEMBER WEINGART: So, to that
21 point, I mean, I am struck by, I have this
22 sense of angst because, on the one hand, this

1 is an enormous vulnerability we have and a gap
2 in the quality of the care we deliver. On the
3 other hand, we may not be reaching, I think to
4 Heidi's point and Vallire's point, this is
5 important, but may not reach the criteria for
6 scientific validity of the measure to
7 demonstrate the care that we want.

8 So, that's it.

9 CO-CHAIR CONWAY: Okay. We have
10 one more. Patricia?

11 MEMBER QUIGLEY: I keep doing
12 that. Thank you. I am dependent on Tracy
13 over here.

14 I would just like to say again
15 that, if this indicator gets developed again,
16 that I would like to certainly encourage that
17 it be education as a document over the episode
18 of care, not just on discharge, and that it is
19 interdisciplinary. And from the patient
20 safety perspective, it needs to include any
21 education related to patients who are
22 anticoagulated, about what to do if they fall.

1 So, I mean, I think that there is
2 other work that needs to be done in this area,
3 but this approach is not really linked to
4 patient safety as it is written.

5 Thank you.

6 CO-CHAIR CONWAY: Okay. Thank
7 you.

8 Any other comments? Janet, any
9 parting comments?

10 (No response.)

11 Okay, hearing none, shall we move
12 on to voting? Jessica?

13 MS. WEBER: Importance to measure
14 and report. Are all three subcriteria met,
15 high impact, performance gap, evidence?

16 (Whereupon, a vote was taken.)

17 Try voting again. One more vote
18 needed.

19 Janet?

20 MEMBER NAGAMINE: Moderate.

21 MS. WEBER: It's yes or no.

22 MEMBER NAGAMINE: Oh, I'm sorry.

1 Oh, that's tough.

2 Yes.

3 MS. WEBER: Ten yes, 11 no.

4 CO-CHAIR CONWAY: All right.

5 Next?

6 MS. BOSSLEY: Now should we
7 briefly talk about any -- I would say we call
8 them typically conditions -- additions that
9 you would like made to the measure? We can
10 either vote on this as it currently is, and
11 then, if this doesn't pass, we can then
12 revisit, if they made a few changes, then vote
13 again on scientific acceptability. We can do
14 it that way if everyone would like.

15 So, we will vote as the measure is
16 right now. Okay.

17 MS. WEBER: Scientific
18 acceptability of measure properties,
19 reliability and validity. It is a yes/no
20 question.

21 (Whereupon, a vote was taken.)

22 Janet?

1 MEMBER NAGAMINE: No.

2 MS. WEBER: Four yes, 17 no.

3 MS. BOSSLEY: I mean, the one
4 question would be, if they made -- and I think
5 we would have to define what those
6 modifications would be, and they would have to
7 be somewhat small -- if they made those, would
8 you want to then revisit the vote on
9 scientific acceptability? So, I think what I
10 heard was, I think the major one is that it be
11 provided to them in their own language. That
12 was the only one that I think I have taken
13 away as a possibility.

14 MEMBER MCGIFFERT: I think the
15 other one that someone raised was that they
16 are provided through some kind of oral
17 communication with the written language, with
18 a written document.

19 MEMBER NAGAMINE: The other caveat
20 -- this is Janet -- is they may speak English,
21 but they might have significant dementia. So,
22 what do you do there? Ensure that there is a

1 family member or somebody else? Those are
2 things that we incorporate to our teachings.

3 DR. BRATZLER: Yes, the measure
4 does allow you to give the information to
5 caregivers.

6 CO-CHAIR CONWAY: Iona?

7 MEMBER THRAEN: I would argue that
8 putting it in their own language, which is a
9 small change, is a minimum state of change for
10 this particular measure, would make me feel
11 less guilty for voting it down. But it
12 doesn't accomplish the task at hand in terms
13 of really trying to change patient outcome,
14 and that the issues of relating the use of
15 this medication back to fall risk, the issue
16 of literacy in general, as well as language
17 issues, and also delivering this information
18 not just at discharge, but multiple times
19 iteratively over the course of the stay by
20 multiple providers, those are a number of
21 different changes that I think this measure
22 needs to address.

1 CO-CHAIR CONWAY: Patricia? Okay.

2 Sorry. All right, Jason?

3 MEMBER ADELMAN: I was just going
4 to say perhaps you can also add as an
5 exclusion, if you modify it, patients
6 transferred to long-stay care. If they are
7 going to go someplace else where nursing is
8 taking care of them, I don't know that we need
9 to give them instruction. Or maybe we do. I
10 don't know.

11 CO-CHAIR CONWAY: So, maybe a
12 different way to --

13 MEMBER NAGAMINE: This is Janet.
14 I have a comment.

15 CO-CHAIR CONWAY: Yes, go ahead,
16 Janet.

17 MEMBER NAGAMINE: Tagging onto
18 what Iona said about ultimately affecting
19 outcomes, and after having studied this in our
20 system, we actually concluded that, despite
21 the rigorous education that patients get, it
22 impacted the outcome less than we had hoped.

1 And where we directed our focus was getting
2 better at determining who should be on
3 warfarin and really calculating upfront the
4 risk/benefit ratio better, so that the
5 outcomes would be impacted.

6 CO-CHAIR CONWAY: Let me ask
7 Heidi's question in a different way. Of the
8 people who voted no -- I want you to raise
9 your hand -- if the Joint Commission further
10 specified the kind of education, how many
11 people would change their vote?

12 It is undefined. I mean, if they
13 did all the things that were requested,
14 language, oral discussion, and whatnot, to the
15 education process, how many no votes would
16 that change? Raise your hand.

17 (Show of hands.)

18 MS. BOSSLEY: In an informal vote,
19 that makes it 8 yes and 13 no -- I haven't had
20 enough coffee -- 13 no. So, it is still,
21 again, the informal does not pass scientific
22 acceptability.

1 MEMBER PROBST: It seems to be
2 such an important issue in terms of patients
3 coming back, care transitions. You know, I
4 have had family members that -- fortunately,
5 I was a nurse -- but they got no education
6 about that they had congestive heart failure
7 or were going home on warfarin. And when I
8 asked about it, they said, "Well, we didn't
9 expect them to live." I said, "Well, they did
10 live," you know, and "so they need the
11 education."

12 (Laughter.)

13 And so, it really needs to happen.
14 So, I am just worried that at this point in
15 time, if we don't support the measure, what
16 kind of message -- I mean, I am just thinking
17 about being on the Purchaser Committee and
18 trying to explain to people why the Steering
19 Committee didn't think education was important
20 enough to keep a measure there.

21 So, I know that it is not perfect.
22 And I also know that, if you keep passing a

1 non-perfect measure, there is no incentive to
2 get it perfect. But it seems something that
3 is pretty counterintuitive.

4 CO-CHAIR CONWAY: Let me just
5 clarify. I don't think anybody here said
6 education wasn't important. So, for you and
7 Iona that feel bad, this is about feasibility
8 and scientific validity.

9 MEMBER McGIFFERT: And I think it
10 would be really good if we could send that
11 message out, that we feel that it is essential
12 and that this is not a vote against education,
13 but it is a vote against inadequate education.

14 CO-CHAIR CONWAY: We also don't
15 have a measure to hold people accountable for
16 that that is scientifically valid.

17 MS. WATT: Can you hear me now? I
18 feel like a commercial.

19 You know, you are coming through
20 loud and clear. And you are not telling us
21 anything that we don't know and haven't
22 thought about. What we don't know how to do

1 -- and this is what I am asking your help, and
2 I am sincerely asking your help -- how do we
3 make a measure for education at the inpatient
4 level of care that would address the issues
5 that you bring up?

6 I mean, we are stymied, to be
7 perfectly honest with you. If you could make
8 measure that it would meet your threshold for
9 meeting these criteria, what would it say?
10 How would it look? Gladly, we will write it.
11 I just don't know how.

12 CO-CHAIR CONWAY: I think we have
13 some volunteers.

14 (Laughter.)

15 We will go around this way,
16 Richard first.

17 MEMBER WHITE: You would have to
18 have a validated educational material shown,
19 when given to the patient in their language,
20 improved outcomes. And no one has done all
21 that research, but, I mean, that is what you
22 would like. Then, you say -- it is like

1 nomogram -- then, you would say, "Yes, we
2 applied this and taught this, which is a
3 validated tool. We don't know if they really
4 learned it." But, I mean, no one has
5 developed --

6 MS. WATT: Well, there is no
7 validated tool.

8 MEMBER WHITE: Yes, right. I
9 know.

10 MS. WATT: That's the problem.

11 MEMBER WHITE: I know, that's the
12 problem.

13 MS. WATT: And so, are performance
14 measures to remain silent on this very, very
15 important issue of education because nobody
16 has made validated tools? You know, that
17 doesn't feel right, either.

18 CO-CHAIR CONWAY: John and then
19 Vallire.

20 MEMBER NAGAMINE: My hand is up,
21 Bill.

22 CO-CHAIR CONWAY: Okay.

1 MEMBER CLARKE: The Joint
2 Commission might want to consider something
3 very radical, since this is ultimately an
4 outcome measure. And that is to make sure
5 that the patient has adequately demonstrated
6 an understanding of what is going on. That
7 is, that they actually have responded in
8 writing to questions about what they should do
9 under what circumstances.

10 MS. WATT: Post-test-type stuff?

11 MEMBER WHITE: I can't get my
12 medical students to answer them right.

13 CO-CHAIR CONWAY: Right. Order in
14 the house.

15 Vallire and then Janet and then
16 Jim.

17 MEMBER HOOPER: I guess no one
18 disagrees that education is important, but
19 there are so many components to education. I
20 mean, I agree, John, a post-test would be
21 great. But now bedside nurses can barely get
22 everything they need to get done to take care

1 of that patient and keep them alive from one
2 shift to another.

3 And education occurs in every
4 patient contact that is no formal education,
5 nor is it always documented. I mean, every
6 time you walk in that room, there is some
7 component of patient and/or family education,
8 and it is not always going to be documented.

9 I don't think education is your
10 problem. I think you have got to get to the
11 outcome and drill down on the problems with
12 the outcome that will then guide you to the
13 process problems.

14 As a long-time bedside nurse, to
15 say, "Well, now only have I now got to make
16 sure I get back and check my 20 checks in the
17 electronic chart, but I have also got to
18 complete a post-test for the patient" is just
19 beyond capacity. I mean, it is just is.

20 So, I just really think that
21 education is important, but it is not the
22 focus of a performance measure. It has got to

1 be an outcome.

2 MS. WATT: But the outcome occurs
3 after the hospitalization.

4 CO-CHAIR CONWAY: Okay. Let me
5 point out something to the panel members. The
6 staff do a very good job of capturing the rich
7 nature of this discussion, and the report that
8 comes out of this will not be a simple yes/no
9 vote. It will contain some of this discussion
10 of the rationale, and you get to see a draft
11 of the report, right, before we release it?
12 So, it will be sent around to you.

13 So, a lot of the rationale behind
14 these votes is included in the report. So,
15 you are not going to go public with a vote
16 against patient education.

17 Stephen? And then, we will get on
18 this side of the table.

19 MEMBER LAWLESS: Thank you for
20 that clarification, Mr. Chairman. I don't
21 like minimum security prisons.

22 (Laughter.)

1 For the Joint Commission, if you
2 want an idea, a 24-hour post-discharge phone
3 call to clarify how well these guidelines have
4 actually been done or the instructions have
5 been followed up or followed through, as a
6 suggestion. It is not going to impact my
7 vote. But if you want a suggestion, that is
8 one I will give you.

9 CO-CHAIR CONWAY: Janet, you have
10 something to say? Janet?

11 MEMBER NAGAMINE: Yes. So,
12 stepping back, I think the intent of this
13 measure is to reduce events on warfarin. And
14 after having studied this, I think we also
15 have to look much more closely at who we put
16 on warfarin because what we found was that the
17 ones who had bleeding events were the ones
18 that were older, had dementia, fall risk, et
19 cetera.

20 And so, you can focus on
21 education. But I also want to throw out there
22 and the question which I really appreciate is,

1 what do we do about this problem?

2 I think we need to look closely at
3 the risk/benefit ratio. So, if mom is 92 and
4 has dementia and is falling every day and has
5 A-Fib with a 5 percent risk of stroke per
6 year, what does that do for her versus her
7 risk of bleeding? And I think we can't just
8 talk about education without looking at the
9 people we are putting on warfarin as well.

10 CO-CHAIR CONWAY: Okay. Thank
11 you.

12 Mary, and then Louise.

13 MEMBER SIEGGREEN: I agree with
14 Janet. I think sometimes it the clinician's
15 judgment call.

16 But I wanted to back up to some
17 statements about the patient education. And
18 having a patient sign something that they have
19 received the education or that they understand
20 it doesn't mean that there is going to be any
21 followthrough. And we see this, I see this
22 over and over again when I ask the patients in

1 the clinic, "Nobody ever told you about
2 smoking and what a problem it was, right?"
3 And they can rattle off every single problem
4 there is with smoking, and, yet, they are
5 still smoking. So, for some reason, that
6 hasn't hit them.

7 I think it is the same thing with
8 any education. If you don't know what the
9 little key is that is going to make this
10 person or influence this person's behavior,
11 then it is very difficult. You can't ensure
12 that, again, because I told you have learned
13 or because I have told you you are going to
14 change your behavior.

15 So, I think adding more things for
16 the healthcare provider to do just makes more
17 work for the healthcare provider, but it is
18 not necessarily going to get us to the
19 outcomes that we want. So, maybe looking at
20 that patient who is, quote/unquote -- I hate
21 this word -- "non-compliant" is not the person
22 who belongs on Coumadin or warfarin.

1 CO-CHAIR CONWAY: Richard?

2 MEMBER WHITE: Yes, we are doing a
3 VTE measure and not an A-Fib measure. So, we
4 are moving discussion into a whole different
5 realm about the indications.

6 So, these people are at very high
7 risk for recurrence right after they are put
8 on anticoagulation. So, they have got to be
9 on warfarin or one of these new
10 anticoagulants, once it is FDA-approved.

11 So, this whole discussion about
12 appropriateness doesn't apply to the VTE
13 group. They really have to be on this
14 anticoagulation for at least three months.

15 MEMBER NAGAMINE: That's true.
16 Thank you. Risk/benefit is there.

17 CO-CHAIR CONWAY: Patricia, is
18 your card up?

19 MEMBER QUIGLEY: Thank you.

20 My question is related to process.
21 I wondered if we could finish the voting
22 process, and then maybe have some open dialog

1 with the Joint Commission, so we could help
2 them with what they are asking.

3 CO-CHAIR CONWAY: Sure. We are
4 done voting, and we are in open dialog.

5 MEMBER QUIGLEY: Oh, so we have
6 voted? We are not having to go through all
7 the rest, as we have done before?

8 MS. BOSSLEY: Right.

9 MEMBER QUIGLEY: Oh, okay.

10 MS. BOSSLEY: So, importance and
11 scientific acceptability are must-pass. So,
12 it passed, well, came close to passing
13 importance, which is why we went on to
14 scientific acceptability. It, I think,
15 clearly, did not pass scientific
16 acceptability.

17 MEMBER QUIGLEY: Oh, thank you.

18 CO-CHAIR CONWAY: Okay. Iona?

19 MEMBER THRAEN: And this is just
20 feedback to the Joint Commission. I don't
21 know if there are equivalent measures
22 associated with other kinds of chronic

1 diseases like diabetes and asthma in terms of
2 the educational process or the intervention
3 process, in terms of getting patients up-to-
4 speed with their disease and the use of their
5 medications, et cetera, et cetera, that could
6 be adapted or adopted in this arena that might
7 be useful.

8 CO-CHAIR CONWAY: Okay. Carol?

9 MEMBER KEMPER: Just one other
10 comment to what Iona said. I am more familiar
11 on the pediatric side, obviously. And so, for
12 me, asthma is the core measures that we use.
13 There is a very similar measure as to this one
14 in the asthma core measures.

15 And what we have found is we have
16 done a lot to make sure that our medical
17 record, that it is very easy for people to
18 check those off. But in some research that
19 has been done across freestanding children's
20 hospitals, we found that there has not been
21 any impact in that or in correlation with then
22 return to the hospital.

1 So, I think we are still trying to
2 figure out -- I just want to reiterate; it
3 goes back to what Mary said -- we have got to
4 figure out how to do the education, and we
5 don't know that yet.

6 And so, it makes us feel good that
7 we can check that off, but it shouldn't
8 because we are still not seeing that we are
9 creating the impact that we want to.

10 CO-CHAIR CONWAY: Okay. Thank you
11 for that rich discussion, which will get
12 captured in the report.

13 All right. We are on to Measure
14 0376. This is an outcome measure, incidence
15 of potentially preventable venous
16 thromboembolism.

17 DR. BRATZLER: I would like to
18 make a comment for the discussion. We
19 actually do not consider this an outcome
20 measure.

21 We had a long discussion with our
22 Technical Expert Panel about this when we came

1 up with it. We actually considered this a
2 process measure. Some people called it an
3 intermediate outcome, but it really focuses on
4 whether patients -- the denominator population
5 are those patients who develop hospital-
6 acquired VTE events. And the process is, did
7 they receive prophylaxis or not? If they
8 received prophylaxis, even if they got the
9 event, we consider it not preventable.

10 So, what you are trying to define
11 here is a group of patients who got a
12 hospital-acquired VTE event who did not
13 receive prophylaxis. It says something about
14 that process. It also says something about
15 the adequacy of the hospital's risk-assessment
16 profile, because if you have a lot of patients
17 getting VTE events that did not receive
18 prophylaxis, it may reflect the fact that you
19 are not giving a prophylaxis to high-risk
20 patients.

21 So, we actually don't consider it
22 an outcome measure. It is really focused on

1 did they receive prophylaxis or not? Were
2 they given the chance to prevent the event?

3 CO-CHAIR CONWAY: Good. Thanks
4 for that clarification.

5 And, Saul?

6 MEMBER WEINGART: So, thank you.

7 So, the measure is, as you said a
8 minute ago, kind of a look-back. We look at
9 the denominator of folks who had hospital-
10 acquired VTEs and then look back and see
11 either they had prophylaxis, and it is not
12 ordered, but it actually looks like it is
13 supposed to be received.

14 And the criteria is also met if
15 there is a reason stated for exclusion. In
16 other words, if the patient declines or if it
17 is thought not to be appropriate. So, there
18 is a risk assessment built into it, and it
19 prevents the organization from being dinged on
20 that one.

21 And then, there were a number of
22 other exclusions, high length of stay, comfort

1 measures only, somebody in a clinical trial,
2 or the DVT or PE was present on admission.

3 So, the group discussed it a bit,
4 and we had a couple of observations that I
5 thought I would share with the group.

6 First, there was a discussion
7 about whether present on admission was easily
8 or not easily ascertained. I think there was
9 a sense that we are getting increasingly good
10 at doing this, or at least having the medical
11 decoders document this in the medical record.

12 I think there is some question
13 about whether a VTE diagnosed in the first two
14 or days or so maybe was there on admission,
15 but wasn't picked up at the time of admission.
16 So, I think there is a little bit of an
17 ambiguity in that respect.

18 As we have discussed multiple
19 times today, there is some component of risk
20 assessment built in. In other words, you
21 could exclude an individual for whom
22 anticoagulation was not appropriate. But when

1 summing up individuals over the course of a
2 hospital, if you have an oncology population,
3 an orthopedic population, a population with
4 high thrombophilia, this may result in sort of
5 failure to account for those differences
6 across institutions or services.

7 The staff identified in the
8 measure the need to identify what an episode
9 of care entailed. I think the measure assumes
10 that this is an admission. It does sort of
11 beg this question of whether time at risk is
12 a vulnerability that ought to be taken into
13 account. In other words, if you have a long
14 length of stay, you are more at risk of an
15 event, and failure to anticoagulate or to
16 prophylax in some way might be overrepresented
17 in groups that have longer time at risk. On
18 the other hand, we don't do this routinely for
19 the other measures. So, it is just something
20 I think to bear in mind.

21 Another thing which came up was a
22 question of the adequacy of prophylaxis. This

1 is an issue we discussed early on about
2 whether mechanical prophylaxis is acceptable,
3 and I don't want to belabor that now.

4 The other two things I thought I
5 would mention is it doesn't assess whether the
6 anticoagulation is adequate. In other words,
7 they might be on warfarin, but it might not be
8 therapeutic. So, that is not taken into
9 account.

10 And then, finally, this is a
11 measure where we need to acknowledge that
12 there is a certain amount of treatment
13 failure. Even with patients who are
14 appropriately prophylaxed, they might still
15 develop an in-hospital event.

16 So, all in all, I think there are
17 some issues with the measure and there are
18 with any measure. My own view on it is that
19 I think it is a pretty interesting way to get
20 at whether practices are in place at the
21 institution. And it is tied to perhaps a
22 harder measure that is closer to outcome than

1 we are used to, and that these concerns and
2 reservations I think are something that we
3 ought to discuss and think about, but don't
4 necessarily mean it is not a valid and
5 important measure for us to consider.

6 Oh, I didn't go over the rankings.
7 You can't actually see the rankings. Mostly
8 good.

9 DR. BRATZLER: I did want to
10 comment on one thing you said, and that is
11 treatment failures. That is actually why we
12 developed the measure the way we did, because
13 we recognize that, even with appropriate
14 prophylaxis, some patients will get events,
15 but those cases pass because they got
16 appropriate prophylaxis or they got
17 prophylaxis. So, the measure really is
18 looking at a patient who develops a hospital-
19 acquired event and got nothing.

20 CO-CHAIR CONWAY: Okay. Questions
21 from the panel members or comments?

22 MEMBER NAGAMINE: I just had one

1 comment about present on admission. The other
2 thing we discussed in our subgroup was there
3 are patients who leave the hospital and come
4 back within a day or two with a DVT or PE.
5 And although it probably originated in the
6 previous admission, this population would not
7 be captured in the preventable VTE group. And
8 I believe Richard sent around an article that
9 estimated that that would be about 30 percent
10 of patients, if I am not mistaken.

11 Richard, could you comment on
12 that?

13 MEMBER WHITE: There was a paper
14 presented at ASH last week, American Society
15 of Hematology, "Root Cause Analysis of Failure
16 of Prophylaxis in Hospitalized Medical
17 Patients". And so, they isolated these cases,
18 and it wasn't strictly on ICD-9 codes. It was
19 out of England. So, they had a different way
20 of finding them.

21 And when they looked, there was
22 all sorts of failures. I think 25 to 30

1 percent got no prophylaxis, 15 percent got
2 prophylaxis but not all the time, 10 percent
3 didn't get the right dose. So, you see all
4 sorts of failures in there. And I think 20
5 percent to 25 percent got perfect prophylaxis
6 and still got a VTE.

7 So, there's all sorts of ways
8 things can fail. It just showed the
9 complexity. It has taken this author a year
10 and a half of combing through these charts to
11 get this quality data on several hundred
12 patients. So, it was a big effort. But it
13 just shows you the complexity of analysis.

14 CO-CHAIR CONWAY: So, you said,
15 was this 30 percent of admitted DVT cases
16 had --

17 MEMBER WHITE: No. Thirty percent
18 of hospital-acquired VTE cases in retrospect
19 got, I think 30 percent got appropriate
20 prophylaxis during the entirety at the right
21 dose. And then, there was 20 percent who
22 didn't get any prophylaxis whatsoever, and a

1 lot of other stuff in between.

2 DR. BRATZLER: And I wanted to
3 comment on the issue about the readmission.
4 Actually, I do think that is a key issue, that
5 a patient may have not gotten prophylaxis
6 during a first stay, went home, developed a
7 VTE, and comes back into the hospital. We
8 wouldn't capture those because it would have
9 been present on admission.

10 But, again, because there is no
11 way to know that the patient is going to be
12 admitted to the same hospital the second time,
13 there is no way for us to account for that in
14 this performance measure. So, we have to look
15 at the episode of one acute care event.

16 MEMBER WHITE: Who is in the
17 denominator? How do you identify these
18 patients? Is this ICD-9 discharge VTE POA?
19 No?

20 DR. BRATZLER: Yes. Yes, they
21 have to have a discharge diagnosis of a VTE.

22 MEMBER WHITE: It is not another

1 assay of hospital-acquired? It is coded --

2 DR. BRATZLER: It has to be
3 confirmed. The diagnosis has to be confirmed
4 by a test.

5 MEMBER WHITE: And it is in the
6 administrative data?

7 DR. BRATZLER: Right. So, there
8 has to be administrative data that they had
9 the event, but, also, then, they look at the
10 chart to make sure that there was a
11 confirmation test of the event.

12 MEMBER NAGAMINE: My understanding
13 is that with HAI there is a way to link it to
14 a prior admission. So, if you were to define
15 a short period of time, would that be
16 workable? Just a question.

17 DR. BRATZLER: So, I guess you
18 could ask the question whether they had been
19 recently in the hospital. The problem is the
20 hospital that is capturing this data has no
21 influence over, may not have any influence
22 over the previous stay. So, it could have

1 occurred in a previous hospitalization, but
2 the hospital that is reporting this measure
3 can't be held accountable for something that
4 happened in the prior -- particularly if it
5 was a different hospital. So, that is the
6 challenge.

7 MEMBER NAGAMINE: Right. And how
8 do they handle that in HAI?

9 DR. BRATZLER: I'm not sure.

10 MEMBER THRAEN: Sorry. That is
11 for CMS Medicare patients. And so, they are
12 looking at the billing for individual
13 patients. So, if they are showing up in the
14 hospital within their 30-day readmission, or
15 whatever the case might be, associated with a
16 healthcare-acquired infection, then that is
17 sort of how it plays itself out from a billing
18 perspective for Medicare.

19 MEMBER SIEGGREEN: What if they
20 don't show up in the hospital, but they get
21 treated for a urinary tract infection in a
22 physician's office post-hospitalization?

1 MEMBER THRAEN: Right now, it is
2 the hospital level.

3 CO-CHAIR CONWAY: Okay. Jason?

4 MEMBER ADELMAN: I'm confused a
5 bit by the process measure versus outcome
6 measure. I mean, I understand what you said.

7 Well, first, I should ask, is the
8 intention to report just the rate or the
9 numerator and denominator and then calculating
10 the rate? Because, you know, if you are going
11 to report the numerator and denominator, then
12 it is both an outcome measure and a process
13 measure, right? Because once you give out the
14 denominator, you are giving out -- the next
15 measure we are going to discuss is the AHRQ
16 PSI on DVTs. Also, if we are going to be, by
17 doing through charts, giving out the
18 denominator, that might be a more accurate way
19 than simply using the AHRQ PSI. So, that
20 denominator is an outcome.

21 I have a second part to that
22 question, but maybe I will pause.

1 DR. BRATZLER: I think I
2 understand your question. So, I can't speak
3 to Joint Commission, but for the Hospital
4 Compare, actually, you can download a database
5 that has the numerator and denominator, but
6 the rate typically is what is actually
7 reported.

8 MEMBER ADELMAN: So, then, in the
9 patient safety world, we often talk about not
10 really looking at the outcome when judging a
11 provider, for example. Like take Saul is at
12 Dana-Farber and I am at a general medical
13 hospital. And so, there's a lot of oncology
14 patients. So, we could have the exact same
15 level of compliance with the very first
16 measure we discussed, VTE prophylaxis. But
17 because you are using an outcome as the
18 denominator, his rate will seem worse than
19 mine.

20 DR. BRATZLER: No, no. So, that
21 is why it is reported as a rate, because you
22 both have equal opportunity to determine, when

1 a patient comes into your hospital, whether or
2 not they are at risk for VTE events.

3 Now, I would agree that the
4 oncology hospital would likely have more
5 events. But I would also expect that an
6 oncology hospital would assess that their
7 patients are at greater risk and would put
8 more of them on VTE prophylaxis. So, the
9 measure only reports the proportion of
10 patients who didn't get prophylaxis who had an
11 event.

12 So, the whole conversation, when
13 we were talking about this measure early on,
14 focused on behavioral health, where we
15 excluded behavioral health from the first
16 measure because no good data. And that is one
17 place in the hospital where you sometimes find
18 truly fully ambulatory patients. But it
19 doesn't mean that all of those patients are
20 not at some risk for VTE.

21 And if you in this sixth measure
22 start to see patients who are having hospital-

1 acquired events and aren't getting
2 prophylaxis, then you can start to assess,
3 well, is my risk assessment at the time of
4 admission missing patients that I ought to be
5 prophylaxing?

6 So, you are absolutely right that
7 the rate of events, the number of events would
8 vary. We would expect it to vary between
9 hospitals. But that is not what the measure
10 is. It is, if a patient had an event, did
11 they receive prophylaxis or have that
12 documented contraindication to prophylaxis?

13 MEMBER ADELMAN: I understand, but
14 I don't totally agree with -- I can have a
15 medicine patient, he can have an oncology
16 patient that both meet indications for DVT
17 prophylaxis. And we can both not -- you know,
18 so based on the risk stratification, we can
19 both not give the prophylaxis. His patient
20 will be more likely to have an outcome. So,
21 we both failed on that first measure. So, you
22 would see a gap between the very first measure

1 we reported this morning and this one, where
2 I will do worse on the earlier one and better
3 on this one.

4 DR. BRATZLER: See, I think you
5 are actually making my point, though, that
6 this is almost a proxy measure of the
7 effectiveness of the hospital's risk
8 assessment protocol. Because I would expect
9 Saul's risk assessments to consistently show
10 relatively high risk for VTE events. And so,
11 I would expect their risk assessment to have
12 many more patients getting prophylaxis than
13 your general medical patients.

14 So, I mean, that's why I say it
15 somewhat reflects how good the hospital's risk
16 assessment is for patients. Because if they
17 have high-risk patients and they are not
18 giving prophylaxis, then the number of
19 patients who have an event that didn't get
20 prophylaxis is going to be higher.

21 MEMBER WEINGART: But I think
22 Jason's point is that treatment failures are

1 likely to be higher in certain groups than
2 others, even if you do the risk assessment
3 appropriately. I think you acknowledged that.

4 DR. BRATZLER: Right, right.

5 MEMBER WEINGART: Yes.

6 DR. BRATZLER: So, treatment
7 failures, though, pass the measure as long as
8 they got prophylaxis. By definition, if they
9 were a treatment failure, they got
10 prophylaxis.

11 CO-CHAIR CONWAY: Okay. Lisa?

12 MEMBER MCGIFFERT: I wanted to go
13 back to the issue of whether you would report
14 the numerator and the denominator. Did I hear
15 you correctly that you would not? You would
16 only report the rate? And if that is the
17 case, I think I would like to have a
18 discussion about whether we should always have
19 the components of what went into the rate, I
20 think is very important to be part of this.
21 And especially in this kind of situation where
22 one of the elements of the rate could actually

1 be an outcome measure, we should seriously
2 consider that.

3 MS. WATT: The answer to the
4 question is that this measure is publicly
5 reported on the Joint Commission's website
6 quality check. And what is reported on those
7 screens is the overall rate.

8 Now, just as with Hospital
9 Compare, there is the capability, if people
10 want to download the entire dataset to do
11 their own analysis, or whatever, they can do
12 that. That is not a real transparent process.
13 I mean, when you are looking at the web page,
14 you are seeing a rate.

15 MEMBER MCGIFFERT: So, the rate,
16 all the data is available for download if
17 someone wanted to get it on the Joint
18 Commission page?

19 DR. BRATZLER: On Hospital
20 Compare. On Hospital Compare. You can't get
21 it at --

22 MEMBER MCGIFFERT: On the Hospital

1 Compare? Well, you know, Hospital Compare,
2 for example, is not going to include the
3 numerator and denominator for infections. And
4 we, frankly, see a big problem with that, and
5 I hope that that is not a trend that we can
6 expect.

7 But, you know, I think it is
8 really important to have all the elements that
9 go into that rate available to the public in
10 some form.

11 DR. BRATZLER: I can't speak to
12 the infections, but I know for most of the
13 process measures on Hospital Compare you can
14 download at the hospital level the numerator
15 and denominator, not the patient-level data,
16 but the numerator --

17 MEMBER MCGIFFERT: "You" meaning
18 me? Okay.

19 DR. BRATZLER: "You" meaning you.

20 CO-CHAIR CONWAY: All right.

21 Richard and then Patricia.

22 MEMBER WHITE: So, the

1 denominator, this includes all of the events
2 picked up by PSI-12, postop, medical,
3 everybody in the hospital?

4 MS. WATT: This measure looks at
5 patients within ICD-9 principal or other
6 diagnosis code of VTE.

7 MEMBER WHITE: It shouldn't look
8 at principal. That's why they came in the
9 hospital.

10 MS. WATT: Sorry, sorry, sorry.
11 My error. Secondary, other --

12 MEMBER WHITE: With the flag POA
13 no?

14 MS. WATT: Correct.

15 DR. BRATZLER: And the "and" is
16 there also has to be a test confirming the
17 diagnosis in the chart.

18 MEMBER WHITE: Right. Okay. So,
19 a couple of little questions.

20 So, if you screened a patient for
21 asymptomatic and found it, if it was coded, it
22 would be included --

1 DR. BRATZLER: It could be
2 included, yes.

3 MEMBER WHITE: -- but it is not a
4 symptomatic event? It happened to get
5 screened, right?

6 DR. BRATZLER: Correct.

7 MEMBER WHITE: And you also --
8 just real nitpicking -- so, you put in 45387
9 so you could get an upper extremity thoracic
10 vein, and you excluded all the other upper
11 extremities and you put in a couple of non-
12 specific codes that are not upper extremity or
13 lower extremity or anything, 45389 and 453.9.
14 So, you've got some real non-specific codes in
15 there that might be excluded.

16 DR. BRATZLER: Right. So, we have
17 checked with Patrick about some of the --

18 MEMBER WHITE: Clean it up, yes.

19 DR. BRATZLER: Yes. I know the
20 PSI-12, I think it is 12, has been updated,
21 and we have been looking at some of those
22 codes also.

1 MEMBER WHITE: So, it will include
2 all of the postoperative as well as the
3 medical though?

4 DR. BRATZLER: Yes.

5 MEMBER QUIGLEY: Thank you.

6 My question is directed towards
7 Jason. Jason, I was wondering, are you always
8 going to do it as a way of risk-adjusting?
9 Because I know in the stratification details
10 it says that there is no risk adjustment or
11 risk stratification. I didn't know if you
12 were asking if there could be a way to do
13 that. Were you looking for that?

14 MEMBER ADELMAN: No, not exactly.
15 I was just confused about the denominator.
16 Like we have the first measure where we are
17 looking at documentation of DVT prophylaxis
18 over everybody, and then the next one,
19 documentation over just people with VTE. And
20 it just seems the first one is more reliable.

21 Like I could ask Dr. Clarke about,
22 if we measured on marking the site of every

1 case in OR and then have another measure of
2 marking the site only when there is wrong site
3 surgeries, and we often just move away from
4 like judging, when there happens to be a bad
5 outcome, that is when we judge. We try to
6 look at everybody whether there is a bad
7 outcome or not.

8 So, I don't see the point of
9 having both of these measures. And the first
10 measure seems like a more reliable one. That
11 was the point I was trying to make.

12 DR. BRATZLER: I guess I would
13 just argue that, when we would talk about this
14 particular performance measure, it gets back
15 to some of the discussion we had about VTE-1
16 where there were questions about the lack of
17 validated risk adjustment protocols. And it
18 also reflected the fact that the feeling of
19 our Committee was that the majority of
20 hospitalized patients are at risk of VTE
21 events. In this day and age, most people have
22 risk factors.

1 And so, the sense was that, if
2 your rate of potentially preventable events
3 was high, that you are probably not adequately
4 risk-assessing your population and you need to
5 focus on those that are developing VTE.

6 MS. WATT: You know, it really is
7 a mechanism for hospitals to use to perform
8 that quality improvement assessment. Okay.
9 So, now we have this. Why? It helps to drill
10 down, I think.

11 CO-CHAIR CONWAY: Iona?

12 MEMBER THRAEN: So, Richard
13 confused me. And I am going to raise the
14 question of, quote, "harmonization". You used
15 the PSI-12 measure as a reference to this
16 measure?

17 MEMBER WHITE: No, I know the
18 PSI-12 pulls out all that administrative data
19 on patients who go for surgery.

20 MEMBER THRAEN: Okay.

21 MEMBER WHITE: So, the coder or
22 the software, or whatever is done, they are

1 pulling it out on medical patients as well.

2 In other words, we are going to look at all
3 the VTEs that develop in the hospital,
4 essentially. There might be some subtle
5 difference in codes.

6 I was just trying to see if this
7 measure, how much it overlaps with PSI-12. It
8 takes all the PSI-12 cases and you have to go
9 look to see if they got adequate prophylaxis.
10 So, I was just trying to clarify if it is that
11 or just medical patients.

12 MEMBER THRAEN: So, the PSI only
13 looks at those that have VTE?

14 MEMBER WHITE: No. Those that
15 have a major operating room procedure and then
16 develop VTE.

17 MEMBER THRAEN: And the VTE?

18 MEMBER WHITE: Right.

19 MEMBER THRAEN: And this looks at,
20 of those that had the VTEs globally --

21 MEMBER WHITE: Yes, no matter
22 what.

1 MEMBER THRAEN: -- who got
2 prophylaxis?

3 DR. BRATZLER: Did they get
4 prophylaxis, which is --

5 MEMBER THRAEN: So, they are
6 related, but not the same?

7 DR. BRATZLER: Right.

8 MEMBER THRAEN: All right. That's
9 all I needed.

10 CO-CHAIR CONWAY: Any further
11 questions or discussion?

12 (No response.)

13 Janet, do you have anything?

14 MEMBER NAGAMINE: No. Thank you.

15 CO-CHAIR CONWAY: Okay. Shall we
16 move on to voting? Jessica?

17 MS. WEBER: All right. Importance
18 to measure and report, high impact,
19 performance gap, and evidence. It's a yes/no
20 question.

21 (Whereupon, a vote was taken.)

22 Janet?

1 MEMBER NAGAMINE: Yes.

2 MS. WEBER: Twenty yes, 2 no.

3 We have a new panel member.

4 Scientific acceptability of
5 measure properties, reliability and validity.
6 It's a yes/no question.

7 (Whereupon, a vote was taken.)

8 Janet?

9 MEMBER NAGAMINE: Can you come
10 back to me? I need to look up what I put
11 here. Hang on.

12 MS. WEBER: Sure.

13 Twenty yes, 1 no.

14 Janet, would you like to add
15 yours? Or we can come back to you later.

16 MEMBER NAGAMINE: I put yes.

17 MS. WEBER: Okay. Twenty-one yes,
18 1 no.

19 Usability, high, moderate, low, or
20 insufficient.

21 (Whereupon, a vote was taken.)

22 Janet?

1 MEMBER NAGAMINE: Mod.

2 MS. WEBER: Seven high, 14
3 moderate, 1 low.

4 Feasibility? It is a high,
5 moderate, low, insufficient.

6 (Whereupon, a vote was taken.)

7 One more vote needed. Go ahead
8 and cast your votes again.

9 Janet?

10 MEMBER NAGAMINE: Moderate.

11 MS. WEBER: Seven high, 13
12 moderate, 2 low.

13 Overall suitability for
14 endorsement. Does the measure meet all the
15 NQF criteria for endorsement?

16 (Whereupon, a vote was taken.)

17 Janet?

18 MEMBER NAGAMINE: Yes.

19 MS. WEBER: Twenty yes, 2 no.

20 MEMBER WHITE: Can I make one more
21 comment to add to it? This gets kind of
22 nitpicky, but we did a big chart review of a

1 lot of medical cases that were coded this way.
2 It is really confusing when the diagnosis is
3 made on hospital day one or two. No one can
4 decide if it was present on admission or not.

5 So, the only thing I would say is
6 I would like them to do the retrospective
7 review of the cases that developed in the
8 hospital after hospital day three. In fact,
9 for the Joint Commission, if you go 24 hours,
10 you still pass their test for starting
11 prophylaxis and you get events occurring.

12 It is just very confusing. I
13 don't know if it is worth the time of the
14 hospital reviewing the cases that developed on
15 hospital day one or two. So, that is the
16 comment I will make.

17 CO-CHAIR CONWAY: Okay. Thank
18 you.

19 We are at kind of a decision point
20 here. Measure 0503 has been withdrawn. We
21 can explain that later. And that leaves us
22 with one VTE measure. Should we push on or

1 should we break for lunch? Push on? Okay,
2 right.

3 Jean, would you introduce
4 yourself?

5 MEMBER DE LEON: Jean de Leon. I
6 am a wound care specialist at Baylor in
7 Dallas.

8 CO-CHAIR CONWAY: Great, great.

9 And to the Joint Commission that
10 is packing up and getting ready to leave,
11 thank you very much for your participation
12 this morning.

13 So, next will be Measure 0450,
14 postop pulmonary embolism or DVT rate from
15 AHRQ. And our reviewer was Jason.

16 Jason?

17 MEMBER ADELMAN: Yes. So, I
18 should mention that when we went around I
19 didn't say anything interesting about myself.
20 There really is nothing interesting about me
21 except that I have two very cute girls.

22 (Laughter.)

1 Okay. So, we had a phone call
2 beforehand. Since the call, I think everybody
3 here got an email that evidence was added
4 based on the questions that we asked during
5 our call about the evidence around the
6 validity.

7 Our group I think all agreed, and
8 you can see in the votes there, that this is
9 a high-impact measure. It is really an
10 outcome measure just looking at DVTs in postop
11 patients and VTEs, and that there is a
12 performance gap.

13 I believe that the software is
14 reliable in pulling from the coding data
15 information, but there is a question of the
16 accuracy of the coding and, ultimately, the
17 validity of the measure.

18 And so, last night these
19 additional references came out. So, I pulled
20 them and I emailed everybody. And I am just
21 going over them because I think they are
22 important.

1 So, there were four articles sent.
2 And I have found one or two others. I will
3 just summarize very briefly.

4 One of them is in review, so I
5 couldn't pull. But the three, each one of
6 them discussed the positive predictive value
7 of the tool.

8 There was the one by Kyle Farney
9 at the VA. It is called "Validity of
10 Selective Patient Safety Indicators". This
11 was a study published in 2011, but had data
12 from 2003 to 2007. It actually looked at
13 three PSIs, and this being one of the three.
14 And for this particular PSI, they looked at
15 112 records, and the positive predictive value
16 was 43 percent.

17 Another study by White, et al., in
18 2009, this was using UHC hospitals. The title
19 of the article was "How Valid Is the ICD-9 CM-
20 based AHRQ Patient Safety Indicator for Postop
21 VTEs?"

22 And there, they looked at 121

1 cases, about the same. And the positive
2 predictive value was 48 percent, about the
3 same.

4 Then, one study was under review,
5 as I mentioned. The last study was Henderson,
6 2009, 112 cases, about the same. This time
7 the positive predictive value was 54 percent.
8 So, you are talking about high forties to low
9 fifties.

10 There was another article that I
11 found that wasn't sent which actually was
12 published by -- the authors were from AHRQ.
13 It was in the Joint Commission Journal in
14 2007. Jim Battles was one of the authors.

15 In that study, the positive
16 predictive value was 29 percent. So, you are
17 looking at 29 percent up to 54 percent,
18 average in the forties. So, to me, that
19 really puts into question the validity of the
20 measure, that the positive predictive value is
21 really like 50 percent, just barely.

22 Second, another point I wanted to

1 make was that in one of the studies that was
2 given to us, one at the VA, there were three
3 PSIs in that study. The positive predictive
4 value for iatrogenic pneumothorax was 73
5 percent and for accidental punctures was 85
6 percent.

7 And I just want to point out that
8 this varying positive predictive value, we
9 will see reports of all the AHRQ PSIs and you
10 will see numbers. But if you were to correct
11 for positive predictive values, one of them
12 you would have to take 40 percent of the
13 measures, the ones we are talking about. For
14 accidental puncture, it would be 85 percent.
15 And so, it is, to me, hard to interpret
16 because there's such varying positive
17 predictive values for the different PSIs.

18 And finally, the reason why I was
19 asking the question from the Joint Commission
20 about if the denominator would be published,
21 because there was mention in the instructions
22 about related competing measures. So, here we

1 have another measure that is up for discussion
2 that is going to rely on chart reviews and
3 other mechanisms, more reliable mechanisms, I
4 think, to find the amount of VTEs. And it
5 seems to me that perhaps we should favor that
6 over something that has a positive predictive
7 value in the high forties.

8 That is pretty much my comments.

9 CO-CHAIR CONWAY: Thanks, Jason.

10 Is AHRQ here for any comments?

11 DR. ROMANO: Hello. This is
12 Patrick Romano.

13 Yes, so we have been through quite
14 a saga with this indicator. So, let me try to
15 give you a little bit of historical
16 perspective.

17 So, we did collaborate with both
18 the University Health System Consortium and
19 the VA, as well as with the network of
20 hospitals that joined AHRQ's Pilot Project to
21 undertake the three studies described that
22 generated positive predictive values,

1 basically in the high forties.

2 So, we obviously undertook kind of
3 a careful examination to see what was going on
4 there and what was the explanation for these
5 false-positives. We found that the two most
6 important explanations were that some patients
7 came in with VTE that was present on
8 admission. And second was that some patients
9 had upper extremity thrombosis or superficial
10 thrombosis that were getting labeled as VTE by
11 the indicator because the codes, the ICD-9
12 codes, were non-specific. The codes for
13 thrombosis were less precise than the codes
14 for thrombophlebitis. And so, people prefer
15 to use the codes for thrombosis, and they were
16 defaulting to the non-specific codes.

17 So, what we did in response to
18 that was two things. One is that we
19 incorporated the present-on-admission
20 information into the specification of the
21 indicator now, so that those are excluded.
22 And second, we petitioned the ICD-9 CM

1 Coordination and Maintenance Committee to
2 change the codes actually for thrombosis, so
3 that there are now separate codes for upper
4 extremity thrombosis and superficial
5 thrombosis, and also, to separate the codes
6 for acute thrombosis and chronic thrombosis.

7 So, that change was just
8 implemented in October of 2009, right? So, we
9 have only one study now that has looked at
10 this systematically since that coding change
11 was implemented. And that was the additional
12 reference that was under review.

13 In that study, we did two things.
14 One is we worked with UHC again to look at a
15 sample of patients who had total knee
16 arthroplasty. They wanted to focus on
17 patients who were known to be at high risk.
18 And this was part of a case control study
19 looking at potentially modifiable risk factors
20 for those events. But, in the course of that,
21 we basically found that the PPV in that
22 population was 99 percent now after POA and

1 the new coding.

2 We also looked at a separate group
3 of seven hospitals that volunteered to look at
4 all their surgical cases. In those hospitals,
5 using the new specification, the PPV was 81
6 percent.

7 So, basically, from those two
8 studies, we have seen what we expected, which
9 was a substantial improvement in the positive
10 predictive value as a result of the
11 combination of using POA information and the
12 new codes.

13 So, that is what we are basically
14 coming back to, to say that I think that we
15 have made an effort to address that problem
16 through working with the Coordination and
17 Maintenance Committee for ICD-9-CM, with the
18 coding community, and with, obviously, the
19 state health data agencies that are now
20 increasing collecting POA information.

21 CO-CHAIR CONWAY: Thank you.

22 DR. ROMANO: I might add just one

1 other point which is interesting from the
2 study, which is under review, which is that we
3 looked at modifiable risk factors because it
4 was sort of a matched-case control methodology
5 where we match cases in each hospital with
6 controls.

7 And one of the things that we
8 found was that controlling for age and gender
9 and obesity, and so forth, risk factors for
10 these events, all of these patients which were
11 total knee patients, all these patients had
12 some form of prophylaxis that was SCIP-
13 compliant. But three risk factors, bilateral
14 total knee as opposed to unilateral, odds
15 ratio of 4.2; receiving pharmacologic
16 prophylaxis instead of just mechanical
17 prophylaxis, according to recommended doses,
18 odds ratio of 0.5, and ambulation on or before
19 the second postoperative day, odds ratio of
20 0.3.

21 So, these are the kinds of
22 opportunities for improvement that we are

1 trying to identify and encourage hospitals to
2 look for.

3 MEMBER ADELMAN: If I may, I would
4 question I guess everybody, should we wait
5 before affirming this request for the new
6 request to be published and to be scrutinized,
7 where we get a chance to see the methods and
8 see the "N's" and everything else? Or is it
9 acceptable to act on the data that was just
10 given, you know, knowing that we haven't
11 really scrutinized any of the research? I
12 don't know the answer, but I would put that
13 out to everyone.

14 CO-CHAIR CONWAY: Okay. Good
15 question.

16 We are open for questions and
17 comments.

18 Richard and then Saul.

19 MEMBER WHITE: I have two. One is
20 I think Dr. Romano should make a comment or
21 two about the fact that for the PSI-12 one of
22 the unique aspects of that measure is it is

1 possible to get a really sick patient and they
2 would be in the hospital for two weeks before
3 they have surgery, right? And they get a DVT
4 before the surgery. So, some of the loss of
5 predictive value is that they didn't pick up
6 the fact that it was a preoperative VTE.

7 So, the thing he brought up is
8 something that I have been thinking about.
9 Perhaps we could get two outputs from the PSI.
10 One is a measure for everyone who got surgery
11 on hospital day zero or one, all the elective
12 cases, in which case I think it is going to
13 even have higher predictive value, and then a
14 total, you know, the PSI for all-comers, which
15 is going to include some people in the
16 hospital for 60 days who had to have a
17 laparotomy or a test lump extraction on the
18 35th day but had a VTE on day seven, had
19 surgery on day 35.

20 The real good numbers came out of
21 the total knee. So, if we have to force them
22 to have surgery early, then the PSI is

1 probably going to be an even better predictor.
2 So, that report might be even better, I think,
3 than the ones where you've got these super-
4 sick patients.

5 The second comment is we have just
6 finished an audit of the new codes for medical
7 VTE. In other words, we have got all these
8 new codes. We only look at the DVTs and PEs.
9 And we look to see whether the ones that are
10 in the hospital, medical patients, POA no, had
11 it.

12 And again, the answer is it is
13 very good, but if it fails in the medical
14 patient, it fails with the people who are
15 diagnosed on hospital day zero, one, or two,
16 because, again, I think I mentioned that
17 earlier. It is very confusing whether it was
18 really new in the hospital or not.

19 So, some of these administrative
20 cuts having to do with when the diagnosis is
21 made or when surgery is made might improve the
22 predictive value.

1 CO-CHAIR CONWAY: Great.

2 Saul?

3 MEMBER WEINGART: Yes. So, to
4 Jason's point, I think the Committee is in an
5 awkward position because the overwhelming
6 weight of scientific evidence suggests that
7 the measure may not meet our criteria. On the
8 other hand, Dr. Romano describes some
9 promising research that is just over the
10 horizon, although, clearly, the results are
11 excellent, but in a narrow population.

12 So, that would also make it a
13 little bit awkward for us. So, I think it is
14 in awkward. In some ways, I wonder if the
15 wisest thing might be to defer a vote rather
16 than to sort of repudiate the measure or to
17 endorse it, but rather to postpone it.

18 MS. BOSSLEY: I think my one
19 question is, how soon is the review coming
20 out? I mean, that will help us decide, I
21 think.

22 Patrick, do you have any idea on

1 that?

2 DR. ROMANO: Well, both of these
3 papers are under review currently. I think
4 that we do have the ability to share at least
5 an abstract of the information with the
6 Committee.

7 I mean, many of you are as
8 familiar about journal policies as I am.
9 Generally, journals do allow sharing of
10 information with publicly-constituted bodies
11 of this type. So, we will have to explore
12 that a little bit further, but I am sure that
13 we could create some redacted version of the
14 documents that we could share with the
15 Committee.

16 MEMBER WEINGART: To what extent
17 do you think that the knee replacement
18 population makes the results look better or
19 worse than they would in a more general
20 surgical population?

21 DR. ROMANO: I think certainly the
22 knee replacement population makes the results

1 look better. So, I trust the 81 percent that
2 I cited from seven general hospitals much more
3 than the 99 percent, simply because the total
4 knee patients are kind of selected to be
5 relatively healthy patients when they are
6 coming in for elective surgery.

7 By the way, to one of Jason's
8 points, I don't want to be accused of covering
9 up anything, the paper by Battles, it showed
10 the lower PPV around 29 percent. I do have a
11 copy of that.

12 The reason we didn't include that
13 is because they did not specifically address
14 the PSI. In other words, the PSI logic has
15 certain exclusions that raise the PPV;
16 whereas, they just purely looked at the
17 underlying codes.

18 CO-CHAIR CONWAY: On this issue of
19 having review of that data, we do have a Phase
20 2 set of measures to review. We could, if you
21 will let us --

22 MS. BOSSLEY: We could or we can

1 at least huddle with John and Patrick. I
2 don't want to jinx you, but you may not get
3 through all your measures today and tomorrow.

4 (Laughter.)

5 So, if you don't, you will have at
6 least one more conference call, and you may
7 actually have one measure that we are still
8 talking to the developers on whether they have
9 full testing information to provide to you.

10 we may be able to come back to you
11 and have a very brief call, not like the last
12 safety project, I promise, and entertain this.
13 So, if you want to, I think it would be
14 helpful to talk through this measure all the
15 way through. But if you want to hold any
16 decisions until we get to touch base with AHRQ
17 and figure out, is it Phase 2 or is it in a
18 couple of weeks, a month, we can go from
19 there.

20 CO-CHAIR CONWAY: So, why don't we
21 see if there are other issues to get on the
22 table? I think John had his card up, and then

1 we will come back this way.

2 MEMBER CLARKE: This is just a
3 general comment that has to do with the
4 patient safety indicators and the predictive
5 value. And it illustrates the tension of
6 using these patient safety indicators.

7 That is that my understanding is
8 that patient safety indicators were developed
9 in order for an institution to capture their
10 patient safety adverse events. As such, they
11 tried to cast a wide net in order to capture
12 all the events. And when you want to capture
13 all the positives, you inevitably have to
14 capture more false-positives.

15 So, it is inherent that these
16 patient safety indicators, because of why they
17 were designed, are going to have lower
18 positive predictive values than something else
19 that could be developed in a "never event"
20 kind of mentality where you were inarguable
21 about what was inside the net.

22 I think the problem comes from the

1 fact that these patient safety indicators are
2 now being used by secondary agencies as
3 indicators of safety. I think that is where
4 some of this tension lies.

5 But it is inevitable that they are
6 not going to have positive predictive values
7 of 98 or 99 percent. In fact, as a
8 researcher, I would be concerned if they did
9 because I would wonder how many things were
10 outside the net that we weren't seeing.

11 CO-CHAIR CONWAY: Louise and then
12 Iona.

13 MEMBER PROBST: I might be naive,
14 but it seems to me, if it is not supposed to
15 happen, I really am not as concerned about
16 predictive value. I need to kind of have you
17 explain more to me. If I don't want to have
18 an infection, if it is zero tolerance and I
19 don't want to have a DVT, I understand some of
20 them are going to happen, but if you get too
21 high of a predictive value, I think I would be
22 concerned that the measure is not appropriate.

1 So, help me understand why this is
2 a problem.

3 MEMBER CLARKE: In fact, you want
4 to capture all the events. So, you say
5 something like, if the patient has a positive
6 BQ scan, we count them. Well, you are not
7 going to get every patient with a DVT. So,
8 then, you say, well, everyone who has an
9 abnormal finding on chest x-rays consistent
10 with DVT. Well, you are going to capture
11 more, but you also are going to capture some
12 people who didn't have DVTs. So, the wider
13 you go in order to get every patient who has
14 the event, the more false leads you have to
15 follow up in the process.

16 CO-CHAIR CONWAY: Iona?

17 MEMBER THRAEN: Okay. So, I am
18 stepping outside of the conversation and going
19 in a different direction. There was a recent
20 publication in April that looked at the AHRQ
21 PSIs, the voluntary reporting of sentinel
22 events, and the IHI global triggers, and the

1 evidence associated with that comparison.

2 So, my question back to you is
3 that this is a claims-based, an administrative
4 claims-based approach. Is there an equivalent
5 IHI global trigger or clinically-based
6 approach that would get us closer to where we
7 want to go in terms of sensitivity and
8 specificity that we ought to be considering in
9 light of this measure as well?

10 DR. ROMANO: Well, the paper that
11 you are referring to I think was really
12 focused on the fact that the AHRQ PSIs really
13 just pick out a very selective subset of
14 events. And so, if you really want to
15 understand the full spectrum of patient safety
16 and patient experiences in hospitals, you
17 really need a much wider set of events.

18 And the gaping hole, for example,
19 is with medication errors and problems related
20 to medication errors, which aren't addressed
21 in our PSIs at all. So, that is a valid
22 concern looking at the indicators of the set.

1 I think our strategy has been to
2 focus on specific types of events where there
3 are felt to be opportunities for improvement
4 and perhaps greater actionability, and where
5 we also have the ability to identify the
6 accuracy of the data, to improve the accuracy
7 of the data, and so forth.

8 So, I think that the argument that
9 we would make is that, for a clear clinical
10 diagnosis like postoperative venous
11 thromboembolism, where there is specific
12 treatment that follows from specific
13 diagnostic tests, the ICD-9-CM-coded data
14 should give us what we need to know. And if
15 it doesn't, then it is because either the
16 coders aren't doing it right or because the
17 codes aren't precise enough.

18 So, we fixed the latter problem.
19 The former problem is an ongoing process of
20 education.

21 But I guess I would sort of throw
22 the question back to you. Like is it

1 necessary to have a completely sort of
2 parallel process for collecting data when
3 coders are already supposed to be going
4 through the record finding diagnoses just like
5 this that affect the treatment of patients in
6 a hospital?

7 That is what we are striving for,
8 is to use administrative data in creative ways
9 where we can get not to 100 percent, but to an
10 acceptable range of 80 percent or 85 percent
11 or so. I think that is what we have seen in
12 terms of the sensitivity of the indicators.
13 The two most recent studies showed 87 percent
14 and 95 percent sensitivity. So, again, we are
15 missing a few of these events, but probably
16 not enough to really make a big difference.

17 CO-CHAIR CONWAY: Okay. Steve and
18 then Saul.

19 MEMBER LAWLESS: Yes, just a
20 question for the people from AHRQ again. My
21 preference with me would be, instead of just
22 seeing an abstract, I mean the publication you

1 are talking about in print, the abstract, you
2 know, it is kind of like looking at the
3 National Enquirer headline and then you buy
4 it.

5 (Laughter.)

6 And so, I would say that your
7 judgment, if it is going to be that impactful.
8 to wait until the article comes back. If it
9 is not that impactful, then it doesn't really
10 make a difference. But I would leave it to
11 your judgment. But the abstract wouldn't do
12 it. It would either be get an early release
13 or not at all.

14 MEMBER WEINGART: So, I want to
15 respond to two quick comments that were made,
16 and then Patrick's comment about the use of
17 administrative data for quality measurement.

18 I mean, I think one of the
19 important points we have learned from using
20 these indicators is that we need to code
21 better. And if we code better, then we will
22 get better measures. And I don't see the

1 chart review as an alternative, but as a
2 complementary way of getting at this
3 information.

4 To the question about PPVs, I
5 mean, I think my first project ever was to
6 work on the validation of PSIs. And Patrick
7 is nodding because he tortured us over this
8 for quite a long period of time.

9 (Laughter.)

10 And the initial concept was, to
11 John's point, that we wanted to use this for
12 case finding. You know, if the PPV is 20
13 percent, well, that means I don't have to
14 review 100 charts; I only need to review a
15 smaller number because I know it will be
16 enriched in these events that I am looking
17 for.

18 And I think that is kind of a
19 well-heeled and well-established use for these
20 things. The thing that people have been
21 concerned about is, can it also be used as a
22 quality measure to compare across hospitals?

1 And that is an area that Patrick has made a
2 lot of his career investigating.

3 And so, I think there are two
4 separate uses for this. One of the concerns
5 is, if the PPVs are low and the sensitivities
6 are low, then maybe it is not a very accurate
7 measure, and hospital performance is being
8 inaccurately presented. And perhaps we
9 shouldn't be promoting the use of a tool that
10 does this.

11 On the other hand, the value for
12 finding cases that you think are potentially
13 problematic for peer review, and so forth,
14 that is I think well-established.

15 Equal time?

16 (Laughter.)

17 DR. ROMANO: I will recognize
18 Saul's seminal contributions to the literature
19 in this area with Lisa Iezzoni.

20 (Laughter.)

21 Really, their work on the
22 complication screening program inspired the

1 development of the patient safety indicators.
2 And so, I think what AHRQ tried to do was to
3 build on the best of their findings and try to
4 work on further specifications to improve the
5 performance of the indicators and to get them
6 out to a wider audience to stimulate
7 improvements in coding. So, I agree with
8 Saul.

9 CO-CHAIR CONWAY: John, is your
10 card up?

11 MEMBER CLARKE: It was for my
12 previous comment. If there's no other
13 comments, how about we consider deferring
14 this?

15 MEMBER THRAEN: I just have one
16 quick clarification question. So, in light of
17 the new research that you just discussed, the
18 present-on-admission question to help with the
19 predictive value, is that included in this
20 measure as it is currently being proposed?

21 DR. ROMANO: Yes, it is, yes, as
22 well as the changes in the coding

1 specification that we discussed, the exclusion
2 of non-specific codes.

3 The issue that Dr. White raised
4 that has not been addressed, because I think
5 honestly there is some controversy about it,
6 is there is a subset of patients, probably 10
7 to 20 percent of the false-positives, that we
8 are labeling as false-positives, but they
9 really did have a hospital-acquired VTE, but
10 it was before the surgery. And some of those
11 patients came in with a hip fracture, and they
12 were left to sit around in a hospital for a
13 week without prophylaxis. And they got a DVT.
14 Big surprise.

15 Other patients had some kind of a
16 complicated course with trauma and ended up
17 having to go back to the OR after two weeks.
18 In those cases, we might want to hold the
19 hospital harmless for the fact that the
20 patient got a DVT.

21 So, it is a little bit of a
22 complicated situation with those hospital-

1 acquired, but preop thrombosis. Those are
2 still in at this point.

3 CO-CHAIR CONWAY: We have had
4 three or four requests to defer this. Would
5 there be anybody here opposed to deferring
6 this to our second phase of work?

7 Okay. Jason?

8 MEMBER ADELMAN: I just have one
9 last question for Patrick. Today and
10 tomorrow, there is a lot of PSIs and PDIs that
11 we will be discussing. Saul and John made
12 these points about the difference between the
13 net for finding cases and then using it as a
14 tool to evaluate hospitals.

15 And just looking at some of the
16 references, the positive predictive values are
17 all over the place. It seemed from what you
18 said, the high forties was not acceptable and
19 80 percent now is acceptable.

20 What do you use? Like you could
21 leave the tool today as is and not come here
22 and ask to make it an official NQF-endorsed

1 measure. What do you consider a positive
2 predictive value or sensitivity/specificity
3 that gets to the level of where we can
4 actually judge hospitals?

5 DR. ROMANO: Well, ultimately, I
6 am going to say that that is a policy decision
7 which is for the National Quality Forum and
8 its Steering Committees and CSAC to make.

9 What we are trying to do is to
10 present the information, to improve the
11 indicators to present the information. There
12 is certainly a lot of demand from
13 stakeholders, especially in the purchaser
14 community and the consumer community, to get
15 these kind of indicators out there. But,
16 ultimately, it is your call what the right
17 threshold is.

18 CO-CHAIR CONWAY: So, if we defer,
19 one thing I would like to ask the original
20 Workgroup on VTE if you will be the people
21 that will agree to review the additional data?

22 And then, two, we would have to

1 get some agreement on what data we would like
2 to see. Is the request that it be more than
3 an abstract? Is that acceptable?

4 DR. ROMANO: Absolutely. Thank you.

5 CO-CHAIR CONWAY: Okay.

6 DR. ROMANO: I will confer with
7 staff about the circumstances under which we
8 can share that information.

9 CO-CHAIR CONWAY: Okay.

10 And then, Richard?

11 MEMBER WHITE: I am not sure
12 totally it should be focused on the positive
13 predictive value because I think for reporting
14 the key issue is risk adjustment, right?
15 You've got a hospital that takes on the tough
16 cases, and, okay, you've got better PPV. You
17 get a higher rate, right? It's got a good
18 positive, you've got it, but now you have got
19 to risk-adjust appropriately.

20 Does AHRQ have any data from any
21 hospitals where they have a high observed-to-
22 expected to kind of find out whether or not

1 the excess cases were much more difficult,
2 impossible to predict? Is there any feedback
3 on the public reporting part of it, which has
4 to do with the risk adjustment that is done on
5 this administrative data?

6 DR. ROMANO: Very good question.
7 I don't know if -- I think Jeff Geppert, who
8 leads our analytic work, is on mute.

9 MS. BOSSLEY: Operator Jason?
10 Operator, can you see if Jeff Geppert is on
11 the line?

12 OPERATOR: Absolutely.

13 MS. BOSSLEY: And open his line,
14 too.

15 DR. ROMANO: In the meantime, I
16 will say that the risk-adjustment model that
17 is used for this includes a set of age
18 coefficients, a set of coefficients for
19 modified DRGs, basically, the type of surgery
20 that the patient is having, the body system in
21 which the surgery occurred, and about 18 or 20
22 different comorbid conditions that may

1 increase or decrease the risks of the overall
2 C statistic which measures the determination
3 of the model is 0.745, which is about average
4 for these kinds of outcome measures.

5 To get to your question, I don't
6 think we have any specific information about
7 the performance of the risk-adjustment model
8 across different hospitals. It is an
9 interesting question, more difficult to
10 organize those kinds of studies. I would
11 certainly be interested in collaborating
12 with --

13 CO-CHAIR CONWAY: Here's a
14 suggestion: I would suggest this line of
15 discussion will occupy us most of this
16 afternoon, since we are doing PSIs and PDIs
17 this afternoon. So, we may want to kick that
18 down the road a little bit.

19 So, it sounds like, do we need to
20 formally vote on deferring?

21 MS. BOSSLEY: No.

22 CO-CHAIR CONWAY: Okay. It looks

1 like there is support for deferring.

2 The 0503, Heidi could explain what
3 happened there. The American College of
4 Emergency Physicians pulled that out.

5 MS. BOSSLEY: Right. So, several
6 of the measures that are under consideration
7 have first been reviewed within -- I'm sorry,
8 clearly, I haven't had enough coffee today.
9 Several of the measures were reviewed where
10 they had met all the criteria with the
11 exception of two, reliability and validity.
12 They had not yet tested the measure.

13 This was one of them. You will
14 have several others. What we had done was
15 incorporated them into full maintenance
16 because they got into the three-year review.

17 Emergency Physicians are in the
18 process of testing this measure now. So, we
19 want to give them a little more time to bring
20 that data back to you. So, that measure we
21 will just move to Phase 2. It is in the
22 summer. And then, you will be reviewing it at

1 that point.

2 CO-CHAIR CONWAY: Do we need to go
3 to public comment?

4 MS. BOSSLEY: That would be good.

5 CO-CHAIR CONWAY: Jason, the
6 operator Jason?

7 Where did he go?

8 MS. BOSSLEY: I don't know.

9 Is there anyone in the room who
10 has any public comment?

11 (No response.)

12 Well, we will have another period
13 as well. So, hopefully, Jason comes back.

14 CO-CHAIR CONWAY: So, lunch, that
15 sounds good to me, Heidi.

16 (Laughter.)

17 MS. BOSSLEY: So, lunch is outside.

18 CO-CHAIR CONWAY: All right.

19 Let's break for lunch.

20 (Whereupon, the foregoing matter
21 went off the record at 1:11 p.m. and resumed
22 at 1:40 p.m.)

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

2 1:40 p.m.

3 CO-CHAIR CIPRIANO: Okay. One of
4 the things that several of you have asked, if
5 we could describe the remaining work for this
6 group following this meeting, which will span
7 into next summer and fall. Heidi is going to
8 go over that.

9 There was a little bit of
10 information in the original slide deck for the
11 orientation for the Committee. So, you may
12 have seen something a while ago.

13 So, Heidi is going to walk through
14 that, which, again, is sort of an expanded
15 timetable. It includes not only our work, but
16 then the subsequent approvals that occur as
17 part of that.

18 MS. BOSSLEY: Okay. So, I am
19 first just going to talk about this phase.
20 So, we divided this project into two phases,
21 in part, because of the number of measures we
22 knew we had just undergoing maintenance.

1 Safety is one of our biggest groupings of
2 measures in our portfolio.

3 So, we are currently in the
4 screening and evaluation piece, which is what
5 you are doing today and what you will do on
6 perhaps one conference call after this.

7 What Andrew, Jesse, Jessica, and
8 myself will do in the next few weeks is take
9 all of your discussion and your votes and
10 write up a report. And it is a very technical
11 report now where it discusses the overarching
12 issues that you have discussed.

13 I think we will have some on the
14 outcome and process links. There's a few
15 things you have talked about even just from
16 this morning that I know we will pull out into
17 broader, more overarching discussion points.

18 Then, we will actually have a
19 table for each of the measures that will show
20 your ratings of each criteria and the
21 rationale as to why you went about voting the
22 way you did. So, all your conversation here

1 today is what we are taking notes on
2 furiously, and we will try to summarize.

3 That will come back to you to look
4 at. We may have a conference call, depending
5 on where we are with everything, where we are
6 with the measure you just deferred, where we
7 are with the one measure we have that we are
8 talking to developers on whether they have
9 tested or not.

10 If you get through every measure
11 here, you may actually not have any conference
12 calls after this. And we may just write up
13 your report and then have you review it, and
14 we will go out for a 30-day public and member
15 comment.

16 So, typically, with the comments,
17 we will get anywhere from 150 to 200 to 300
18 comments. We will, as staff, take that to
19 create themes out of it, have you look at
20 every individual comment as well as the major
21 themes.

22 And then, you may revisit the

1 recommendations you just made today, and you
2 may be swayed by the comments that you receive
3 that you want to change your recommendation.
4 Either you will or will not recommend a
5 measure, that kind of thing. You may actually
6 add more gap areas because that is the other
7 part we would like you to identify. If not
8 today, we will definitely do it over email.
9 You started doing it just even in your
10 discussions.

11 All those comments are then taken
12 along with the report and your recommendations
13 to our Consensus Standards Approval Committee.
14 Pam sits on that group.

15 Their responsibility is to make
16 sure, No. 1, you follow the process and the
17 criteria; to make sure that the
18 recommendations you are making fit within the
19 parameters of where they think the portfolio
20 should head. And then, all of that goes --
21 I'm sorry, I misspoke.

22 So, it goes out for comment and

1 then it goes out for member vote. That, plus
2 everything else, goes to the CSAC.

3 And then, it goes to the Board for
4 ratification. Then, we have a 30-day appeals
5 process, where any individual can actually
6 come back and say they would like the CSAC and
7 the Board to revisit a decision that was made
8 on the measure endorsed.

9 So, that is the timeline we have
10 got on this phase. We are basically going to
11 replicate that same thing with Phase 2. So,
12 we will schedule another meeting with you, not
13 in June. I don't know what month we will go
14 into. Well, we had June marked. So, we will
15 look at what date we are going to pick.

16 And that phase is looking at, do
17 you remember what topic areas, Andrew?

18 MR. LYZENGA: We have falls and
19 pressure ulcers sort of grouping -- I'm sorry
20 -- falls and pressure ulcers as sort of a
21 group of measures; a group of mortality
22 measures, the AHRQ mortality indicators.

1 I am trying to think of what --

2 MS. BOSSLEY: We will get to the
3 list to you.

4 MR. LYZENGA: Yes, I will get the
5 list.

6 MS. BOSSLEY: I have lost track.
7 Phase 2, and that is in the second
8 round.

9 MR. LYZENGA: Oh, HAI measures as
10 well. I think those are the three main
11 groups.

12 MS. BOSSLEY: Okay. And so, you
13 will go through the same process. We will
14 divide you into Workgroups. We will have you
15 then come as a group together, make your final
16 recommendations, and then it follows through
17 the process.

18 The timeline on that one right now
19 is that we would have a call for measures
20 starting in January. Well, actually, I don't
21 know if we will do a call for measures because
22 we already did one.

1 We may have a few new measures
2 come in that we know need to be done, given
3 all the federal programs out there.

4 Submission would be due by
5 sometime in March. And then, we would have
6 you meet, let's say it is May or June, and
7 then go through the same process. So, that is
8 kind of the timeline we are looking at and the
9 next steps.

10 Does that make sense?

11 CO-CHAIR CIPRIANO: Any questions
12 at this point?

13 Jim?

14 MEMBER SMITH: As a novice in this
15 process, I just want to thank the Chairs and
16 the staff for both that review that I needed,
17 but also getting to this point. It has been
18 very informative, and thank you.

19 CO-CHAIR CIPRIANO: Thank you.

20 I think the other thing is that,
21 with more lead time with the second phase of
22 work, it won't feel quite as much of a sprint

1 trying to get everything together.

2 Okay. What we thought would help
3 for looking at Workgroup C's measures is you
4 see the way they are organized on the agenda,
5 the first four do deal with PDIs and PSIs. We
6 thought it might be beneficial to have a
7 general discussion about that prior to the
8 detailed discussion of each of the measures.

9 And so, we would invite --
10 Patrick, are you chewing -- we would invite
11 you to help introduce that discussion.

12 DR. ROMANO: Right. So, the rest
13 of the measures that we will be talking about
14 this afternoon and tomorrow from AHRQ are in
15 the realm of what you might call procedure-
16 related mishaps. They obviously reflect
17 different types of mishaps. Accidental
18 punctures, lacerations is an obvious generally
19 surgical mishap, as well as foreign body. We
20 will be talking tomorrow, I think, about
21 transfusion reactions which are a transfusion-
22 related mishap.

1 So, each of these events has sort
2 of a clearer component of preventability, if
3 you will. And some of them are more common.

4 APLR, PSI-15, which we will be
5 talking about shortly, is relatively common.
6 But transfusion reactions and foreign bodies
7 after procedures are very rare, very rare.

8 So, I think it raises some
9 questions that started to come up in the
10 discussion this morning about what is the role
11 of these measures and how should these types
12 of measures be used.

13 The accidental puncture or
14 laceration measures and the iatrogenic
15 pneumothorax measures are reported as risk-
16 adjusted rates, recognizing that different
17 patients have different risk factors that put
18 that at higher or lower risk of these events.
19 And that is incorporated into the risk
20 adjustment.

21 But foreign body and transfusion
22 reaction are so rare that they are reported as

1 counts rather than as rates. And most
2 hospitals actually have zero. And the
3 hospitals that have one or more generally only
4 have one during any given reporting period.

5 So, this is a very different type
6 of measure, and I just wanted to kind of put
7 this on the table initially. Those measures,
8 in particular, are not really designed for
9 comparative evaluation of hospital
10 performance. They are submitted, they were
11 submitted in the spirit of encouraging
12 transparency.

13 So, as NQF's perspectives have
14 evolved, there may be a need to sort of have
15 more of a discussion about whether those types
16 of measures should still be NQF-endorsed. But
17 the principle is that, for those measures, we
18 are not reporting rates; we are reporting
19 counts of events.

20 And we are suggesting that it
21 should be in the public domain to foster open
22 discussion and debate about what happened and

1 how to prevent those events in the future.

2 But it is not intended for direct comparison
3 of different providers.

4 So, I don't know, John, if you
5 want to add anything to that. But I just
6 wanted to kind of lay out that framework
7 before we get into the discussion of these
8 specific measures.

9 CO-CHAIR CIPRIANO: Thank you very
10 much.

11 Saul?

12 DR. ROMANO: Saul was going to
13 comment on the pediatric ones. And, of
14 course, the issues, the pediatric ones are
15 designed in parallel with the adult ones, but
16 the pediatric ones are generally even rarer
17 than the adult equivalents. So, the issues of
18 reliability and difficulty of measuring and
19 comparing hospital performance and ranking
20 hospitals are even more pressing for the
21 pediatric versions.

22 CO-CHAIR CIPRIANO: John?

1 MEMBER CLARKE: We discussed this
2 in our group. I support the comments that
3 were just made.

4 There are basically two kinds of
5 events. One that you could envision, even
6 with the best care you might get an adverse
7 outcome. And obviously, those are risk-
8 adjusted and are only really properly
9 interpreted if there is a risk adjustment.

10 There are some things which the
11 NQF has called serious reportable events, but
12 which stem from the concept they should never
13 happen, that should never happen under any
14 circumstances. And under those premises, they
15 need to be risk-adjusted because there's no
16 one who is at risk. You might argue that
17 someone who is obese is at risk for a retained
18 foreign object, but that is not going to
19 alleviate you from the responsibility of not
20 having a retained foreign object, even in that
21 patient.

22 And there is a second sequelae

1 that comes from that. That is this idea of
2 rates. We discussed this as well.

3 When you have an event that should
4 never happen, the issue is, did it happen or
5 did it not happen? And so, a rate is kind of
6 irrelevant because the only acceptable rate is
7 zero. Whereas, if an event is something like
8 an infection that could happen, then you are
9 just trying to drive the rate down, and you
10 need to have some kind of risk-adjusted rate.

11 The other reason for having this,
12 there are two other implications of having a
13 rate. One is that, if you talk about a rate
14 and you are trying to drop the rate down, it
15 is not axiomatic that the correct rate is
16 zero; whereas, if you have a number and you
17 are trying to drive the number down, the
18 logical conclusion is that the correct number
19 is zero. You are actually trying to achieve
20 zero.

21 And with these rare events, as
22 Patrick mentioned, the other implication is,

1 if you have a rate that is in the order of 1
2 in 5,000 which is a retained foreign object,
3 or 1 in 10,000, which is a wrong site block,
4 if you want to prove that your rate has
5 dropped significantly, I am going to say 1 in
6 10,000 to 1 in 20,000, you need so many cases
7 that the rate becomes irrelevant because I
8 can't provide any statistical validity to a
9 change in the rate from 1 in 30,000 to 1 in
10 80,000. We don't have enough denominator to
11 do that.

12 So, I am all in favor of these
13 events that should not happen to anybody being
14 numerical rather than risk-adjusted rates.

15 MEMBER THRAEN: And then, a third
16 issue that came up in our group was the idea
17 of why there were separate pediatric measures
18 for the same problem, and why it wasn't a
19 combined measure with stratification.

20 CO-CHAIR CIPRIANO: And, Patrick,
21 is that something that you guys will answer?

22 DR. ROMANO: Well, in some sense

1 it is a labeling issue. You know, it is
2 really when we originally designed some of the
3 patient safety indicators based on the work
4 that Saul and his mentor did years ago at
5 Harvard, they included both adults and
6 children. But, then, stakeholders said to us,
7 well, you know, "We are particularly
8 interested in children" or "We are
9 particularly interested in adults." And so,
10 we separated the indicators, and AHRQ
11 supported a particular process to develop
12 pediatric indicators where we convened a whole
13 separate set of clinical panels with
14 pediatricians and obstetricians, and so forth,
15 to focus on pediatric indicators.

16 So, to some extent, it is an
17 artifact of the process by which stakeholders
18 requested a separate set of pediatric
19 indicators, and then we convened separate
20 clinical panels to review and endorse some of
21 those indicators.

22 MEMBER THRAEN: Because you went

1 through a separate process, are there inherent
2 differences between the adult versus the
3 pediatric version?

4 DR. ROMANO: The major differences
5 for these indicators, for the ones that are
6 risk-adjusted, is that the risk-adjustment
7 models are different, and they incorporate
8 different factors, as you might expect.

9 MEMBER THRAEN: Okay. All right.

10 DR. ROMANO: So, the comorbidities
11 that apply to adults don't apply to children.
12 We don't have too many kids with diabetes, but
13 we have a lot of kids who have congenital
14 heart disease or congenital anomalies.

15 But, you know, this is open for
16 discussion certainly. So, I think that there
17 would be a possibility of consolidating these
18 indicators, but it is just not the process by
19 which they were established.

20 CO-CHAIR CIPRIANO: Charlotte?

21 MEMBER ALEXANDER: Your comments
22 about the low numbers and wishing to report as

1 a pure number, as we are looking at quality
2 and trying to understand if we are improving
3 our process and what the value is for quality
4 reporting, it is helpful for me to know where
5 I came from and where I am today, and where I
6 might go tomorrow.

7 And so, the talk as I heard it in
8 our discussion was partly to ask for a rate or
9 some way that we could trend, that we could
10 get a grasp on where we are on and is this
11 reporting doing us any good, or are we just
12 reporting to be reporting.

13 DR. ROMANO: Well, I think what we
14 do is within an individual organization you
15 can't really trend these. In other words, you
16 can look and say: "Okay, well, we have been
17 event-free for two years and that's great.
18 We're on the right track, and, hopefully, we
19 will stay event-free for more years to come."
20 But you can't trend it in a statistical sense.

21 On the other hand, we can trend at
22 the population level. And so, there is, I

1 think, in some of the forms there is some data
2 about these events. Most of these events have
3 sort of dropped from 10 to 20 percent overall
4 over the past five or six years. And we hope
5 that they would continue to drop further.

6 So, that is the level, I think, at
7 which we can do trending for the population to
8 see if we are driving improvement in the
9 overall healthcare system.

10 CO-CHAIR CIPRIANO: Vallire?

11 MEMBER HOOPER: I will tag onto
12 what Charlotte said. I think, as a group, we
13 were somewhat split on count versus rate.
14 Because, while statistically you would need a
15 large set of numbers, from a consumer
16 perspective, if you are looking at a general
17 region, I think it is very important to know,
18 was it 1 in 1,000 cases; was it 1 in 10,000
19 cases. You know, trending types of cases with
20 wrong site surgery, there are certain
21 procedures that are more prone to wrong
22 site/wrong procedure as opposed to other

1 areas.

2 So, I think that while we
3 appreciate the statistical issues related to
4 trending up and down, that at the same time
5 there were a good number of us that would
6 still like to see a numerator and a
7 denominator, and particularly at the regional
8 and local level. So that the healthcare
9 consumer can truly look at these numbers and
10 make some decisions.

11 CO-CHAIR CIPRIANO: And I guess,
12 Patrick, a question back to you, then, is,
13 what we are hearing is, does AHRQ -- because
14 I don't know -- does AHRQ do that kind of
15 rollup and, if so, where do you report that
16 now? Because, again, it would be non-specific
17 to the measure, because the measure is coming
18 forward as an institutional report, versus
19 what aggregation can AHRQ do in order to
20 satisfy that need?

21 DR. ROMANO: Yes, I think most of,
22 if not all, of these measures have area-level

1 versions. So, if you go to the
2 qualityindicators.ahrq.gov website, you will
3 see that there is an area-level version of
4 these indicators, which is generally designed
5 for application to counties or states,
6 although it could be applied to smaller areas
7 as well.

8 And there are also some
9 comparative benchmarking data that are
10 available on the AHRQ website and through the
11 HCUPnet utility which would allow you to look
12 at the trends over time in a particular area.

13 CO-CHAIR CIPRIANO: Thank you.

14 And so, I think maybe what is also
15 inherent in the discussion is that, with
16 subsequent reviews of these measures, those
17 regional and national trends would be
18 reviewed, again, to look at whether or not the
19 measure should be continued.

20 Does that make sense, I mean, if
21 the group had that discussion? In other
22 words, would we need to keep the measure? If,

1 in fact, this national/regional rate were
2 dropping so dramatically that it was no longer
3 an issue, which would be the only way we would
4 know, should those data be part of the review,
5 subsequent reviews?

6 Okay. So, let me see, we have --
7 is it Tracy? Yes. And, John, is yours still
8 up as well? Okay. And then, Susan. Then, we
9 will come over here.

10 MEMBER NAGAMINE: And my hand is
11 up.

12 CO-CHAIR CIPRIANO: Okay.

13 MEMBER WANG: I appreciate the
14 discussion on the rate versus count because
15 that is one of the challenges I had when I was
16 looking through these measurement sets.

17 I think, as a consumer, also as a
18 non-clinician in this group, I appreciate
19 information being reported, whether it was
20 count or rate. But I wanted some guidance
21 from NQF regarding, when we are evaluating the
22 measures, if it is a count, so for me, it does

1 not pass some of these scientific
2 reliability/validity testing, if I use these
3 rigid criteria, most likely we are not going
4 to be able to endorse this metric.

5 So, discussing this metric, I
6 wanted some guidance on how we should be
7 evaluating this.

8 MS. BOSSLEY: That is a good
9 question. I think it would be helpful if we
10 actually get into it and talk about the
11 scientific acceptability of one of the
12 measures. Because that issue of whether you
13 could actually evaluate the measure on
14 reliability and validity based on a count
15 versus rate, I don't know that I have ever
16 heard a committee debate that. In part, you
17 are just looking at how that measure is
18 constructed and the data that they provide
19 based on it.

20 But let me ask -- I don't want to
21 put Karen on the spot, but -- go ahead.

22 CO-CHAIR CIPRIANO: Well, Steve,

1 you're going to address this point? Go ahead.

2 MEMBER LAWLESS: No, I was just
3 thinking in terms of the count versus the --
4 you have such a low number. It is a sentinel
5 event or it is a "never event". And you treat
6 it as that and you make it public as that, and
7 try to create something that looks like is
8 there a rate on top of that, just something
9 that shouldn't happen.

10 I think there are forums for that
11 piece. I don't necessarily see the public
12 understanding of, if you have one and you
13 stand out, and there's a graph and everybody
14 is zero and you have one, it gives an
15 impression that is not really there.

16 CO-CHAIR CIPRIANO: Okay. Susan,
17 Jason, Lisa, and John, and then I would like
18 to move to the measure. Oh, I'm sorry, who's
19 on the phone? Janet.

20 MEMBER MOFFATT-BRUCE: One of the
21 things our group actually discussed at length
22 was, while these are "never events" and the

1 counts are reasonable, it is a fairly small
2 group that we are actually looking at here.
3 These measures speak to general surgery
4 patients, which I can assure you this happens
5 in every type of surgical patient.

6 So, is there a consideration for
7 making this a much broader and, therefore,
8 probably more scientifically-valid measure,
9 whether or not it is a rate or a count, to
10 more applicable surgical procedures?

11 DR. ROMANO: I don't think that is
12 quite correct. I mean, these measures, the
13 foreign body measures apply to almost any
14 hospitalized adults. The accidental
15 puncture/laceration measures have fairly
16 limited exclusions for certain types of
17 surgery, and so forth, transfusions.

18 MEMBER MOFFATT-BRUCE: But I think
19 we need some clarification. Perhaps I am not
20 reading the -- when I look at "subjects/topics
21 areas", it says surgery, general surgery.

22 DR. ROMANO: Oh, that is just some

1 boxes that we have to check off on the NQF
2 form.

3 (Laughter.)

4 MS. BOSSLEY: We can go back and
5 revisit where boxes should or should not be
6 checked.

7 MEMBER MOFFATT-BRUCE: Because
8 that was part of our discussion in the group.

9 MS. BOSSLEY: Yes. So, we allow
10 developers to pretty much select whatever they
11 would like to say this measure applies to
12 because it helps with the search engine that
13 we have that, once it is endorsed, people can
14 find it.

15 But what we are finding is that,
16 by allowing that broad categorization, you are
17 getting probably more than you want. So, I
18 think we need to revisit whether it probably
19 makes sense to include it or not.

20 DR. ROMANO: In general, it should
21 be interpreted as general, not general
22 surgery.

1 MEMBER MOFFATT-BRUCE: I am in
2 absolute agreement with you, absolutely.

3 CO-CHAIR CIPRIANO: Okay. Good
4 point. We can come back to that.

5 Jason?

6 MEMBER ADELMAN: So, talking
7 generally about the PSIs and PDIs and sort of
8 bringing it back to the conversation earlier,
9 all of these measures, to me, they are
10 different than the others that we have
11 discussed and the others that we have
12 reviewed.

13 The ones that rely on chart
14 review, I feel like there is a lot less, I
15 will call it false accusations. Like, for
16 example, at our institution we find that we
17 have five pneumothorax. And then, we look and
18 three of the five weren't pneumothorax at all;
19 it was just miscoding, and it doesn't feel
20 good.

21 Then, people dismiss the whole
22 AHRQ PSI tool as not valid. And also, they

1 are upset by it because the tool is accusing
2 us of doing things that we didn't do.

3 I understand that there are
4 validity issues in some of the other tools --
5 maybe because of lack of charting, something
6 was missed -- but not as much of these false
7 accusations. There is probably a better term
8 for that. And because the numbers are so
9 small, they feel very real.

10 I had asked earlier Patrick, and
11 he deferred back to us about, what would be a
12 good positive predictive value? And he
13 deferred to us. And I would almost ask NQF,
14 like we are physicians and nurses and patient
15 safety experts, but it is almost like a
16 statistics question. Like I want my
17 statistician back from the medical school to
18 come and ask him this question.

19 I know you weigh-in in a very
20 formal way on what makes good evidence. I
21 feel like 40 percent of a positive predictive
22 value was generally accepted as bad, and 80

1 percent seems to Patrick to maybe be okay.
2 And what if it was 65 percent? Then, where
3 would we be? And am I the right person to
4 judge that?

5 And so, perhaps NQF could help
6 because it crosses all these measures. They
7 seem very different than everything else.

8 I guess that is what I wanted to
9 say.

10 MS. BOSSLEY: Sure. So, I may go
11 see if our resident methodologist can come up
12 to help with this because I am in no way -- I
13 am a nurse. I didn't quite study this as
14 much.

15 But I will tell you, we had the
16 Testing Task Force take a look at our criteria
17 last year. They struggled with, is there a
18 way to provide even more guidance on what C
19 statistic, what statistic, what would you be
20 looking for? And they felt that they couldn't
21 do that. They couldn't give you an absolute.

22 So, it is to a certain extent at

1 the discretion of the Committee on what you
2 feel is appropriate. That is how you do your
3 ranking of the reliability and the validity.

4 You may rank your reliability low
5 because of the results you see. You may also
6 rank the validity low. And if those are low,
7 then you would actually not move the measures
8 forward.

9 What they have done, and AHRQ can
10 talk more about their testing because I went
11 and looked at it. I didn't want to answer the
12 previous question because I hadn't looked at
13 it in a while.

14 We allow testing at either the
15 data element level, so individual data
16 elements, or at the measure score level. And
17 that is what they have done, which is look at
18 the counts, the data, across and done a
19 signal-to-noise ratio on it, and provided
20 back, I think it was kappa statistics on it.
21 I will have look again because I have lost
22 track.

1 You need to look at that and
2 determine whether you feel that it is
3 sufficient to support the measure as it is
4 specified. If you need additional assistance,
5 though, we are happy to ask our staff to take
6 a look at it who have more expertise in this
7 or have an outside consultant take a look at
8 it. So, that is something I think you just
9 need to let us know.

10 But we haven't yet felt
11 comfortable giving a hard-and-fast because it
12 does depend on the measure, the level of
13 measurement you are talking about, the amount
14 of patients you are looking at. There's no
15 many variables, they couldn't come out with a
16 specific. So, it is a little vague
17 intentionally, and I'm sorry about that, but
18 yes.

19 Does that help?

20 CO-CHAIR CIPRIANO: Okay. Lisa?

21 MEMBER MCGIFFERT: I wanted to
22 weigh-in on the rate-versus-number issue. I

1 think that we should always try to give as
2 much information as possible in different ways
3 because every consumer looks at things
4 differently. Some people look at pictures,
5 and some people look at numbers. And some
6 people want to know all the background stuff,
7 and some people just want stars. So, that is
8 always a factor.

9 But I think I agree that with
10 these "never events" the number is absolutely
11 essential, and the rates are pretty
12 meaningless to consumers because it is such a
13 weird rate.

14 But I also agree with you that
15 there needs to be some context. That can be
16 bed size of the hospitals. It could be some
17 of the states arrange the information by type
18 of hospital. So, you put all the trauma
19 centers together and you put all the rural
20 hospitals together. And so, there are lots of
21 different ways to do that.

22 You know, I was on another NQF

1 committee on frameworks, on how to present
2 information. And I know I advocated to get
3 that in there. I am not sure that it made it.
4 But I think that that is the kind of advice
5 that should go along with this. But putting
6 it in context by size of hospital might be a
7 slight bit of difference than putting it in a
8 rate, you know.

9 CO-CHAIR CIPRIANO: Okay. John?

10 MEMBER CLARKE: I just wanted to
11 follow on this rate business. As Patrick
12 mentioned, in a hospital which either does or
13 doesn't have an event, a rate is really
14 irrelevant. At the national level, the only
15 difference between a rate and a number is that
16 you have also collected the denominator.

17 The only issue is when it comes to
18 comparison. And my concern about comparison
19 is that people will make false comparisons if
20 they compare, say, Minnesota with
21 Pennsylvania, for example, false comparisons
22 because our definitions are different. Diane

1 Rydrych at Minnesota just has done a survey of
2 all the state reporting in every state of
3 wrong site surgery, and every state has a
4 different definition of what wrong site
5 surgery is.

6 And then, in addition to that, if
7 our rate is 1 in 30,000 and her rate is 1 in
8 60,000, is that different? The average person
9 on the street would conclude it is, when, in
10 fact, there may be no statistical difference
11 between the two at all.

12 I also would like to address
13 Jason's comments and maybe steer the Committee
14 in a different direction. Because the
15 predictive value of a positive test is not an
16 indicator of the test. It is a combination of
17 the indicator of the test, the sensitivity and
18 specificity of the test, and the prevalence of
19 the problem in the population. And you can
20 change the predictive value of a positive test
21 by doing nothing to the test but just changing
22 the population being tested.

1 If you want a parameter of the
2 test itself, you use the ratio of the
3 sensitivity true-positive rate and the false-
4 positive rate, which is called the likelihood
5 ratio. So, if you want to get into a
6 measurement as to what is the correct number
7 to cut off, it wouldn't be a number based on
8 the predictive value of a positive test. It
9 would be a number based on the ratio between
10 true-positives and false-positives, which is
11 called the likelihood ratio. And that would
12 be the correct parameter to use to evaluate
13 what you are doing.

14 CO-CHAIR CIPRIANO: Okay. Thank
15 you.

16 Iona?

17 MEMBER THRAEN: So, along the same
18 lines -- and this may be too far out there,
19 and I will appreciate being pushed back into
20 the box, if it is appropriate -- one of the
21 things I am struggling with, and maybe it is
22 my need for a little bit more concreteness in

1 context, as people have described, and, again,
2 we are in the maintenance phase of these
3 measures. So, the assumption, operating
4 assumption, is that the sponsors have
5 collected data with these measures in some
6 fashion or another.

7 And for purposes of understanding
8 how these measures translate into information,
9 it would be helpful -- and I don't want more
10 work; I don't want more information -- but it
11 would be helpful to see what that data looks
12 like. Because we are trying to do is we are
13 trying to move towards knowledge.

14 And if the way in which it is
15 currently constructed yields some way of
16 presenting information, and we look at that
17 information and it doesn't make any sense,
18 doesn't give real value, it helps for me,
19 anyway, to bring that contextual framework to
20 these measures that we are looking at in the
21 abstract.

22 CO-CHAIR CIPRIANO: Patrick, did

1 you want to respond at all?

2 DR. ROMANO: I will just wait
3 until we get into the individual measures.

4 CO-CHAIR CIPRIANO: Okay. Janet?

5 MEMBER NAGAMINE: Yes, my question
6 about the general group is about added value.
7 Given the small numbers -- and I am assuming
8 these are all reportable events that will have
9 had a root-cause analysis done, and that the
10 Joint Commission will have aggregate data --
11 it seems that there is sort of a mechanism to
12 address these events.

13 And so, I guess I am just kind of
14 generally wondering, what would be the added
15 value of reporting them, particularly if these
16 rates or numbers may or may not make sense to
17 people, and they may or may not be accurate?
18 Like someone mentioned the five
19 pneumothoraces. It feels bad, but they didn't
20 actually really even happen.

21 And so, I guess that is my
22 question going into this.

1 CO-CHAIR CIPRIANO: Well, I think
2 in general terms, any Joint Commission
3 reporting process would be completely separate
4 from what the use of this measure is. And so,
5 it does not really play into our
6 deliberations.

7 MEMBER NAGAMINE: So, I guess what
8 I am saying is, what is the added value of
9 doing this? Because what we want to do is
10 make sure that we address these problem areas,
11 and it seems to me that they may be addressed
12 already in a different venue.

13 CO-CHAIR CIPRIANO: While I think
14 we would agree, I think that is beyond the
15 scope of our work to say something --

16 MEMBER CLARKE: May I comment on
17 that?

18 CO-CHAIR CIPRIANO: -- is being
19 done.

20 MEMBER CLARKE: I think one value,
21 Janet, is that the NQF provides consistency.
22 For instance, in Pennsylvania we rely heavily

1 on the NQF definitions of wrong site surgery
2 and retained foreign object, and so on and so
3 forth.

4 And I think to the extent that the
5 NQF can develop a process that is nationally
6 embraced, it helps the various states who are
7 charged with monitoring these events. And so,
8 I see a consistency as a useful byproduct of
9 these kind of deliberations.

10 MEMBER NAGAMINE: Got it. Thank
11 you. Thanks.

12 CO-CHAIR CIPRIANO: Carol?

13 MEMBER KEMPER: Just for a point
14 of clarification, for the Joint Commission it
15 is not required to even report a sentinel
16 event to them, as long as you are using the
17 process that they establish. So, it is
18 certainly they wouldn't be capturing all of
19 these.

20 CO-CHAIR CIPRIANO: Okay. Thank
21 you.

22 We would like to move into the

1 actual measures. We will probably not get
2 through the four measures that we have been
3 talking about within the context because we
4 are going to need to take a break on those
5 from 2:30 to 3:30 because we are going to lose
6 Patrick for that time of discussion.

7 But let's go ahead and start with
8 Measure 0344.

9 And, Charlotte, I think that's --
10 no, I'm sorry, that's not you. Steve has
11 0344.

12 MEMBER LAWLESS: I have nothing to
13 add to the entire discussion. We can move on
14 to the next measure.

15 (Laughter.)

16 Measure 0344 is a pediatric
17 measure, obviously, accidental puncture or
18 laceration rate. The numerator is present at
19 discharge -- this is using administrative data
20 -- that have had a coded, ICD-9 coded,
21 accidental cut, puncture, perforation, or
22 laceration during a procedure in a secondary

1 diagnostic field. The denominator is all
2 surgical and medical discharges under age 18
3 in specific DRGs. They do exclude in this
4 normal newborns, the very, very low-birth-
5 weight babies, and probably due to the
6 powerful orthopedic lobby, complex spinal
7 cases in orthopedics. I don't understand why
8 they would be excluded, except they are
9 probably so bloody anyway that nobody could
10 tell.

11 But, anyway, that was the measure.
12 What was striking was that the rates or the
13 incidences were very low. They are a
14 percentage of a thousand cases across the
15 board.

16 I think some of the numbers they
17 are actually quoting are actually even
18 outdated from the newer data that has been
19 published.

20 And the risk adjustment, there is
21 some risk in terms of type, you know, teaching
22 hospital, non-teaching hospital, age,

1 whatever. But some major risk factors are not
2 in the risk adjustment. And that is by
3 specialty, whether it is a pediatric
4 specialist doing it or an adult specialist,
5 non-pediatric-trained person doing it versus
6 a pediatric surgical person doing it; body
7 part, which makes an impact. If you are doing
8 belly surgery on someone versus you are doing
9 retinal surgery, the only difference is
10 visibility as it is occurring.

11 Whether the child has had a prior
12 surgery or not; you dealing with small
13 cavities, and that was not put into it. So,
14 a prior condition would be was that cavity
15 entered prior to that, and that would be a
16 risk factor, or type of procedure.

17 And again, pediatric hospital
18 versus non-pediatric hospital.

19 The measure itself has been
20 reported for years. So, there is NACHRI and
21 the CHC hospitals have been getting this data
22 for years. They have been collecting it. It

1 has been out there. It has been low rates.

2 So, it is not surprising or it is not new.

3 However, what has been new is that
4 there is a group, a pediatric offshoot of the
5 National Surgical Quality Improvement Program,
6 or the NSQIP program, that actually is now for
7 pediatrics. It is up to about 45 to 50 of the
8 pediatric specialists across the country
9 looking at this type of thing.

10 And their rates by specials vary
11 dramatically. They do their reviews not based
12 on administrative data; they do their reviews
13 by direct case reviews and 30-day followups.

14 I don't have the rates in front of
15 me, but the rates do vary from zero to a very,
16 very small percentage. And I think they are
17 all from NSQ.

18 So, there is a newer group looking
19 at this in a lot more scrutiny than the
20 historic by administrative coding because you
21 do rely on administrative coding on the
22 practitioner saying, "Whoops, I hit the

1 vessel," and they may or may not done that.

2 So, there are some concerns along those lines.

3 And then, if you look, I think
4 somebody pointed it out -- I think John Clarke
5 brought it up -- if you look at the number
6 needed to treat to see a real difference among
7 groups, the number needed to treat starts
8 getting into the thousands. And so, going
9 from a .007 to a .002, we will find that most
10 institutions it gets to be, well, where is the
11 real difference here and where is the
12 variability?

13 And then, the final thing I would
14 mention is that -- and I couldn't get this
15 from NSQ -- was whether things like central
16 lines and putting in central lines, where from
17 personal experience, because I am a pediatric
18 intensivist, you do tend to lacerate vessels
19 sometimes putting in central lines. That
20 causes a big problem whether that would be
21 considered a secondary or not. Or during a
22 cardiac catheterization, the same thing

1 happens, or during a chest tube placement you
2 may have blood, which by nature is hitting a
3 blood vessel. So, I don't know if they are
4 included or not.

5 So, not a new measure in itself,
6 it has been reported, so it is not a surprise.
7 But I think from a standardization, I think
8 there has been some refinement since this data
9 was actually captured and numerous sources of
10 data which may be able to be brought into
11 this.

12 CO-CHAIR CIPRIANO: Patrick, would
13 you like to comment on 0344? Specifically, if
14 you could address an option for different data
15 reporting, I mean rather than using only
16 claims data?

17 DR. ROMANO: Oh, okay. Well, in
18 general terms, of course, all of the AHRQ
19 indicators were originally designed to be used
20 with administrative data. That was the
21 genesis of the program, was that people wanted
22 to -- there was a demand for indicators that

1 could be applied to administrative data. And
2 so, AHRQ responded to that demand.

3 Now in the last couple of years,
4 we have seen that some states are beginning to
5 add more data elements to their administrative
6 datasets. And of course, as users transition
7 to electronic health record systems, they have
8 additional data that is available to them
9 internally.

10 So, we have done some pilot work,
11 for example, incorporating laboratory data
12 into the design, particularly for the risk
13 adjustment of selected indicators. So, that
14 is a trend for the future.

15 And I will encourage John to say
16 something about AHRQ's priorities for
17 development and evolution of the measures.

18 Just to address a couple of
19 technical comments, so the risk adjustment,
20 because these are rare events, that limits the
21 number of parameters that you can estimate in
22 a risk-adjustment model. And so, this risk-

1 adjustment model has a C statistic of 0.93,
2 which is actually a very high C statistic.
3 And it is driven largely by the body system
4 that was operated on. So, certain body
5 systems, of course, have much higher risk than
6 others.

7 And it is driven by a marker, an
8 indicator, of basically the number of
9 procedures, and whether it was a diagnostic or
10 therapeutic procedure. Obviously, therapeutic
11 procedures are higher risk than diagnostic
12 procedures. Patients who had multiple
13 procedures are at higher risks than patients
14 who had a single procedure. So, that is part
15 of the risk-adjustment model.

16 But, of course, it can't account
17 for anything prior to the index
18 hospitalization. That is an inherent
19 limitation of using these kinds of data.

20 But the overall C statistic is
21 0.93, which is quite, quite good for these
22 types of models.

1 The point about there's no
2 question that there is some heterogeneity in
3 this type of an outcome indicator. So, there
4 is a mixture of different types of lacerations
5 and punctures. And, yes, the physician
6 documents that they punctured the carotid
7 artery and that they had to do something, they
8 had to have a nurse at the bedside for six
9 hours to tamp down the bleeding, then that
10 could be certainly captured.

11 On the other hand, if it was just
12 sort of routine bleeding in the course of a
13 chest tube insertion, for example, that
14 typically would not be coded because there
15 wouldn't be any defined anatomic structure
16 that was punctured or lacerated. So,
17 generally, in order to kick in this code,
18 there would have to be documentation that a
19 specific structure was punctured or lacerated.

20 Ideally, there may be a separate
21 code to indicate what specific structure that
22 is. But the coding rules don't require the

1 use of both of those codes. So, that is why
2 we haven't been able to incorporate that into
3 the logic.

4 So, I think that is the technical
5 comments. Let me defer to John on the AHRQ
6 priorities.

7 MR. BOTT: Well, we are actually
8 in the throes of defining what our priorities
9 will be measure development and measure
10 refinement over the next few years at this
11 given time. So, it is hard to comment on that
12 specifically.

13 But I would just echo what Patrick
14 said about AHRQ is anxious to adopt other data
15 sources wherever possible and exploring some
16 of those avenues in the most immediate -- in
17 fact, we just wrapped up a project which
18 looked very promising, which was incorporating
19 lab values in the outcome measures for a
20 number of the PSIs. And that looked very
21 promising to pursue that work in the future.
22 We seem to be fairly likely to continue that

1 work.

2 CO-CHAIR CIPRIANO: Okay. Great.

3 Thank you.

4 Comments or questions from the
5 Committee?

6 MEMBER CLARKE: I have a question.

7 CO-CHAIR CIPRIANO: John. Sorry.

8 MEMBER CLARKE: Well, two comments
9 and two questions. The one comment is a
10 general comment. And that is, as a surgeon,
11 I don't think the critical issue in accidental
12 perforations and lacerations is accidentally
13 perforating or lacerating something. I think
14 the critical issue is not detecting it and
15 fixing it right away.

16 The critical issue comes when you
17 do something and you don't realize you have
18 done it, and then you get a complication as a
19 result of it. If I nick the bowel and I sew
20 it up with a stitch, I am not going to get a
21 bad result. But I don't realize that I nicked
22 the bowel and I don't sew it up or I sew it up

1 a day later, then I am going to get into big
2 trouble. And that is true for the adult
3 version as well.

4 There is a comment in this
5 particular thing proposing that there needs to
6 be a minimum pediatric threshold in which to
7 apply this standard. I would like to stand
8 against that concept, at least in the
9 aggregate.

10 It seems to me in things that are
11 volume-related like pediatric surgery, where,
12 presumably, greater volume means greater
13 expertise, to only look at the high-volume
14 places is to miss one of the really critical
15 factors.

16 And I can understand that you
17 might not want to look critically at a single
18 hospital that only does one colon Hirschsprung
19 pullthrough a year, but you certainly want to
20 look very critically at all the hospitals that
21 fall into that group as an aggregate.

22 So, I would be against having some

1 kind of minimum volume threshold and something
2 that is minimally volume-dependent.

3 And then, I have two questions,
4 and they have to do with the exclusion of the
5 low-birth-weight babies, which I assume was
6 only related to the fact that it is such a
7 rare event, and the exclusion of newborns.
8 Now I could understand that a newborn, you
9 would think that a newborn baby popping out
10 and going home would not be subject to
11 accidental perforations and lacerations, but
12 you would be surprised, if it is a cesarean
13 section, they often -- not often -- but they
14 occasionally get nicked in the process of
15 doing the cesarean section. We have a number
16 of reports in our database of babies who have
17 been accidentally cut, developed a skin
18 laceration as a result of having been
19 delivered by C-section.

20 MS. BOSSLEY: Could you use your
21 microphone, please, Vallire. Vallire,
22 microphone, please.

1 MEMBER CLARKE: You could call it
2 anything you want, but it happens.

3 MEMBER HOOPER: I'm sorry, my
4 question was, would that fall under the adult
5 measure or the pediatric measure because,
6 technically, it is an adult surgery? I know
7 this sounds crass, but the nick of the baby
8 would be no different than nicking another
9 body part, a bowel.

10 DR. ROMANO: Actually, if I could
11 address, it is fairly simple to answer. If
12 falls under a completely different -- it is a
13 perinatal indicator, and it falls under the
14 birth trauma indicator, which was evaluated
15 and discussed by the Perinatal Steering
16 Committee earlier this month. And that was a
17 separate discussion.

18 So, normal newborns are excluded
19 because they basically add noise without
20 adding much information. At some hospitals,
21 it is a very large percentage of their total
22 volume. Of course, those patients are

1 extremely low-risk, absent birth trauma. So,
2 they really just add noise.

3 The very low-birth-weight infants,
4 less than 500 grams, are excluded across the
5 board from most of these indicators, just
6 because hospitals -- well, they are just
7 obviously a very different type of clinical
8 situation, and you are close to the limits of
9 liability there on some of those. Infants may
10 be allowed to die shortly after birth,
11 especially under 400. So, that is a fairly
12 extreme cutoff for birth weight. But we do
13 keep the ones that are over 500 grams.

14 CO-CHAIR CIPRIANO: Okay. Steve?

15 MEMBER LAWLESS: Yes, I'm going
16 back to AHRQ in a second.

17 The question I think was, the
18 administrative data versus the American
19 College of Surgery has now defined or growing
20 together as consensus for both their adults
21 and pediatric worlds what the definition is
22 laceration is, how they are defining it.

1 That data source is like a lab. I
2 would actually reach out to them and say,
3 "Guys, let's be consistent here." They are
4 using it now for their maintenance and
5 certifications, other things. So, it adds a
6 little better consistency in terms of the
7 definition.

8 The other is to Mr. Clarke's
9 feeling, going with your rates versus
10 individualities. Having one or two events a
11 year, but having them in someone who has only
12 done one of these procedures a year is
13 entirely different from one of these events a
14 year happening in someone who does 50 of these
15 or 100 of these a year.

16 So, I think one of the bigger
17 things which I would also agree don't exclude
18 is -- don't put in a minimum threshold and do
19 sort it out by pediatric versus adult and
20 level of experience somehow, because I think
21 that is what a big key of this whole thing is,
22 versus the people who report all the time.

1 CO-CHAIR CIPRIANO: Could you
2 comment on the minimum threshold?

3 DR. ROMANO: So, two quick
4 responses. So, I think the threshold issue
5 may be a misunderstanding. Where are you
6 seeing that in the document? The top of page
7 13?

8 MEMBER CLARKE: "This problem
9 could be minimized by focusing on public
10 reporting of this indicator on hospitals that
11 meet a minimum pediatric volume threshold or
12 by incorporating" --

13 DR. ROMANO: Oh, could it be
14 minimized by focusing public reporting? So,
15 that is not --

16 MEMBER CLARKE: That is my point.
17 I mean, if you say only pediatric hospitals of
18 more than 200 beds are going to be evaluated,
19 then a hospital of 200 beds is doing to look
20 bad compared to another hospital of 200 beds,
21 when they are both highly superior to any
22 other hospital in the country.

1 DR. ROMANO: No, that is a good
2 point, but it is nothing intrinsic to the
3 design of the indicator. It is just an issue
4 that people have to confront in the field when
5 they apply the indicator and figuring out how
6 to apply it, and if they want to do public
7 reporting, how to do that. But it is nothing
8 about the design of the indicator that would
9 impose a threshold.

10 The other question that I wanted
11 to -- oh, yes, the American College of
12 Surgeons. So, we welcome opportunities to
13 work with others in the field to clarify these
14 definitions and to develop more precise
15 definitions. Because coders come to us and
16 say, "Well, I don't really know what this is.
17 The surgeons tell us it is this, but, then, in
18 some other hospitals surgeons tell us it is
19 something else."

20 And so, we will get to foreign
21 bodies later. But through the foreign body
22 process, actually, there has been quite a bit

1 of discussion with the surgical community,
2 through the SRE process that NQF has led. It
3 has led to some consensus about even something
4 as narrow as when surgery ends. It turns out
5 to be a fairly critical question.

6 So, I think we would welcome the
7 opportunity, and we have the mechanism to go
8 back to the Coordination and Maintenance
9 Committee and say, "Well, hey, we should
10 change the code." We're also looking forward
11 to ICD-10-CM implementation in October 2013,
12 and these codes will become more specific in
13 ICD-10-CM.

14 So, there is an opportunity
15 definitely to make the codes line up better
16 with surgeons' understanding of the events
17 that should be captured. But, fundamentally,
18 this is about public use data as opposed to
19 private registry data. So, we want to
20 harmonize but still retain the focus on public
21 use data.

22 CO-CHAIR CIPRIANO: Okay. Any

1 others? Oh, Jason, okay.

2 MEMBER ADELMAN: John made a
3 comment before which I appreciated, but I
4 didn't totally get the punchline. It was when
5 you talked about the difference between a
6 laceration that you can correct immediately
7 with one stitch versus one that goes unnoticed
8 and leads to a real adverse event.

9 It made me think of another
10 indicator that we are talking about later, the
11 retained foreign bodies. Just the name
12 retained foreign bodies immediately makes me
13 think of somebody left a sponge in.

14 And when I read some of the
15 articles, I realized that very few of those
16 are actually like a sponge that was
17 accidentally left in. Many of them are
18 intentional microneedles that I have heard
19 surgeons tell me -- the point I am trying to
20 make is it seems to be in both these
21 indicators, from what you said about the
22 lacerations and another one, that there is a

1 mixture between things that surgeons will
2 generally think are benign versus things that
3 are really bad, and where that mixture is is
4 unclear. It puts into question the meaning of
5 the information.

6 There is 153 retained foreign
7 bodies. I just don't know how much are --

8 MEMBER CLARKE: Yes, I think it is
9 important to clarify the difference, although
10 your point is excellent, which is that there
11 are benign misadventures and there are
12 malignant misadventures. I think the
13 undetected accidental perforation versus the
14 immediately-recognized one is an example of
15 that.

16 But the other thing we are talking
17 about, though, there is a very important
18 difference between a retained foreign object
19 which is unintentionally left behind and what
20 they call, or what the FDA calls an
21 "unretrieved device fragment". So, for
22 instance, you are drilling into the femur.

1 You break the end of the drill off. You
2 realize that the end of the drill is broken
3 off, and you make a medical decision at that
4 moment in time, do I want to dig that out of
5 the head of the femur? And your answer is,
6 no, I don't; it is more benign to leave it in.
7 That is, by most definitions in my
8 understanding, is not called a retained
9 foreign object; it is called an "unretrieved
10 device fragment".

11 MEMBER ADELMAN: In these
12 indicators, it is a retained foreign object.
13 What you just called the unretrieved --

14 MEMBER CLARKE: Not by the
15 definitions I have been using.

16 MEMBER ADELMAN: Oh, I am
17 misunderstanding what I read.

18 DR. ROMANO: Maybe we can stay
19 on --

20 MEMBER ADELMAN: I only bring it
21 up because it just seems that sometimes we are
22 stuck by what we can do instead of what we

1 really want to do. And because of that, we
2 are just trying to make the best of something
3 that seems less than ideal. And it is just
4 two parallel examples of a code will indicate
5 a laceration. Whether it is meaningful or
6 not, they don't tell us. And so, we just have
7 to list them all. And that was the point I
8 was trying to make.

9 DR. ROMANO: Right. Well, I think
10 that is an important point, and the Committee
11 needs to recognize that. We are very upfront
12 about that. In fact, in the paper that we
13 cite related to the adult indicator, which was
14 led by my colleague Garth Etter, we reported
15 91 percent PPV overall for the adult
16 indicator, 226 of 249 events, but 56 of the
17 true-positives, 24 percent of the true-
18 positives were of the nature that John
19 described. They were minor mishaps that would
20 either fix themselves or were caught
21 immediately. So, you might say that those
22 events are not clinically-consequential.

1 But that comes with the bath
2 water, so to speak. You have to decide
3 whether catching those mishaps, how bad is
4 that, to include that in the overall basket?

5 CO-CHAIR CIPRIANO: Okay.
6 Vallire? And then, I think let me just see if
7 we are ready to make a conclusion on this one.

8 MEMBER HOOPER: Going back to
9 John's comment regarding the difference
10 between recognizing an accidental puncture or
11 laceration and doing something about it versus
12 truly from a PACU perspective, from a recovery
13 room nurse perspective, when you see the truly
14 sick patient, it is the patient who got
15 discharged from the PACU 24 hours ago and
16 looked fine, and then 24 or 48 hours later
17 they had a lacerated bowel and they come back
18 septic.

19 So, I am looking at this summary
20 of evidence and high impact, and it talks
21 about the high cost and increased length of
22 stay. But I wonder if that data is related

1 to, as John was saying, the laceration that
2 was caught and remedied at the time that it
3 occurred versus the accidental puncture or
4 laceration that is not detected.

5 And so, I guess what am wondering
6 is, is this measure truly sensitive to what is
7 adversely impacting the patient outcome? And
8 I think is the undetected laceration or
9 puncture typically more so than the detected
10 laceration or puncture.

11 MEMBER CLARKE: Well, yes and no.
12 There is no question, if you stick a trocar in
13 the bowel and you don't recognize it, you are
14 in big trouble. However, I can think of some
15 counter-examples whereby, for instance, you
16 lift a little retina off the eye and then you
17 sew it back on right away, but you still have
18 a worse result than if you had never lifted it
19 off altogether. Or, in general surgery, if
20 you cut the common duct and recognize it right
21 away, you still wish you had not cut the
22 common duct. I don't mind nicking a bowel; I

1 would object strenuously to cutting the common
2 duct in half.

3 (Laughter.)

4 CO-CHAIR CIPRIANO: Okay. Well,
5 what we have before us is Measure 0344,
6 though, which is an accidental puncture or
7 laceration rate in pediatrics. And so, I
8 think you have pretty much had a chance to
9 explore the issues related to how this measure
10 is constructed and what information it does
11 yield.

12 So, are we ready to vote?

13 Janet, any questions, any comments
14 from you?

15 MEMBER NAGAMINE: No. Thanks.

16 CO-CHAIR CIPRIANO: Okay.

17 Jessica?

18 MS. WEBER: All right. Importance
19 to measure and report, high impact,
20 performance gap, and evidence. It is a yes/no
21 question.

22 (Whereupon, a vote was taken.)

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Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Eighteen yes, 3 no.

Scientific acceptability of
measure properties, reliability and validity.
It is a yes/no question.

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Eighteen yes, 3 no.

Usability? High, moderate, low,
or insufficient.

(Whereupon, a vote was taken.)

Janet? Janet?

OPERATOR: She is disconnected.

MS. WEBER: Oh, okay.

Three high, 13 moderate, 4 low.

Feasibility?

(Whereupon, a vote was taken.)

Eight high, 10 moderate, 2 low.

Overall suitability for
endorsement. Does the measure meet all of the

1 NQF criteria for endorsement?

2 (Whereupon, a vote was taken.)

3 Nineteen yes, 2 no.

4 CO-CHAIR CIPRIANO: Okay. John,
5 the next measure.

6 MEMBER CLARKE: I think we can
7 keep this short. The adult recommendations
8 follow the pediatric. There are fewer
9 exclusions for, say, the neonates and the
10 underweight babies, et cetera.

11 Almost everything that we could
12 have said about this we have said about the
13 pediatric. So, I don't think there is
14 anything that I can add to the discussion.

15 CO-CHAIR CIPRIANO: So, are there
16 any additional comments or questions? Or are
17 you ready to vote?

18 (No response.)

19 Okay. We are voting on 0345,
20 accidental puncture or laceration rate, which
21 is adults.

22 MS. WEBER: We will need a moment

1 to upload the voting.

2 CO-CHAIR CIPRIANO: Okay. Janet,
3 are you back on yet?

4 MEMBER NAGAMINE: I am. Sorry. I
5 managed to disconnect myself.

6 CO-CHAIR CIPRIANO: That's okay.

7 MS. WEBER: Okay. Importance to
8 measure and report, high impact, performance
9 gap, and evidence. It is a yes/no question.

10 (Whereupon, a vote was taken.)

11 We need two more votes. Try
12 casting it again.

13 Janet?

14 MEMBER NAGAMINE: Yes.

15 MS. WEBER: Twenty yes, 2 no.

16 Scientific acceptability of
17 measure properties, reliability and validity.
18 It is a yes/no.

19 (Whereupon, a vote was taken.)

20 Janet?

21 MEMBER NAGAMINE: Yes.

22 MS. WEBER: Twenty yes, 2 no.

1 Usability? High, moderate, low,
2 or insufficient.

3 (Whereupon, a vote was taken.)

4 Janet?

5 MEMBER NAGAMINE: High.

6 MS. WEBER: Three high, 16
7 moderate, 3 low.

8 Feasibility? High, moderate, low,
9 or insufficient.

10 (Whereupon, a vote was taken.)

11 We need one more vote.

12 Janet?

13 MEMBER NAGAMINE: High.

14 MS. WEBER: Nine high, 11
15 moderate, 2 low.

16 Overall suitability for
17 endorsement. Does the measure meet all the
18 NQF criteria for endorsement?

19 (Whereupon, a vote was taken.)

20 We need one more vote.

21 Janet?

22 MEMBER NAGAMINE: Yes.

1 MS. WEBER: Twenty yes, 2 no.

2 CO-CHAIR CIPRIANO: Okay. Thank
3 you very much.

4 What we will do is move to two
5 additional measures and hold off right now on
6 the foreign body measures. Okay? So, we can
7 come back to those when Patrick rejoins us.

8 So, we are going to move to 0263
9 and 0267, but let's do 0267 first, for those
10 of you that are tracking in an electronic file
11 since it is in the same Workgroup.

12 So, 0267, we have Iona.

13 This is wrong site, wrong side,
14 wrong patient, wrong procedure, wrong implant.

15 MEMBER THRAEN: Okay. Thank you.

16 First of all, this is an
17 Ambulatory-Surgical-Center-sponsored
18 indicator. And many of the issues we have
19 already talked about relevant to this
20 particular one -- one is the use of a rate
21 versus a count. The sponsor is proposing a
22 rate, and they identify in their data, in

1 their information, that the rate of surgeries
2 involving wrong site, dah-dah-dah-dah-dah,
3 range from a minimum of 0.00 percent to a
4 maximum of 0.31 percent, mean rate of 0.00
5 percent, standard deviation of 0.02 percent,
6 median rate of 0.00 percent.

7 So, the conversation we had in our
8 discussion was, again, the idea of the rate
9 versus the count. I would add to that that
10 the seriously-reportable events of wrong site
11 surgeries that apply to hospitals tends to be
12 a count measure, and that I know that
13 historically -- I don't know how strong it is
14 currently because hospitals seem to be buying
15 up ambulatory surgical centers, but at least
16 in my community there is sort of a competition
17 that goes on between ambulatory surgical
18 centers and hospitals. And using a rate in
19 one sector and a count in another sector
20 creates an uneven situation environmental
21 context for trying to judge outcomes. So,
22 that is one of the issues.

1 Another question that was raised
2 was whether or not the universal protocol
3 process really is decreasing these wrong site
4 surgeries. One of the comments by Dr. Clarke
5 was that, well, if it is done right, yes.
6 However, it goes back to that question we had
7 earlier about implementation issues in terms
8 of how you actually improve care.

9 And then, some of the Workgroup
10 members expressed an interest in seeing that
11 the measure is stratified by procedure.
12 Again, this has been proposed by ambulatory
13 surgical centers. In my local area in the
14 State of Utah, the Association is reporting
15 that many of the wrong site surgeries are
16 related to eye surgeries, eye procedures, and
17 that in the other worlds this is a very small
18 occurring incident, but it does have more of
19 an occurrence in those areas. So,
20 stratification by procedure would make some
21 sense due to that.

22 However, the developer responded

1 it was not feasible to do this at this time.
2 Likely, it will become more feasible as the
3 measure starts being implemented and reported
4 out as part of the CMS mandatory reporting
5 program.

6 Which, then, raises another
7 question on the reference to the CMS mandatory
8 reporting program, how is CMS asking for this
9 to be reported? Are they asking, again, from
10 a count perspective or from a rate perspective
11 or are they using an ICD-9 code? So, that
12 might be something the developer might want to
13 respond to.

14 CO-CHAIR CIPRIANO: Okay. Our
15 measure developers, if you would just remind
16 us of your names?

17 MS. SLOSBURG: Can you hear me?
18 Can you hear me? Okay.

19 I am Donna Slosburg, and I am with
20 the ASC Quality Collaboration. And this is
21 Dr. David Shapiro. On the phone, Operator, I
22 think we have Kim Wood, M.D., and Susan White.

1 So, if I can't answer the
2 technical questions, one of them, hopefully,
3 will.

4 We just wanted for just a brief
5 second to tell you all, I know NQF is very
6 familiar with us because we have six NQF-
7 endorsed measures, but because of the varied
8 experience in the room, we just wanted to kind
9 of give you all a brief overall about the
10 industry and about the Collaboration and how
11 we came about.

12 Basically, the Collaboration was
13 formed in 2006, and our stakeholders include
14 accrediting bodies, professional organizations
15 and associations. We have basically done all
16 of this work voluntarily.

17 Currently, we were just informed,
18 No. 1, that there is going to be quality
19 reporting, as Iona alluded to, starting
20 October 1st, 2012. So, all of the data we
21 have is from approximately, and depending on
22 the quarter, 1300 to 1500 ASCs across the

1 country that are reporting data from 49
2 states. And this data is aggregated up. So,
3 we do report a numerator and a denominator.

4 However, to answer your question
5 about, is it going to be a count with CMS, the
6 specifications guide is not going to be out
7 until the second quarter of 2012 to start
8 reporting October 1st, 2012. We understand
9 that it is going to be a claims-based
10 reporting on Medicare patients, but I don't
11 have all of the details.

12 MEMBER THRAEN: To me, that raises
13 a problem, claims-based, because wrong site
14 surgeries don't really have an ICD-9 claims
15 associated with it, which is why you have a
16 manual reporting system for wrong site
17 surgeries.

18 MS. SLOSBURG: They are in the
19 process of actually -- and, Kim or Susan, if
20 you are out there, if the operator could open
21 up their lines -- but I am going to let
22 David --

1 DR. SHAPIRO: I think the answer
2 to your question -- we are in a transition
3 period. CMS just issued a final rule at the
4 beginning of last month which contemplates
5 their starting to collect data next year, next
6 calendar year 2012.

7 Five of the currently-endorsed
8 measures that you all have endorsed for us in
9 the past, and they include the two that we are
10 discussing with you all today. So, I think
11 you are clearly asking some great questions.

12 As Donna mentioned, we don't have
13 all of the data. We are engaged with CMS in
14 trying to help them through exactly how they
15 are going to get this data.

16 But what it appears that they are
17 going to do is have this on our claims. So
18 that they will initiate some kind of code on
19 each claim that will reflect the absence or
20 presence of either or all of these five
21 seriously-reportable events. We don't have
22 the exact data codes yet, and we also don't

1 have the experience with CMS to answer your
2 other question, which is how they are actually
3 going to report this data.

4 But we certainly do agree that
5 harmonization is something that we strive for.
6 We think this is an important measure, and we
7 hope that, going forward, that CMS understands
8 that this is something that we should be using
9 in a harmonized fashion between all healthcare
10 settings that deliver surgical care of the
11 comparable type. So, we absolutely agree with
12 your comment.

13 MS. SLOSBURG: Back to the
14 question about procedure-specific, we don't
15 have that data right now because, again, this
16 is a total voluntary reporting, the data we
17 have. However, we are all in the process of
18 working on a registry. If that registry gets
19 accomplished, which is our goal, then we
20 certainly could be able to take the data from
21 the wrong site surgeries and slice and dice it
22 by demographics, by procedure, by state, for

1 those that are reporting in the registry.

2 DR. SHAPIRO: I think that answers
3 the question.

4 CO-CHAIR CIPRIANO: Okay.
5 Questions or comments from the Committee?

6 Lisa?

7 MEMBER McGIFFERT: I just want to
8 clarify that what we are voting on is a
9 measure that is presented as a rate and not as
10 a number, right?

11 DR. SHAPIRO: Right. We have been
12 reporting it, we have been doing it, we have
13 been reporting these for the last several
14 years, actually, since the NQF endorsement, on
15 a publicly-accessible website that any of us
16 or anybody, any consumer can look at.

17 And we have been reporting them as
18 a rate to harmonize with the way that
19 reporting is done in other situations. But we
20 do have the aggregated data to be able to give
21 the actual number. And it is easy to
22 calculate the number back from the rate by

1 knowing the amount of participating centers
2 that gave us the data.

3 But I think the main point in that
4 is, as we go through this transition where
5 these become part of the CMS reporting
6 requirements, that our data is going to be
7 really subsumed by the CMS data, which will be
8 certainly much more robust and have much more
9 participating centers that are represented.
10 And they also will not be represented the same
11 way we have been able to, had to do it, in an
12 aggregated manner, but they will be
13 represented individually, as they submit those
14 claims back to CMS on the 1500s.

15 MEMBER MCGIFFERT: But the
16 hospital presentation is by number, not rate,
17 correct?

18 MS. SLOSBURG: Can I clarify or
19 can NQF clarify for the group? To my
20 knowledge, wrong site is a serious reportable
21 event, but there is no inpatient, hospital,
22 wrong site, endorsed measure, correct?

1 MS. BOSSLEY: I looked to be sure
2 that my memory was correct, and that is
3 correct.

4 MS. SLOSBURG: So, I want to make
5 sure that everybody understands. I mean, we
6 want to harmonize, but there is no inpatient
7 wrong site measure. There is serious
8 reportable event for wrong site, but not a
9 wrong site endorsed quality measure.

10 I don't know if that is more
11 confusing or less confusing. And we wanted to
12 make that point.

13 MEMBER MCGIFFERT: My memory is
14 that CMS doesn't count it. They just say, "It
15 shouldn't happen. We're not going to pay for
16 it," period.

17 MEMBER THRAEN: Except that in the
18 provider preventable conditions that has just
19 been released, wrong site surgery is not a
20 claims-based access. The wrong site surgery
21 has been held out as OPPC, Other Provider
22 Preventable Condition, that has a manual

1 reporting system associated with it. So, we
2 are back to the idea of hand-counting and
3 manually reporting to CMS on those,
4 specifically those wrong site surgery events.

5 MS. SLOSBURG: And again, the
6 implementation guide is not out yet. But the
7 information we are getting is verbally, what
8 we are hearing from CMS. So, until it is
9 final, just I don't want to guess incorrectly.

10 CO-CHAIR CIPRIANO: Okay. John
11 and then Saul.

12 MEMBER CLARKE: A couple of
13 comments about this. Unfortunately, I have
14 become the world expert in this topic without
15 ever having done one.

16 We have collected now 466 wrong
17 site events in Pennsylvania over seven and a
18 half years. We have worked in close
19 collaboration with New York, and particularly
20 Diane Rydrych in Minnesota, who has done a
21 terrific job.

22 There are about 19 states that

1 require reporting of serious reportable events
2 as patient safety measures in their states.
3 And all of those, of course, require the
4 reporting of wrong site surgery. So that
5 there is a mechanism in almost half the states
6 for reporting wrong site surgery, and some of
7 them are easily available on the web and some
8 of them are not. But they all report in terms
9 of numbers.

10 So, while I don't think it should
11 affect our assessment of this, I would
12 advocate in terms of reporting out your
13 results as a number, to be concordant with the
14 way the hospitals, who, quite honestly, have
15 a much larger volume and, therefore, have many
16 more of these events.

17 When it comes to another parameter
18 that has to do with rates, however, it is how
19 you measure these. In a couple of instances,
20 in subdivisions -- so, we have gotten so many
21 cases, we can tell you there were 50 wrong
22 level spinal cases, there are 19 stents in the

1 wrong ureter, and there is 1 wrong site
2 cardiac case, and no wrong site upper
3 abdominal general surgical cases, and lots of
4 knees and lots of eyes.

5 But just taking the ureter as an
6 example, in Pennsylvania we have about 80,000
7 ureteral stents done a year -- or excuse me --
8 in eight years. We have about 10,000 a year.
9 But some of those are bilateral stents. So,
10 you are not going to get a wrong side in a
11 bilateral stent. And so, if you just take a
12 simple number of stents inserted, then you get
13 the wrong number. If you take the number of
14 patients who have stents inserted, you get a
15 wrong number. And so, without tweaking the
16 denominator, you can get slightly aberrant
17 results, so another reason for this very rare
18 event just going with the whole numbers.

19 But the fact that I think that
20 this should be on a case base rather than a
21 rate base doesn't mean we can't get the case
22 numbers out of the rate. So, I don't think

1 that should preclude us from looking at this
2 standard.

3 MEMBER WEINGART: Yes, I
4 completely agree with Dr. Clarke's comments
5 and the idea that Minnesota, Pennsylvania, New
6 York, Massachusetts have very carefully
7 specified the definitions of these events in
8 order to exclude the trivial ones.

9 I think the first one in Minnesota
10 encountered, when they turned on their SRE
11 reporting law, was a resident looking in the
12 bladder, going up the wrong ureter, realizing
13 it, coming out, looking at the correct one.
14 There was no harm. There was no injury. And
15 yet, it was publicly reportable. So, I think
16 it is very important to harmonize and align
17 those.

18 I am assuming that by wrong site
19 that also includes wrong level for spinal
20 issues.

21 I think the last thing I wanted to
22 ask you about was the validation piece of this

1 because the documentation we received suggests
2 that the validation process involved sharing
3 a tool with a bunch of clinicians, who then
4 kind of looked it over and assessed the case
5 validity. So, I wonder if there is kind of
6 more to it, to make sure that what we are
7 measuring is actually what happened.

8 That also begs this question, if
9 you go to a claims-based reporting system,
10 then we don't have any evidence on which to
11 assess the validity of the measurement and
12 would be hard-pressed to endorse an approach
13 that has been trialed yet.

14 MS. SLOSBURG: Is Susan on the
15 line? Operator, can you open Susan's line?

16 MS. WHITE: I am. I am, Donna.
17 I'm here.

18 So, reliability was certainly
19 tested. The face validity was tested by
20 sharing the measure with a panel of experts
21 and having them rate on the Likert scale. And
22 the reliability was tested with centers

1 actually or ASCs actually going back and
2 reviewing to check to make sure that wrong
3 sites were properly identified. That was
4 based on a smaller sample of the centers, 21
5 of them in this case.

6 MS. BOSSLEY: Just quickly, what
7 you have put forward to us, though, is just a
8 measure with the data source of paper records
9 right now, correct, not the claims?

10 MS. SLOSBURG: Correct.

11 MS. WHITE: Right. So, I mean --

12 MS. BOSSLEY: Right. And so, I
13 just want to clarify that, if they did come
14 back to us with new specifications, we would
15 take a look at that, then, if it warrants a
16 review.

17 MS. SLOSBURG: And that would be
18 with the annual update, right, Heidi?

19 MS. BOSSLEY: Yes, we would take
20 care of it that way.

21 So, I would just put that -- that
22 is a future potential expansion but not right

1 now.

2 MS. WHITE: Right. Donna
3 mentioned that CMS is going to have measures
4 that will come into play, and we will want to
5 work for harmonization.

6 But, right now, we are not
7 proposing a claims-based measure.

8 CO-CHAIR CIPRIANO: Okay. Vallire
9 and then Bill.

10 MEMBER HOOPER: Just as a point of
11 clarification, is this measure designed to
12 capture wrong site/wrong side surgery just in
13 freestanding ambulatory surgery centers or is
14 it also designed to capture wrong site/wrong
15 side surgery in outpatients that are done in
16 hospital settings? Or do we know what the CMS
17 measure will look like?

18 MS. SLOSBERG: Our group, the
19 Quality Collaboration, our experience and
20 expertise is strictly in ambulatory surgery
21 centers. So, what we have put forth is only
22 measures for ambulatory surgery centers. So,

1 I cannot speak to HOPDs.

2 DR. SHAPIRO: So, the reporting
3 requirement is going to be mandated for
4 approximately 5300 Medicare-certified ASCs.
5 So, we will be reporting on Medicare patients
6 that have their procedures performed in one of
7 those, not necessarily -- freestanding can
8 sometimes be misleading, but it is really the
9 fact that in most states, actually, there is
10 a separate licensure different from an HOPD.
11 And actually, the billing is quite different,
12 and there are a lot of things that are
13 different that pertain to that. But that is
14 the distinction.

15 So, at the get-go, when we start
16 reporting this next calendar year, this will
17 just be for the ASCs. But, again,
18 harmonization in the future is something that
19 we very strongly advocate.

20 CO-CHAIR CONWAY: This is just an
21 aside thought. It is a question to NQF and
22 potentially get a comment on the record.

1 Do we have any effort underway to
2 harmonize reporting? And what I am looking at
3 here is on an event like this you may have to
4 report to the State if you are in
5 Pennsylvania. If you participate in a PSO,
6 there might be a different form to put that,
7 or the Joint Commission. And then, there is
8 now the potential of CMS wanting you to put
9 information probably on a billing form. That
10 is how they usually operate.

11 So, I mean, are we working on
12 that?

13 MS. BOSSLEY: Yes. I mean, we
14 started with, first, the serious reportable
15 events, trying to set definitions that could
16 then be used as individuals develop the
17 measures.

18 With regard to actual
19 implementation, we continue to try to
20 encourage that those be used. They may be
21 used differently in states. I think that is
22 actually fairly common right now. But the

1 goal is to be able to have a standard set of
2 definitions that can go from serious
3 reportable events to the safe practices, to
4 the measures. So that you are at least
5 defining and capturing in the same way, yes,
6 that is the goal.

7 CO-CHAIR CONWAY: But, I mean, you
8 don't usually get into this, but it might even
9 be worth for you to take the leadership one
10 step beyond and get the reporting process, the
11 form, or whatever, standardized as well.

12 MS. BOSSLEY: Yes.

13 CO-CHAIR CONWAY: That would help
14 us out in the field a lot.

15 MS. BOSSLEY: We also are working
16 on the common formats as well for the PSOs
17 with the thought that that is what we are
18 working on as well.

19 But Dr. Clarke?

20 MEMBER CLARKE: If I could inject
21 in that, in Pennsylvania we have tried to
22 solve this problem. Many hospitals use an

1 internal system for reporting adverse events,
2 some kind of risk management system. And we
3 have been mapping to that.

4 So, probably the correct solution
5 to this problem is Riskmaster or one of those
6 other systems that you use for managing these
7 events are developing templates so they can
8 spit out a report to the FDA, they can spit
9 out a report to Pennsylvania, they can spit
10 out a report to CMS. And that is probably the
11 way it is going to go.

12 CO-CHAIR CIPRIANO: Okay. Are
13 there any other comments or questions at this
14 point?

15 Iona?

16 MEMBER THRAEN: I just wanted to
17 sort of summarize with a comment that was made
18 in our review group, which basically said that
19 they thought that this measure had face
20 validity, but it is a public health issue in
21 terms of "never events" and that, in general,
22 there was support for it, even though it is

1 one of those, again, one of those rare events,
2 but, again, the focus being the issue of
3 numbers versus rates.

4 CO-CHAIR CIPRIANO: Okay. Thank
5 you.

6 All right. We will ask Jessica to
7 walk us through the voting, then. This is on
8 0267.

9 MS. WEBER: Importance to measure
10 and report. Are all three subcriteria met,
11 high impact, performance gap, evidence? It is
12 a yes/no question.

13 (Whereupon, a vote was taken.)

14 Janet?

15 MEMBER NAGAMINE: Yes.

16 MS. WEBER: Twenty-two yes.

17 MEMBER THRAEN: I think that is
18 the first time.

19 (Laughter.)

20 MS. WEBER: Scientific
21 acceptability of measure properties,
22 reliability and validity. It is a yes/no

1 question.

2 (Whereupon, a vote was taken.)

3 We need one more vote.

4 Janet?

5 MEMBER NAGAMINE: Yes.

6 MS. WEBER: Twenty-one yes, 1 no.

7 Usability? High, moderate, low,

8 insufficient.

9 (Whereupon, a vote was taken.)

10 Janet?

11 MEMBER NAGAMINE: High.

12 MS. WEBER: Fifteen high, 6

13 moderate, 1 low.

14 Feasibility? High, moderate, low,

15 insufficient.

16 (Whereupon, a vote was taken.)

17 We need one more vote.

18 Janet?

19 MEMBER NAGAMINE: High.

20 MS. WEBER: Twelve high, 9

21 moderate.

22 Overall suitability for

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

3 (Whereupon, a vote was taken.)

4 We need one more vote.

5 Janet?

6 MEMBER NAGAMINE: Yes.

7 MS. WEBER: Twenty-one yes.

8 CO-CHAIR CIPRIANO: Thank you. I
9 apologize.

10 Okay. So, we are moving to report
11 Group D, Measure 0263, which is patient burn.

12 And for that, we do not have the
13 member of the Subcommittee here today. So, if
14 we look at the preliminary voting, this is
15 relatively-consistent with just a little bit
16 of, one vote consistently that is not the
17 same. But, then, feasibility has a number of
18 different variables.

19 It is under D, Workgroup D. It is
20 under Care Coordination. The summary is in
21 there.

22 Okay. So, this is the percentage

1 of ambulatory surgery center admissions
2 experiencing a burn prior to discharge. So,
3 obviously, an intraoperative or episodic
4 unanticipated event of a burn. Okay?

5 All right. So, this is an outcome
6 measure. Paper records are the source. And
7 it is a rate, is that correct?

8 Okay. All right, we will ask
9 David and Donna to speak to it.

10 Are there comments or questions?
11 Are your tents up? John, is yours up also?

12 Okay. All right. We will start
13 with Vallire. Thank you.

14 MEMBER HOOPER: Yes, I just have a
15 question. It seems that this is measuring
16 burns prior to discharge. And sometimes we
17 will see blistering or burns that will occur
18 in the ambulatory patient population post-
19 discharge, because you need to remember that
20 that patient may be discharged within one to
21 two hours of the procedure. And so, while
22 this is a needed measure, I am just curious as

1 to if we are missing issues, if perhaps we
2 should add something about postop followups,
3 as we do routine postop followup calls anyway.

4 CO-CHAIR CIPRIANO: It may be
5 that, since this is beginning to be a little
6 bit of a consistent concern that the group is
7 very appropriately identifying, which does
8 fall under the continuum of care, care
9 coordination issues, that as we identify
10 situations where we are only recording this
11 measure in a particular setting, that we need
12 to convey the importance across all the
13 measures, that there need to be opportunities
14 to have sort of the next step of the measure
15 that occurs, whether it is at home, whether it
16 is at the followup visit, whether it is in a
17 followup call, or whether it is hospital to
18 other level of care, because I think that is
19 where we don't really have a lot of those
20 measures right now.

21 And again, that relates to the
22 need for the development of longitudinal

1 measures with multiple sites that, again, are
2 not in existence right now. So, I think if we
3 could put that in that category as well?

4 And clarify for us, for any of the
5 measures that you have sponsored, not just
6 these two, it does relate to the episode of in
7 the door/out the door, as opposed to any post-
8 procedure --

9 DR. SHAPIRO: Exactly. Exactly,
10 and that was as a result of a lot of
11 discussion amongst ourselves in terms of
12 formulating these measures. But we really
13 wanted to make sure that it was under the
14 direct observation for all of, especially the
15 serious reportable events, during their
16 limited stay in the ASC.

17 And this is an inherent issue with
18 postoperative with ASC patients, is we don't
19 necessarily know what happens to them, even
20 though we do as much arduous followup as we
21 can with patient calls, surveys out to
22 physicians. But we, for the purposes of

1 starting this measure, at least limited it to
2 their experience within the perioperative
3 time. And it is actually a perioperative
4 measure. It is not just intraop. So,
5 anything that occurred adverse, even the falls
6 that could occur in recovery, so it is from
7 really admission to discharge. And that goes
8 for the other measures that you have endorsed
9 in the past that relate to the status, not
10 this particular measure.

11 CO-CHAIR CIPRIANO: John?

12 MEMBER CLARKE: I would like to
13 speak in favor of monitoring this. It is
14 actually more rare than both retained foreign
15 objects and wrong site surgery. However, it
16 has really serious consequences, not only to
17 the patient, but, in fact, in some instances
18 to the rest of the hospital staff in the room
19 and even in the rest of the hospital. So,
20 when they occur, they can be real disasters of
21 the first order.

22 In our experience, only a small

1 percentage of them are surface burns due to
2 thermal injury such as an inappropriate Bair
3 Hugger's hot water, and so on and so forth.

4 So, most of them have to do with
5 the combination of the cautery and free
6 oxygen. Most people don't realize that
7 anything, even fire blankets, will burn in
8 over 50 percent oxygen, and rather rapidly at
9 that.

10 So, I think that we are capturing
11 most of the events with this.

12 Again, I would argue, because this
13 is rare and because it varies by type, it
14 would make more sense to just report the
15 number of events. For instance, eye cases,
16 very unlikely that you have free oxygen and
17 electric cautery in the same place at the same
18 time. And so, very low risk of events.
19 Whereas, ENT cases or facial plastic surgery,
20 a very high risk.

21 And so, if you start comparing
22 places that are eye clinics with classic

1 surgery clinics, you are going to have a
2 difference just based on the different
3 population and the different risk.

4 CO-CHAIR CIPRIANO: Carol?

5 MEMBER KEMPER: My comments are
6 similar to Vallire's, that I was concerned
7 about detection. I am not sure, even within
8 our own institution with same-day surgery that
9 we are even doing a skin assessment on these
10 patients as they leave. And so, certainly
11 there's the cases -- and we have seen those --
12 where some days later it is recognized.

13 But I just kind of wondered a
14 little bit about your processes to detect
15 these because I didn't know if like, for
16 example, skin assessment might capture them,
17 some of them, even immediately before they
18 leave.

19 CO-CHAIR CIPRIANO: Stephen?

20 MEMBER LAWLESS: Yes, I second
21 what Carol just said about the skin
22 assessment, because most of these are around

1 the pad or the Foley itself or the pad is
2 where you see the redness. Most of the people
3 burned, there is some irritation or redness
4 that, then, they could to key into, hey, let's
5 look at this and follow this. So, most of
6 them, you kind of know it is happening or
7 there is a good indication that something has
8 happened around there. So, I think that would
9 be a very strong one to probably add to this,
10 the skin integrity, but also around the pad.

11 CO-CHAIR CIPRIANO: Okay. And
12 just so you know, there is no hospital measure
13 for this as well, inpatient hospital measure.

14 MEMBER THRAEN: It is an SRE,
15 though?

16 CO-CHAIR CIPRIANO: Yes. Yes.

17 Charlotte? And then John again.
18 And, Carol and Vallire, are yours up or down?
19 You're up again? Sorry.

20 Okay. Charlotte, please.

21 MEMBER ALEXANDER: Thank you.

22 I would add to the surgical pad

1 the tourniquet because our alcoholic prep
2 sometimes goes underneath the tourniquet and
3 can cause burns.

4 CO-CHAIR CIPRIANO: Okay. John?

5 MEMBER CLARKE: This would be one
6 where I would actually advocate that we not
7 only get patients who have been set on fire,
8 but just fires in general. I think any fire
9 on the field, the operative field, whether or
10 not it actually harms the patient, is a very
11 dangerous situation.

12 There are near-misses and there
13 are near-misses. This is one near-miss I
14 don't want to have happen to me in the
15 operating room.

16 CO-CHAIR CIPRIANO: Vallire?

17 MEMBER HOOPER: While I agree this
18 measure seems to be focusing a good bit on
19 electrical burns and fire in the surgical
20 field, we do need to be aware of preoperative,
21 intraoperative, and postoperative warming, and
22 particularly on the frail elderly patient.

1 And this is where that post-discharge
2 followup, because it is somewhat like a
3 sunburn in that sometimes you stay out and it
4 is several hours later that you notice that,
5 oh, I got sunburned.

6 And what we will see sometimes is
7 that this will occur with particularly some of
8 these elderly patients with very frail skin.
9 So, I think we need to be aware of this
10 outside of just the electrical burn and fire
11 in the surgical field.

12 MS. SLOSBURG: This is Donna. Can
13 I just comment?

14 We do have a definition in our
15 measure specific to that, and we do recognize
16 six recognized mechanisms: scalds, contact,
17 fire, chemical, electrical, or radiation.

18 MEMBER HOOPER: I don't believe
19 that that definition would include forced air.

20 MS. SLOSBURG: Forced air? Can
21 you give me an example?

22 MEMBER HOOPER: Bair Hugger.

1 MS. SLOSBURG: Bair Hugger. Yes,
2 that's a contact.

3 MEMBER HOOPER: Okay.

4 MS. SLOSBURG: I mean, our goal is
5 to include all burns.

6 MEMBER HOOPER: I don't know what
7 you would call it, but I would --

8 MS. SLOSBURG: To a clinician, it
9 is a contact. I don't know if --

10 MEMBER HOOPER: Okay. Okay.

11 MS. SLOSBURG: Dr. Shapiro?

12 DR. SHAPIRO: Absolutely, it is a
13 contact. And it goes back to the whole issue
14 of the perioperative period that this measure
15 covers. It is that Bair Hugger burn, and
16 does, unfortunately, or packed with warm
17 blankets, occur interoperatively, but also
18 postoperatively.

19 Although I will say my personal
20 experience with having this happen to patients
21 is there is some recognition of it during the
22 time of admission. Because part of our

1 definition is causing the tissue injury, and
2 if there is even a minor tissue injury, there
3 is enough time in the postoperative period for
4 that to be recognized. But often, you know,
5 it certainly could; there is always the
6 outlier.

7 CO-CHAIR CIPRIANO: Okay. Just
8 FYI, this may be part of a risk-adjusted case
9 mix, adjusted, elderly surgery outcome
10 measure. I don't have the details up, but it
11 does come up under fire. So, at some point,
12 we should probably just check for any kind of
13 harmonization with that measure as well, for
14 whatever elderly conditions.

15 Mary?

16 MEMBER SIEGGREEN: So, this is
17 strictly thermal and doesn't have anything to
18 do with chemical at all?

19 DR. SHAPIRO: No. Here, let me
20 read our six. It's scalds, contact, fire,
21 chemical, electrical, or radiation.

22 MEMBER SIEGGREEN: Okay.

1 CO-CHAIR CIPRIANO: Okay. Any
2 other comments or questions on this measure?

3 (No response.)

4 All right. Jessica, please move
5 us --

6 MS. WEBER: Importance to measure
7 and report. Are all three subcriteria met,
8 high impact, performance gap, evidence? It is
9 a yes/no question.

10 (Whereupon, a vote was taken.)

11 We need two more votes. Go ahead
12 and cast your votes again.

13 Janet?

14 MEMBER NAGAMINE: Yes.

15 MS. WEBER: Twenty-two yes.

16 Scientific acceptability of
17 measure properties. Are both reliability and
18 validity rated moderate or high? It is a
19 yes/no question.

20 (Whereupon, a vote was taken.)

21 Janet?

22 MEMBER NAGAMINE: Yes.

1 MS. WEBER: Twenty-one yes, 1 no.
2 Usability? High, moderate, low,
3 insufficient.

4 (Whereupon, a vote was taken.)

5 Janet?

6 MEMBER NAGAMINE: Mod.

7 MS. WEBER: Seventeen high, 5
8 moderate.

9 Feasibility? High, moderate, low,
10 insufficient.

11 (Whereupon, a vote was taken.)

12 We need one more vote.

13 Janet?

14 MEMBER NAGAMINE: Mod.

15 MS. WEBER: Eight high, 13
16 moderate.

17 Overall suitability for
18 endorsement. Does the measure meet all the
19 NQF criteria for endorsement?

20 (Whereupon, a vote was taken.)

21 You need two more votes.

22 Janet?

1 MEMBER NAGAMINE: Yes.

2 MS. WEBER: Twenty-two yes.

3 CO-CHAIR CIPRIANO: Okay. All
4 right.

5 DR. SHAPIRO: Thanks to you all.

6 CO-CHAIR CIPRIANO: Yes. Thank
7 you, Donna, David, Susan, and Kim. We
8 appreciate it.

9 MS. SLOSBURG: You're welcome.
10 And thank you all, because we do take your
11 comments very seriously.

12 I remember when you were talking
13 about fires, that was a very heated, large,
14 long discussion with the Steering Committee
15 regarding fires versus burns.

16 So, we do listen, and as we go
17 through the annual process, we will take your
18 comments very seriously.

19 Thank you.

20 CO-CHAIR CIPRIANO: Okay. Thank
21 you.

22 All right. I think we will take a

1 quick break, in hopes that Patrick will be
2 back. And then, we will finish the AHRQ
3 measures, the two on foreign bodies, and then
4 we will move into the other two for this
5 afternoon on monitoring of persistent
6 medications and high-risk meds in the elderly.

7 So, take 15 minutes.

8 (Whereupon, the foregoing matter
9 went off the record at 3:29 p.m. and resumed
10 at 3:44 p.m.)

11 CO-CHAIR CIPRIANO: If everyone
12 could take their seat, Bill is going to go on
13 Measure 0021 and 0022. So if you would locate
14 those. Those are actually in Workgroup A
15 Medication Safety. So if you are opening
16 files, Workgroup A. And we don't have a
17 sponsor to talk to the first one from the
18 committee, so Bill is going to take it away.

19 CO-CHAIR CONWAY: We do actually.

20 CO-CHAIR CIPRIANO: Oh, you do?

21 Okay. Did we ask someone? Christina?

22 CO-CHAIR CONWAY: Christina.

1 CO-CHAIR CIPRIANO: Okay.

2 Christina will introduce the workgroups work,
3 the topic.

4 DR. MICHALEK: Okay, so Measure
5 0021 is looking at annual monitoring for
6 patients on persistent medications. Those
7 medications were defined as ACE Inhibitors or
8 ARBs, dig, diuretics, certain specific
9 anticonvulsants, carbamazepine, phenytoin,
10 phenobarbital, valproic acid.

11 For the digoxin, diuretics, ACE
12 inhibitors and ARBs, it is going to look at
13 patients who get at least one serum potassium
14 and either a serum creatinine or BUN within
15 the measurement year. The measurement year,
16 as best we could understand was 180-day period
17 of time that they are looking at the patients
18 are on these medications and receive one of
19 those tests. And then for the
20 anticonvulsants, there would be a drug level,
21 a therapeutic drug level.

22 Our concerns that we had that we

1 discussed as a group, we wanted some
2 clarification on whether the measure included
3 monitoring for statins. They were mentioned
4 within the measure but not within the
5 description of the measure and we did get
6 clarification that they were excluded. I
7 think they had been included previously.

8 We also had some question about
9 the rationales to why the medications in
10 particular were chosen. Based on some
11 information that we are aware of in new
12 studies that had come out, you know, these are
13 included as implicated in hospitalizations but
14 not high on the lists. For example warfarin
15 and insulin, patients on those medications,
16 like we discussed previously, are more likely
17 to have return hospitalizations due to being -
18 - factors of being on those medications. So
19 we were unclear why these medications rose to
20 the top in this measure.

21 Also some of the data that was
22 cited wasn't specific to these drugs. It was

1 kind of in general one article was specific to
2 levothyroxine which isn't even a drug that is
3 included in the measure. We talked about FDA
4 drug labeling guidelines for these
5 medications. And again, they don't really
6 support what this measure is calling for.
7 There is some talk with some of these
8 medications about monitoring at initiation of
9 therapy. There really isn't anything that
10 talks about, you know, annual monitoring of
11 these items for patients that are on these
12 medications. And it doesn't include any
13 patient over the age of 18. It certainly is
14 not harmful to do it we just had all of those
15 questions as to why these were chosen and why
16 they are included in a measure.

17 It seems reasonable monitoring for
18 these. But like I said, based on the other
19 medications we know are involved in
20 readmissions, we were unclear as to the
21 importance of having these have their own
22 measure.

1 CO-CHAIR CONWAY: Okay, thanks,
2 Christina. If the measure developers, if you
3 could introduce yourself and tell us a little
4 bit about your measure and respond to those
5 questions, if you could.

6 If you keep talking and they turn
7 it on. No, it doesn't do that.

8 CO-CHAIR CIPRIANO: Is our AV guy
9 there? Maybe we can call on Pat while we are
10 waiting.

11 CO-CHAIR CONWAY: Yes, they are
12 trying to record this. So Pat, do you have a
13 question?

14 DR. QUIGLEY: Yes, thank you. I
15 am a member of Group A. And I would just like
16 to say I apologize that my rating is not up
17 there. I had talked with Andrew about this
18 when we had our group conference call because
19 I did really raise this and it is all in
20 there, my feedback is.

21 But as a group member reviewing
22 this, I had expressed my concerns, especially

1 related to the evidence. You know, the age
2 group that this is targeting is 18 and older
3 but if you look at the evidence, it is almost
4 similar to 0022, which is for the elderly.
5 All of the evidence for this is predominantly
6 related to the elderly. So the two indicators
7 in and of itself, you know, the supporting
8 evidence or the liability, the validity, all
9 that information is related. It is almost
10 similar.

11 So that is what I had major
12 concerns about. The evidence in here and how
13 it is supported, the indicator that they were
14 trying to measure. So I did have that also in
15 my notes. So I apologize if they are not up
16 there.

17 CO-CHAIR CONWAY: Okay, thanks.

18 NCQA.

19 MR. REHM: Yes, I'm Bob Rehm
20 again, the Assistant Vice President,
21 Performance Measurement. I had a few comments
22 and then I will try to address some questions.

1 Sorry for being late. The rain held us up a
2 little bit.

3 CO-CHAIR CONWAY: Bob, move that
4 closer.

5 MR. REHM: Oh, I'm sorry. Just so
6 you can appreciate the context here, NCQA has
7 been developing measures for about 21 years.
8 I've been with NCQA 11 months. Dawn, what a
9 little over a year?

10 MS. ALAYON: Almost a year.

11 MR. REHM: Jeremy has been in
12 Performance Measurement about a year and a
13 half?

14 MR. GOTTLICH: Two years.

15 MR. REHM: Two years. And then
16 Erin has been with us two weeks.

17 So we weren't there when these
18 measures were born and we will try to answer
19 your questions as much as possible.

20 Again, we appreciate your
21 consideration of these. These measures were
22 developed in 2004 and began being used in our

1 HEDIS data set in 2005. So they have a very
2 long history and they were endorsed by NQF, as
3 you know, in 2009.

4 These are quite different than the
5 measures you have been looking at today.

6 These are primarily ambulatory care measures.

7 CO-CHAIR CIPRIANO: You need the
8 mike up again.

9 MR. REHM: I'm sorry. --
10 ambulatory care measures and, in fact, come
11 from a sort of preventive sensibility. Both
12 measures are longstanding and they are both
13 quite stable in terms of their performance and
14 variation.

15 They are both performing well.
16 The annual monitoring for patients on
17 persistent medications has improved in all
18 quartiles in the three years of the data that
19 you have. And in fact, this goes back to
20 2005. So the worst performing health trends
21 that report this measure have been improving
22 constantly, as have the highest performing

1 health plans.

2 In terms of the use of these
3 medications in the elderly, this has
4 demonstrated significant improvement over the
5 past year. We would imagine, primarily,
6 because of CMS's Stars rating system and the
7 fact that this measure is in that program.

8 So again, they are both used
9 broadly in public and private programs,
10 including public reporting, pay for
11 performance and accountability initiatives,
12 including NCQA accreditation, CMS Stars, both
13 the public reporting side and the incentive
14 side, CMS PQRS program, IHA's pay for
15 performance program in California, which
16 includes all the health plans there, and
17 NCQA's new ACO accreditation program that was
18 just released a couple of weeks ago.

19 So I just wanted to share that
20 background information with you.

21 And the questions are posted
22 where? I am sorry if I -- Are they up on the

1 screen?

2 CO-CHAIR CONWAY: Christina, would
3 you want to restate those?

4 MR. REHM: So the question in
5 particular that was raised was --

6 DR. MICHALEK: Well, the first
7 question that we had was in parts of the
8 measure it talks about statins and measuring
9 AST and AIT. So that we, everybody received
10 confirmation that that is not part of the
11 measure.

12 MR. REHM: Correct. When we did
13 the measure development back in 2004, we cast
14 a broader net on the types of drugs we felt
15 might be included. So in our field testing,
16 those were drugs that were included in the
17 field testing.

18 And it was in the measure in
19 originally and then later as the measure
20 developed, it was pulled out. So that was an
21 error for including it in the submission and
22 our apologizes.

1 DR. MICHALEK: The other question
2 in general was why these medications. When
3 you look at those medications that are
4 associated with complications, readmissions,
5 these are on the list but they are far lower
6 on the list. Why were these chosen over other
7 medications?

8 MR. REHM: Right. And again, I
9 wasn't there at the birth. I would speculate
10 that they were because they were both, these
11 were drugs that were highly utilized so we get
12 a fairly significant in and we are able to,
13 from the feasibility side those were the drugs
14 that made sense. I'm not sure why the drugs
15 that were on the original field test in the
16 original measure were moved later on.

17 Jeremy?

18 MR. GOTTLICH: This is a measure
19 that looks both for adverse drug effects and
20 therapeutic monitoring and they wanted to, you
21 know, I was talking to some of the people that
22 have been around and might have heard some

1 more about the measure development and I asked
2 an example of why not warfarin. And so
3 warfarin is something that might require more
4 monitoring within the year. You know, this
5 could be a weekly drug. Really we are looking
6 at drugs that we would want one monitoring
7 event in the one year of measurement.

8 MR. REHM: So again, this measure
9 like many of our measures aren't addressing
10 all possible issues known and so, again, it is
11 addressing what it is addressing in a funny
12 way. It is not trying to be a comprehensive
13 measure but a measure that again at its
14 origins was attempting to go after drugs that
15 were used quite frequently and were felt that
16 a conservative recommendation would be
17 monitoring annually would be a quality, an
18 area for quality improvement. And the data
19 that we have on performance tends to indicate
20 that.

21 DR. MICHALEK: The other question
22 that we have is about the measurement and you

1 talk about that 180-day period. Just if you
2 could clarify for us, because I don't know
3 that we got that clarification on our call, if
4 it is day 181, and that is when they get their
5 level drawn or their potassium, it's out, then
6 they are out? They don't count?

7 MR. GOTTLICH: No. The main part
8 of the measure is looking for a numerator
9 event within the measurement year. So the
10 numerator event is a monitoring event.

11 To be in the measure, to be in the
12 eligible population, you just need 180 days
13 that you are on the medication. That could
14 include days in the prior year. So if the
15 medication was dispensed in the year prior to
16 the measurement year, that continues into the
17 measurement year. We count all those days
18 just for your to get in the eligible
19 population. The monitoring event can happen
20 in that 180 days or it can happen a hundred
21 days later.

22 DR. MICHALEK: And the measurement

1 year is a calendar year?

2 MR. GOTTLICH: That is correct.

3 DR. MICHALEK: Okay.

4 MR. REHM: Any other questions?

5 CO-CHAIR CONWAY: Patricia.

6 DR. QUIGLEY: Thank you. I would
7 again just like to help address that the
8 population, the denominator or the numerator
9 are for people 18 and older. It's the entire
10 adult population. Yet in the directness of
11 evidence to this specific measure, which is on
12 page eight, it says, "This measure seeks to
13 monitor the use of persistent medications in
14 the elderly." You know, all of the content is
15 essentially related to the elderly. And so
16 that was why we had difficulty in our
17 discussion about this indicator, the
18 supporting evidence of what it was really set
19 out to measure because of the rest of the
20 discussion that is in this document was really
21 more specific to the elderly, people 65 and
22 older.

1 MR. GOTTLICH: I was looking at
2 the measure workups as we developed the
3 measure and for the most part, the evidence
4 available that we could find was for the 65
5 and older population, which is more vulnerable
6 to adverse drug effects because of
7 polypharmacy.

8 When we did take it to our panel,
9 I was able to speak to someone from our
10 geriatric panel who was there at measure and
11 is still with our panel. She had said that
12 with these drugs, they still require really
13 therapeutic monitoring for the entire adult
14 population of 18 and older. But I think just
15 getting evidence for that group in therapeutic
16 monitoring was a little more difficult but
17 they felt it was really important to include.

18 And if you look at the performance
19 rates for the measure, they are actually
20 highest for the Medicare population and lowest
21 for commercial, which means there is more room
22 for improvement in that group.

1 CO-CHAIR CONWAY: Okay, comments
2 or questions from the panel? John, you were
3 up first.

4 DR. CLARKE: I need some
5 clarification. Are we measuring -- why are we
6 measuring these things? Are we measuring them
7 because they are most likely to cause patient
8 problems down the line? Are we measuring them
9 because they are the most commonly prescribed
10 drugs? Or are we measuring them because they
11 are the drugs that are most likely to have
12 interactions with other drugs? Or are we
13 measuring them because they are the drugs that
14 are most likely to not be properly monitored?
15 What is our intent here?

16 MR. REHM: Again, hard to reflect
17 on the original thinking but I would speculate
18 --

19 DR. CLARKE: Well what is the
20 thinking now?

21 MR. REHM: I'll tell you what the
22 thinking now is. When we develop a measure,

1 we are trying to get an index for medication
2 management. And there are many different
3 places you can go there and different measure
4 developers can go into different directions.

5 I think that these were widely
6 used medications and the labels on these
7 indicate annual monitoring. We are trying to
8 get a measure that captures a health plan's
9 ability to address that to see if they are
10 able to influence that through reminder
11 systems and the variety of tools that they
12 have available to improve what should be done.

13 I don't think after the To Err is
14 Human Report that medication monitoring was
15 something that was not on the table.

16 DR. CLARKE: But if we look at
17 this, one thing we are not doing with this, if
18 I am correct, is deciding whether in fact
19 these medicines are being appropriately
20 prescribed. In other words, I'm on thyroid
21 for the rest of my life. So you monitoring
22 whether I am getting my T-4 level but you are

1 not monitoring whether I can be taken off
2 thyroxin, whether I needed it in the first
3 place, whether I still need to be on it.
4 Right?

5 MR. REHM: Correct. We are
6 capturing -- This is a fairly humble measure
7 in all fairness, as a lot of our measures are.
8 And compared to the kinds of measures you were
9 looking at earlier today, quite a bit
10 different. And I think that what we are
11 trying to do is ascertain from a kind of a
12 population health level, whether things that
13 are fairly straightforward, are feasible to
14 measure are in fact being done.

15 Could we add drugs to this class?
16 Certainly. And when we do our reevaluations
17 we are on a different reevaluation cycle than
18 NQF's Call for Measures because we over a
19 hundred measures in play at any given time.
20 And so this is scheduled, I believe, for 2013
21 or 2012 and that is when we would take a look
22 and see if there are other rug classes or

1 specific drugs that would be appropriate to
2 add to this that would bring greater weight to
3 bear on the measure. We are quite open to
4 that and happy to take your recommendations as
5 well.

6 DR. WEINGART: Yes, my comment
7 echoes the others. You know, there are a lot
8 of prevalent drugs that make us worry. And it
9 does feel like this is a dated measure.

10 And you know in practice the
11 things I worry about are liver function tests
12 on glitazones and EKGs on psychotics and
13 things like that. So it is hard to quarrel
14 that somebody ought to check the potassium
15 once in a while on somebody on a diuretic but
16 it strikes me that there would be more punch
17 in the measure if it was really based on what
18 we perceive the risk to be and what little
19 evidence there is out there on a connection
20 between failure to monitor and adverse events.

21 I guess I am saying what others
22 have said but just maybe louder.

1 MR. REHM: Thank you.

2 DR. MICHALEK: I just want to
3 clarify that this is not recommended in the
4 prescribing information for these drugs. It
5 is not recommended to get these things once a
6 year. I did look that up because I just
7 wanted to see for myself. It is not listed
8 there, although it is reasonable. Okay, it is
9 reasonable to think that you might want to do
10 these things. It just, you know again, and I
11 don't mean to beat it up but to kind of echo
12 what other people are saying, I think it is
13 dated and I think it is light. And I don't
14 know how far we are really going to get from
15 just saying that we want to see that you
16 obtain these once a year.

17 CO-CHAIR CONWAY: John, is your
18 card up? Okay. Iona.

19 MS. THRAEN: I'm just going to
20 focus specifically on the anticonvulsant
21 category of drugs because I do know in a
22 previous iteration of our steering committee

1 there was a focus on epilepsy and the use of
2 anticonvulsants with that group and the
3 performance gaps associated with evaluation
4 and follow-up, etcetera, if you remember that.
5 So I don't know how much that particular
6 subsection actually and I don't even remember
7 if we even approved it. It was a while ago.
8 I don't know that we did, how that subsection
9 relates to that previous measure.

10 And the evidence that was being
11 presented at that time pretty much said that
12 folks with epilepsy and using these kinds of
13 drugs were not getting evaluated on a regular
14 basis. And so I would just call attention to
15 that subcategory for that reason.

16 CO-CHAIR CONWAY: Lisa?

17 DR. MOORES: I just had a similar
18 question along those lines, actually. From a
19 more practical standpoint, when you look at
20 the anticonvulsants that are included in the
21 list, they are ones that you can certainly
22 check a level in and to some degree we target

1 that. But in reality, for a patient for
2 epilepsy, if they have no symptoms and no
3 seizures, their level is therapeutic. I could
4 check a level and I would do nothing with it
5 if the patient is doing well. So I don't
6 really know what this accomplishes in terms of
7 quality.

8 MR. REHM: Well if I can, you know
9 many of our measures are in fact you are
10 trying to get to near 100 percent beta
11 blockers after MI, things like that. And we
12 retire measures when their performance gets to
13 that level.

14 I think in this case we are not
15 trying to -- for people that are being well
16 managed and are in fact not having seizures,
17 then the testing may or may not be relevant.
18 We are not trying to get people to be at 100
19 percent. A lot of people assume that out of
20 the gate. So I don't think that is
21 necessarily the case here.

22 And if you look at the performance

1 on anticonvulsants from the performance data,
2 it is quite a bit, it is a different profile,
3 if you will, than the others. And the others
4 quite often are performing at 85 plus percent
5 as the mean. And you know, the
6 anticonvulsants were quite a bit lower. And
7 I think the reflection is that patients are
8 being managed according to their symptoms and
9 not necessarily by just monitoring them.

10 DR. MOORES: Yes, and I guess that
11 makes sense but again, for that particular
12 class, what does it mean from a quality
13 standpoint to track that at all? Instead
14 maybe what we should be monitoring is clearly
15 they need a level if they come in with a
16 recurrent seizure. That is where they need to
17 be monitored much more closely. Or they come
18 in with other side effects that you suspect
19 are secondary to the medication.

20 MR. REHM: And I think your
21 comments reflect the tension between a measure
22 that is targeted, highly targeted to high-risk

1 individuals and that is a different
2 measurement strategy and approach. And that
3 is not what this measure does. It does what
4 it does. And I think your point about -- I
5 think a lot of our measures you know, around
6 medications, can be taken into several
7 different steps and you can get into very
8 small populations and really try to do a good
9 job of seeing that clinically based care is
10 being delivered. This is a little bit
11 different level of the measurement.

12 DR. LAWLESS: The reporting of
13 this to what level, zip code, hospital,
14 practitioner, the United States?

15 MR. REHM: Right. This measure is
16 a health plan related measure. So all the
17 performance data you see are health plans,
18 Medicaid, Medicare, and commercial plans. So
19 probably covering about 126 million lives.

20 How plans report that, plans use
21 this, for instance in California it would be
22 used in a pay for performance program that

1 goes to physician level. And I am trying to
2 remember I have it right here. Annual
3 monitoring is in the California program. So
4 it is one component of many in an
5 accountability model. In PQRS, as you know
6 how those measures work, the same is the case.

7 So by and large you know, on one
8 hand it is a fairly large denominator measure
9 for a health plan. What the health plans do
10 with that or what CMS does with that in terms
11 of Medicare Advantage reporting is really up
12 to them but quite often it does trickle down,
13 if you will, maybe to clinics. And as ACOs
14 develop measure like this could be
15 incorporated into how they operate, whatever
16 rules they happen to be operating in.

17 CO-CHAIR CONWAY: Iona.

18 MS. THRAEN: So I just want to get
19 from the pharmacists and abstracted view, or
20 at least reflect back what I think you are
21 saying which this is more, it looks more like
22 it is a shotgun approach to monitoring of

1 meds. And you don't perceive or see the real
2 justification in the priorities of these
3 particular medications. Is that correct?

4 DR. MICHALEK: I think there is,
5 we all know there is other medications that
6 are linked more to problems than these are but
7 they are on the list.

8 It is not unreasonable to get
9 these levels once a year in these patients.
10 I just, from a quality standpoint, taking that
11 one level, saying that this is what the
12 measure, we want you to take one potassium
13 throughout the year, is that really going to
14 affect a quality outcome, as opposed to if
15 somebody comes in who is seizing that you get
16 a medication, therapeutic medication level.

17 MS. THRAEN: And I remembered
18 going back to the epilepsy example, I think
19 advocacies group wanted that measure
20 incorporated for purposes of counseling on
21 falls and risks associated with taking the
22 medications and not the seizure condition.

1 And the same conversation took place that if
2 you weren't having seizures, you were
3 therapeutic. So I just remember what that was
4 about.

5 CO-CHAIR CONWAY: Okay, any other
6 questions or comments? Shall we move on to
7 voting?

8 MS. BOSSLEY: Can I ask one
9 clarifying question, please?

10 CO-CHAIR CONWAY: Yes, sur.

11 MS. BOSSLEY: Bob, I just wanted
12 to clarify because I looked back, you put this
13 forward for clinician individual group as well
14 as for health plans. But if I understood your
15 response, you are just saying it is for health
16 plan level of analysis?

17 MR. REHM: Our testing, the
18 testing and the measure specifications are for
19 health plans. The question I asked was does
20 this measure in fact trickle down to other
21 levels of accountability. And the answer
22 would be yes.

1 MS. BOSSLEY: So in the form,
2 though --

3 DR. LAWLESS: In the reporting of
4 it, it goes trickles down but unfortunately
5 it wasn't going to the reporting. So the
6 reports on physicians or physician groups,
7 that is a different --

8 MR. REHM: Yes, but you know this
9 is where we get into kind of measure parentage
10 issues. We have a HEDIS measures parentage is
11 health plans. The measures incorporated into
12 PQRS is accountability is physician level. So
13 I am just telling you that the parenting, the
14 parentage storyline here. the measure that we
15 have put forward in terms of testing and in
16 terms of performance rates are at the health
17 plan level.

18 CO-CHAIR CONWAY: Lisa.

19 MS. MCGIFFERT: I just have a
20 clarifying question. This is a new measure,
21 not one that has been endorsed before. Right?

22 CO-CHAIR CONWAY: No, this is a

1 renewal.

2 MS. MCGIFFERT: It is a renewal.

3 MR. REHM: Yes, it was endorsed in
4 2009.

5 CO-CHAIR CONWAY: Okay, if there
6 are no other questions or comments, Jessica.

7 MS. WEBER: Importance to measure
8 and report high impact, performance gap, and
9 evidence. It's a yes/no question.

10 Janet are you still on the phone?

11 DR. NAGAMINE: I'm here.

12 MS. WEBER: Okay. What's your
13 vote on the importance?

14 DR. NAGAMINE: No.

15 MS. WEBER: Okay. Five yes, 17
16 no.

17 MS. BOSSLEY: So because this
18 didn't pass, importances must pass. So unless
19 there is anything that you would like to go
20 back to NCQA and ask questions or anything
21 else I think we are now done discussing this
22 measure.

1 DR. WEINGART: You know in
2 principle, I think we support this. I think
3 the question is just what is the selection of
4 the drugs. And I think the group would be
5 very receptive to a revised and updated list.

6 MR. REHM: Yes, can I ask a quick
7 question? I mean, if there is a
8 recommendations on that, as I said, the
9 measure is going to our formal reevaluation
10 process where we develop a measurement
11 advisory panel to re-look at the measure.
12 Basically, it is we do start all over again.
13 And so if there are recommendations that you
14 have and would like to make, we would
15 certainly appreciate hearing those.

16 I think keeping on context that
17 currently the measure is kind of a population
18 level approach, shotgun possibly. But that
19 would be quite helpful.

20 DR. MICHALEK: I think if you
21 looked at the --

22 DR. NAGAMINE: Do you want it now?

1 DR. MICHALEK: If you wanted to
2 look at just the subsection of that greater
3 population and just pull out the elderly, I
4 think that would be even more supported by the
5 evidence that is out there as well.

6 MR. REHM: I think that if you
7 were -- I'm not trying to take the role of
8 anything here but if your recommendation was
9 to us -- I mean, we present NQF multiple
10 measures it seems like every week of the year
11 and quite often the panel says, you know, we
12 don't like this measure aspect. We know we
13 are not measure developers but we have a
14 really strong opinion and we think that you
15 know, if you were to make this a 65 and over
16 measure, we would have a different, there is
17 a different evidentiary basis that has been
18 established. The risk is higher. I think we
19 would get it in that case.

20 And if that was the sentiment of
21 the panel, then we would take that back and
22 respond quite quickly on whether was something

1 we would then move forward with. And then in
2 which case, in terms of our measure workup,
3 and we have done this before at NQF, asterisk
4 to the measure, willing to change to 65 and
5 over. Sometimes it is the blood pressure
6 level, sometimes it is something where the
7 science has moved and the timing is bad. So
8 again, we are very open to that.

9 There are some advantages to, if
10 you will, keeping the measure, in terms of
11 timing and keeping the measure, let's call it
12 the measure template, keeping it active in NQF
13 so that then if we were able to do that, then
14 the measure is there and it is simply an act
15 of updating the measure specs.

16 So on the age group, that is
17 simpler because really it is just we can do
18 that. On the drugs specifically that need to
19 be monitored for persistence use, then I think
20 that that might take a bit more time but that
21 is something we would certainly appreciate
22 hearing from.

1 CO-CHAIR CONWAY: Okay, Bob. Why
2 don't we just collect some rapid fire
3 suggestions for you. You don't have to
4 respond to each one. We'll go around and
5 collect them.

6 Steve.

7 DR. LAWLESS: Yes, one thing for
8 NQF also. This is the second or third time I
9 have heard they are doing a measure in
10 revision but it is up for our revision now.
11 So maybe publishing a timetable so they know
12 to revise before they go here versus do all
13 this work and then find out oh we are revising
14 it anyway, you know, --

15 MS. BOSSLEY: Right. This is a
16 constant struggle that I think we have and
17 developers have as well as trying to keep up
18 with each other's schedules. We have tried to
19 create a regular schedule of every three years
20 but I think it is going to take a while.

21 CO-CHAIR CONWAY: I told Heidi
22 earlier they should try to harmonize their

1 schedules a little bit better.

2 MS. PROBST: It just feels too
3 lumpy for me. So if you could kind of break
4 it out and be more specific about types of
5 medications together, classes of drugs and
6 what you are actually looking for, just with
7 greater specificity, then the results would be
8 more actionable.

9 CO-CHAIR CONWAY: Lisa. Lisa, is
10 your card up? Oh, okay. Sorry. Vallire.

11 DR. HOOPER: I would just say
12 coming from the perspective where long-term
13 medication management is not my area of
14 specialty, I struggle with the fact that there
15 was just really not enough supported evidence
16 not being familiar with the material to really
17 know why these meds, why this timing, some of
18 the references were outdated. So I really
19 felt like it needed a lot more work and needed
20 to be updated. So have more strength than the
21 evidence.

22 CO-CHAIR CONWAY: Okay, and Saul.

1 DR. WEINGART: So a couple
2 potential sources you might look at. You know
3 Jerry Gurwitz has done a lot of work on the
4 elderly, community dwelling elderly and drugs
5 at high risk. There have been a couple
6 articles that have been about adverse drug
7 events that result in emergency admissions.
8 The ISMP and MEDMARX collect all kinds of
9 stuff. So I think there are a bunch of
10 organizations that collect information about
11 drugs that commonly result in events that
12 might potentially have been prevented by
13 monitoring.

14 So I think there is a lot of data
15 sources and we would be very receptive to see
16 them.

17 CO-CHAIR CONWAY: I could just
18 provide you some experience from a prior panel
19 some of us were on. I think that there were
20 three or four drug testing new measures that
21 the panel rejected. It is a very complicated
22 area to work in because the decision tree gets

1 very complicated. It is like the example of
2 the seizure patient. If they are not having
3 seizures and not having side effects why do a
4 lot of the blood tests and it may end up over-
5 utilizing tests. But good luck perfecting the
6 measure.

7 We have a couple more comments
8 down here. Patricia.

9 DR. QUIGLEY: I don't have a
10 comment. I believe Janet had some comments.
11 Janet?

12 CO-CHAIR CONWAY: Janet, did I cut
13 you off?

14 DR. NAGAMINE: No. Thank you.
15 Just kind of reiterating what has already been
16 said. My biggest problem with this one was
17 lumping a bunch of different drugs together.
18 So more tightly coupling the evidence and the
19 type of monitoring with the drug would be
20 helpful.

21 CO-CHAIR CONWAY: Great. Okay.
22 And Vallire, you are done? Okay.

1 All right, you've got plenty of
2 food for thought, Bob. Shall we move on to
3 Measure 0022? This is the high-risk
4 medications in the elderly.

5 DR. QUIGLEY: Thank you, Dr.
6 Conway. This was Group A and this is 0022.
7 This indicator was from the National Committee
8 on Quality Assurance as well. And this is a
9 process measure and this one as well is up for
10 renewal. And the descriptor is a percent of
11 Medicare members age 65 and older who are at
12 least on one of the high-risk medications as
13 well as a second indicator where the other
14 percent of Medicare members 65 and older who
15 are on at least two of the high-risk
16 medications. And these medications that were
17 included in here are medications that we know
18 to cause harm or have adverse events for the
19 elderly.

20 The denominator was very specific,
21 all patients who are over the age of 65. In
22 contrast to 0021, our members on our workgroup

1 had high consensus and high agreement for all
2 of the elements of this indicator. We had
3 very little discussion because we did have
4 such agreement. When this indicator was
5 submitted to us, we also had the Beers
6 criteria that was submitted, the 2003 Beers
7 criteria and we had a PDF version of
8 medications and falls risk of optimization.
9 That was provided as well.

10 As we looked at the evidence
11 supporting this and the review of the
12 literature, even though some of the literature
13 might be dated because of the review based on
14 the 2003 Beers criteria, we did think it was
15 all important because we know these
16 medications that are listed on this indicator
17 are indeed those that should not be given to
18 older people and if they, we should find a way
19 to remove the medication from their regime.

20 As part of our discussion, part of
21 what we learned from Chris, our member from
22 IMSP is that the American Geriatrics Society

1 right now has a group of geriatricians who are
2 actually working through the Beers criteria
3 specific to separate out these medications
4 that should not be given to older people by
5 diagnostic cohort, as well as age populations,
6 even separating out the age group. So there
7 is further work being done.

8 But we thought this was very
9 relevant. We thought it was important. We
10 did think it was a major patient safety
11 initiative. In terms of measure, we thought
12 it would inform patient safety, it would
13 inform healthcare, and it would inform the
14 consumer.

15 So we had a high level of
16 consensus among all of our members on our
17 workgroup related to this indicator that this
18 was an important indicator to endorse.

19 Would any of my other team members
20 like to present? Okay.

21 CO-CHAIR CONWAY: Okay. Is there
22 anything you could possibly add to that, Bob?

1 MR. REHM: Thank you.

2 CO-CHAIR CONWAY: Any questions or
3 comments from the panel members? Saul.

4 DR. WEINGART: Yes, I wasn't sure
5 if this was a subset of the Beers or some
6 overlap between Beers and Zaun. It seemed to
7 be a little bit of a mismatch and I wondered
8 if you would comment about that. And also it
9 looked like there were at least a couple of
10 things that aren't available like meperidine,
11 oral meperidine.

12 MR. REHM: Thank you for that. I
13 appreciate the comments on the revisions to
14 the Beers list. I was an ex officio member of
15 the AVS panel during their review which was
16 just completed a couple of weeks ago. We are
17 tweaking it right now. We are actually taking
18 that to our geriatric measurement advisory
19 panel on Monday. So we are doing lots of
20 things all at the same time.

21 So in terms of drugs first that
22 are, essentially no longer available, those do

1 drop off our list. In terms of the measure,
2 again we have a timing issue between the
3 measure specs here and what we call our 2012
4 HEDAS specifications. So quite often -- And
5 then we also have what is called an October
6 update which are reviewed by our pharmacy
7 panel and our GMAP to pull medications that
8 are off. If they are not in use, the fact
9 that they are on is kind of housekeeping. But
10 it is important and we do it quite frequently.

11 So the question about how Beer and
12 Zaun and THICK, the different versions of the
13 original Beers list which was done in the
14 1990s for nursing facilities, you know, I
15 think the reason if I can work backwards, the
16 reason that the AGS took on this project which
17 is a very resource-intensive activity was A)
18 because it had been a long time, B) because
19 when you get into this kind of competitive
20 criteria stuff and how you define the horizon
21 and the vertical are slightly different. And
22 it created, if you will, noise in the clinical

1 marketplace. What should I do? What is the
2 right thing to do? Where is clinical guidance
3 here for me as I go one-on-one with this
4 particular patient?

5 So I think that again the focus on
6 the criteria, the new criteria about to be
7 released was to get this all in a new frame,
8 adopt an approach where these would be
9 routinely updated as opposed to every five,
10 six, three years, whatever the case may be,
11 and have it be consistently done over the
12 common framework.

13 And just to add a note to the
14 AGS's work, we strongly recommended and they
15 followed the recommendation of using the IOM's
16 new guideline recommendations which really
17 outline steps, guideline developers should use
18 in developing recommendations. And while not
19 technically guideline and they are very
20 careful to not use that term, there was a
21 transparent process. There was public
22 comment, which we very much wanted. All of

1 our measures go through public comment.

2 So I think that what you will find
3 is that kind of if you will the variation
4 between those competing reviews will kind of
5 become not to use the word harmonize, but will
6 be much easier to use in clinical practice,
7 once the new list is out. But I do think that
8 the current list shows you the input of
9 clinicians and different panels over time
10 trying to adjudicate between competing
11 perspectives maybe on a particular disease,
12 drug interaction, or on a drug itself for
13 people over 65.

14 CO-CHAIR CONWAY: Christina.

15 DR. MICHALEK: I just have a
16 question. A lot of the medications that are
17 in the measure are over-the-counter. Do you
18 have a mechanism that you thought you would be
19 able to capture that?

20 MR. REHM: So the intention here
21 is that the over-the-counter medications,
22 there is two things going on. From a clinical

1 practice perspective, if I am a physician I
2 may want to say gee now you may want to be
3 careful with that upper respiratory
4 combination or this antihistamine. And that
5 is one thing. So from a quality standpoint,
6 you want to have a broad list of medications.

7 At health plans, health plans
8 generally the theory is that if it is over-
9 the-counter it is not paid for. And there are
10 exceptions to that. And so I think the way
11 NCQA approaches measure development is to cast
12 the broadest net possible so that I will just
13 not speak for -- I will speak for health plan
14 X that has an inspired program that
15 understands that over-the-counter medications
16 when properly prescribed actually are
17 efficacious, they are low cost. They help the
18 system out. And it is not like the patient is
19 using these willy-nilly and adding a
20 moderating influence to the recommended
21 therapy. So you want to make sure that those
22 drugs are in, even though you probably know

1 that maybe ten percent of the plans actually
2 are capturing this data or whatever. We do
3 that quite frequently.

4 So broad net to make sure that
5 people who have programs because programs vary
6 across the country and I think that is the
7 rationale.

8 DR. MICHALEK: Thanks.

9 CO-CHAIR CONWAY: Lisa.

10 DR. MOORES: Bob, just a
11 clarification. I was just curious if you know
12 when this measure was being looked at whether
13 there was any discussion of including some
14 type of exclusion in the denominator if you
15 had a good reason for using these. I hear you
16 keep saying a broad but there certainly are
17 going to be instances where it would be
18 warranted and why that wouldn't be an
19 exclusion.

20 MR. REHM: Yes, thanks a lot.

21 This is where we get into the realm that
22 measure developers face around feasibility.

1 First -- Well, a couple things.
2 In general, NCQA's approach to measures,
3 especially at the population health plan level
4 is to have as few exclusions as possible
5 because there is lots of different reasons.
6 But one is that the exclusions normally -- You
7 know we are trying to measure plan
8 performance, not necessarily get inside the
9 clinician's office and say, it's okay to do
10 this. It's okay to do that. Clinicians have
11 enough guidance to support their clinical
12 judgment and their practice.

13 So if the exclusions are a
14 significant part of the population, then we do
15 entertain those. Where we believe the
16 exclusions are a small part of that population
17 risk, then we try to, we just kind of let it
18 go and understand that there will be examples
19 where it is totally appropriate to use that.

20 The problem -- not the problem.
21 The challenge of the Beers criteria or this
22 whole arena is potentially inappropriate

1 medications. Lots of caveats there. And so
2 this is a measure where we would never, and we
3 would probably not, we would probably hope
4 that there is 100 performance because that
5 would suggest that people are not thinking
6 clinically about what is the right thing to
7 do.

8 So again, I think that getting the
9 right balance here is what we tried to achieve
10 and hopefully it passes the test.

11 CO-CHAIR CONWAY: Okay, any other
12 questions or comments?

13 Should we move on to voting?
14 Jessica.

15 MS. WEBER: Importance to measure
16 and report. Are all three subcriteria met,
17 high impact, performance gap, evidence?

18 Janet?

19 DR. NAGAMINE: Yes.

20 MS. WEBER: Okay, 19 yes, three
21 no.

22 Scientific acceptability of

1 measure properties. It is a yes/no question.

2 Janet?

3 DR. NAGAMINE: Yes.

4 MS. WEBER: Twenty-two yes.

5 Usability: high, moderate, low,
6 insufficient. We need one more vote. Janet?

7 DR. NAGAMINE: Moderate.

8 MS. WEBER: Nine high, 12
9 moderate, one low.

10 Feasibility: high, moderate, low,
11 insufficient. We need one more vote. Janet?

12 DR. NAGAMINE: High.

13 MS. WEBER: Eight high, 13
14 moderate, one low.

15 Overall suitability for
16 endorsement. Does the measure meet all the
17 NQF criteria for endorsement? We need one
18 more vote. Janet?

19 DR. NAGAMINE: Yes.

20 MS. WEBER: Twenty yes, two no.

21 CO-CHAIR CONWAY: Okay, thank you.
22 We are on a roll here. Two more. Next would

1 be 0362. This is foreign body left after a
2 procedure in patients less than 18 years of
3 age. And our reviewer was Vallire.

4 DR. HOOPER: Yes, thank you. And
5 I think 0362 and 0363 we found as a group were
6 basically very similar except one was for
7 pediatrics and one was for adults. So with
8 the group's agreement I think we decided that
9 perhaps we would just team up and discuss both
10 of those together as the issues were very
11 similar. Is that okay?

12 CO-CHAIR CONWAY: Yes. Thank you
13 NCQA.

14 DR. HOOPER: This measure is up
15 for renewal and it was 0362 was originally
16 endorsed in 2008, foreign body left after
17 procedure from AHRQ. And basically it is the
18 counts of discharges with foreign body left in
19 during procedure in medical and surgical
20 patients in patients less than 18 years of
21 age. And 0363, Charlotte, was patients
22 greater than 18 years of age.

1 The numerator is discharges under
2 the age of 18 with ICD-9-CM codes for foreign
3 body left during procedure. And this is a
4 count as opposed to a rate so that there was
5 not a denominator provided. And I think that
6 the major areas of discussion which we have
7 already hit with some of the other AHRQ
8 measures were the issue of count versus rate.

9 We also had some discussion and
10 John help me with this because I believe you
11 were the person that had the greatest
12 knowledge based on the definition in that we
13 needed some definition harmonization on end of
14 surgery. John we talked about --

15 DR. CLARKE: Correct. There is a
16 little inconsistency -- There is a little
17 ambiguity in the description on page nine and
18 it says if relevant resolving discrepancies
19 and the patient has been taken from the
20 operating room.

21 And there is also a discrepancy
22 clinically among people in the field. So if

1 you would ask a surgeon when does it count as
2 wrong site surgery, you will get different --
3 or excuse me -- as retained foreign object,
4 you will get different opinions. So a little
5 ambiguity here.

6 The National Quality Forum
7 definition, however, is very straight forward.
8 The last stitch is put in, the operation is
9 over. Or if it is natural orifice surgery,
10 the instrument has been removed from the
11 natural orifice, the surgery is over. It is
12 not, you are in the room, you get the x-ray
13 back, you open the patient back up. So that
14 just has to be clarified. There is a little
15 bit of ambiguity in there but I think the
16 committee functioned as if we were following
17 the NQF definition.

18 CO-CHAIR CONWAY: Yes.

19 DR. ALEXANDER: I thought you were
20 saying, and correct me if I am wrong, is that
21 the verbiage that is here reflects a 2011
22 update on the National Quality Forum

1 definition. The disparity is between the
2 current National quality forum definition and
3 the CNS definition.

4 DR. ROMANO: Okay, that might be
5 true, yes.

6 DR. ALEXANDER: And whether that
7 needs to be harmonized or not --

8 DR. ROMANO: Right. So we are
9 fortunate here in that the coding clinics for
10 ICD-9-CM, which is kind of the Supreme Court
11 of coding, it adjudicates questions and
12 discrepancies related to coding, has actually
13 deferred to NQF to define when surgery ends
14 from the standpoint of coding this event.
15 They have explicitly referenced the NQF
16 definition. But the NQF definition has
17 changed. And so the 2011 definition which
18 actually says and I quote, surgery ends after
19 all incisions or procedural access routes have
20 been closed in their entirety, devices such as
21 probes or instruments have been removed, and
22 if relevant, final surgical counts confirming

1 accuracy of counts and resolving any
2 discrepancies have concluded and the patient
3 has been taken from the operating procedure
4 room.

5 So the previous definition
6 actually had or logic in it. Now it is and
7 logic. And that was really at the impetus of
8 the surgical community. So the definition of
9 when surgery ends has been pushed forward
10 basically to when the patient leaves the
11 operating room and coders will be following
12 that definition as well.

13 CO-CHAIR CONWAY: So then your
14 current definition is consistent with the 11
15 definition out of NQF.

16 DR. ROMANO: Yes because coders
17 are instructed to follow the NQF definition.
18 It may take them a little while to realize
19 that the NQF definition has changed, to be
20 honest. So that is part of the broader
21 educational process.

22 CO-CHAIR CONWAY: Okay.

1 DR. ROMANO: But one thing I do
2 need to point out since this question came up
3 earlier is that the code does not distinguish
4 device fragments that have broken off from
5 sponges and so forth that have been retained.
6 So that is a distinction with the NQF
7 definition. So the NQF definition
8 specifically excludes those device fragments
9 that are left in after the surgeon makes some
10 effort to remove them and decides that he or
11 she can't do that. From the coding
12 perspective, it is still a mishap. It is
13 still an event that happened to the patient.
14 There were still resources involved in trying
15 to extract the fragment. So it still counts
16 from the coding perspective.

17 And in the VA validation study, I
18 believe that 52 percent of the true positive
19 events were sponge or gauze that was retained;
20 30 percent were instrument or device
21 fragments; nine percent were drain fragments.

22 CO-CHAIR CONWAY: Iona and then

1 John.

2 MS. THRAEN: So I have both
3 measures pulled up side-by-side. And in the
4 0362, the description says count of discharges
5 of foreign bodies left in, this is the
6 pediatric version, among patients less than 18
7 years and not MDC-14, which is pregnancy
8 childbirth, etcetera. And in 0363, if 18 and
9 older but with MDC-14 pregnancy, childbirth,
10 etcetera.

11 So my question is it looks like
12 the females under the age of 18 and pregnancy
13 related conditions where sponges or devices
14 might be left behind C sections etcetera is
15 not counted in either of these measures. Is
16 that the intent? Being from Utah --

17 DR. ROMANO: No. So the adult
18 version, which is PSI-5, does not exclude MDC-
19 14. So basically if it is someone who is
20 under 18 who has the foreign body left in in
21 the course of the delivery, it gets counted in
22 the adult indicator. And that is --

1 MS. THRAEN: Just by virtue of
2 pregnancy?

3 DR. ROMANO: By virtue of the
4 pregnancy and child birth.

5 MS. THRAEN: Okay, thank you.

6 CO-CHAIR CONWAY: John?

7 DR. CLARKE: You have mentioned a
8 couple of things such as the coders are now
9 driving off the NQF definition and your
10 ability you mentioned before about the ability
11 to affect codes and create new codes. I would
12 strongly encourage there to be a recognition
13 of the fact that when you leave something
14 behind that it be classified, intentionally
15 that it be classified differently than if you
16 leave it behind unintentionally. I think even
17 when it comes to a needle that has been lost
18 or a drill bit or a fragment of a drilling, if
19 it is left behind for medically valid reasons
20 because the cost of retrieval is greater than
21 the cost of leaving it behind, the medical
22 cost, that that should not be counted as a

1 ding against the institution. You might count
2 is as a ding against the drill manufacturer.

3 And I think there needs to be some
4 recognition of the difference between a
5 considered medical opinion and neglect

6 CO-CHAIR CONWAY: Okay. Steve and
7 then Jason.

8 DR. LAWLESS: Yes, along the same
9 lines is that unretrievable foreign body. We
10 are finding out that the biggest area is
11 laparoscopic surgery clips. Whoops, it
12 slipped. It slipped, it slipped, and you
13 can't get it. And then it will end up being
14 ten clips in there. Under the definition that
15 you are talking about, where would they be?

16 DR. ROMANO: Well so coders are
17 instructed to apply this code if it has some
18 effect on the management of the patient. So
19 what the effectively means is that if the
20 surgeon dropped a clip and said oh, that's a
21 bad location. I should go in there and try to
22 get that. And it ends up extending the

1 operation while he or she digs around to try
2 to find it. And then after half an hour, it
3 is like whoops, well, I couldn't get it, then
4 it would count.

5 But if the surgeon basically says
6 oh, this is just a routine part of the
7 operation. Sometimes we lose these but that's
8 okay because we leave them in anyway, then it
9 wouldn't count. So that is the distinction.

10 But I would say that I think the
11 FDA has certainly expressed some interest in
12 sort of tracking this problem. From the
13 patient's perspective of course, it doesn't
14 really matter whether the device was left in
15 because the surgeon was careless or because
16 the device was perhaps not optimally designed.
17 But it certainly there would be some interest
18 there.

19 DR. CLARKE: Yes, I think you need
20 to distinguish the two of them so you can
21 track them.

22 DR. LAWLESS: Well I would argue

1 that by not distinguishing them we drive it
2 better. By not distinguishing them we drive
3 it better. You go from rare events to events
4 that have occurred. Whoops, it fell in. It's
5 my judgment. Ten years from now I don't know
6 what is happening. But to better have the FDA
7 and others look at the manufacturers and say
8 design a better clip machine would be this
9 kind of a problem.

10 So I would argue to include them.

11 DR. ROMANO: That's basically what
12 our expert panel argued as well.

13 DR. ADELMAN: So I don't agree
14 with that. First Patrick you said from the
15 patient's perspective it doesn't really matter
16 if it was intentionally or unintentionally
17 left in. But I don't think that is completely
18 true because unfortunately the root cause
19 analysis that I have gone to whether
20 unintentionally left, there are often large
21 sponges that become a real source of infection
22 and the intentional ones are tiny needles that

1 most surgeons thinks are not really a concern.
2 That is the risk-benefit. If they knew there
3 was a huge sponge, they wouldn't stop until
4 they got it.

5 Then what this exactly means, I am
6 just looking at the comparative data for PSI
7 and they list all of the PSIs and data, this
8 is from 2008, from foreign body left in during
9 procedure, it is listed as 184. So I know in
10 my institution when somebody reads that, they
11 are going to think okay 184 sponges were left
12 because that is what we have root cause
13 analysis.

14 I'm just going to point out one of
15 the references that was listed is from 2008
16 pediatrics. In this study they looked at it
17 was 76 children's hospitals, 1.8 million
18 discharges, and they reviewed 1700 charts.
19 And here they found 153 of these retained
20 foreign body indicators. And when they
21 narrowed it down for the present on admission
22 was wrongly coded, the coders made a mistake.

1 And then was not considered
2 intentionally left behind, there is a
3 sentence here that I just wanted to read. It
4 says, "Over a three-year period, reviewers
5 indicated that only three cases occurred in
6 which a physician truly forgot a foreign body
7 in the patient." So it went from 153 down to
8 three.

9 Now I know everyone at my
10 institution that the 153 is the three but
11 really it is not. That is a huge swing. And
12 that is my concern.

13 CO-CHAIR CONWAY: Lisa.

14 DR. MOORES: I think I would kind
15 of say that both parties have a very good
16 argument and I think it depends on the
17 perspective that you are looking at it from.
18 And certainly from a patient perspective, I
19 think you want to follow everything and from
20 a quality, you know, I agree with Jason
21 driving it, but I agree with John as well. It
22 would be very nice to track them both but

1 under different codes because you could
2 actually get a measuring whether the decisions
3 we are making as clinicians are appropriate.
4 If the outcome is the same, then maybe we
5 shouldn't be saying oh that is okay to leave
6 behind. So I think you want to track both
7 outcomes.

8 CO-CHAIR CONWAY: Okay, Charlotte.

9 DR. ALEXANDER: Lisa, I think you
10 are right on. One of the discussions we had
11 was how does this lead us toward improving
12 quality. We don't have any data. This has
13 been out for a while. No one is saying that
14 since we have been tracking this we have
15 decreased the number of foreign bodies. My
16 perception is maybe we have but I don't have
17 that information and I would like to make it
18 be a quality indicator.

19 And when you look at the adult
20 information, 45 percent of them were false
21 positives. And it is a high percentage as
22 well for similar things. They were present on

1 admission, maybe that wasn't documented but it
2 was recognized and they went and changed that.

3 So I would like some help to make
4 it a quality issue.

5 CO-CHAIR CONWAY: Any other
6 questions or comments?

7 DR. ROMANO: could I just ask
8 Jason which paper are you referring to? I'm
9 sure I have it here but, the pediatric paper.

10 DR. ADELMAN: Pediatric --

11 DR. ROMANO: Scanlon, okay.
12 Right. So in Scanlon's paper they reviewed,
13 I'm not sure I see quite the numbers you are
14 referring to but anyway they reviewed 45
15 charts of foreign body left in during
16 procedure. Is that what you are referring to?
17 And they deemed that 51 percent were
18 preventable.

19 DR. ADELMAN: I'm sorry. Hold on
20 one second.

21 DR. ROMANO: Oh, okay, that's a
22 different paper. Sorry.

1 DR. ADELMAN: Yes, I think that is
2 the other paper.

3 DR. ROMANO: Okay.

4 DR. ADELMAN: They are both by
5 Scanlon.

6 DR. ROMANO: Okay. The only thing
7 I would say in general is that the question of
8 intentionality was discussed with our expert
9 panel. And basically there was some debate
10 about the intentionality of at the beginning
11 of the procedure versus the intentionality at
12 the end of the procedure.

13 So from the perspective of some
14 stakeholders, what matters is the intention at
15 the beginning of the procedure. So if the
16 surgeon didn't intend to leave a foreign body
17 in in the course of the procedure, then if he
18 or she later chose to leave the foreign body
19 in because of the circumstances, that is sort
20 of secondary. And so they would still view
21 that as unintentional because from the
22 patient's perspective, it is not part of the

1 intent of the operation.

2 So there is some room for debate
3 about intentionality at what time exactly.
4 But in the meantime, let me look up the
5 Scanlon paper.

6 DR. CLARKE: I have a lot of
7 trouble with that as a trauma surgeon. So I
8 have a patient with a gunshot to the abdomen
9 and I intend to fix them. I get into the
10 operating room and I discover it is a through
11 and through laceration of the liver and then
12 I decide that the most prudent medical
13 treatment is pack that and come back at
14 another time. By your definition, then that
15 I didn't start out intending to leave sponges
16 behind but if I wanted to avoid a retained
17 foreign object, I would have a dead patient.

18 DR. ROMANO: No, no. That is
19 explicitly excluded. I'm sorry. You are
20 quite right. That definitely would not be
21 codable because that would be explicitly part
22 of the surgeon's conduct in the procedure.

1 CO-CHAIR CONWAY: How do you have
2 a coder who is going to figure all those out
3 when intentionality is not one of their
4 measures.

5 DR. CLARKE: Well how does that
6 differ from dropping a needle tip and knowing
7 that you will never be able to find it on x-
8 ray or looking for it and just saying oh the
9 heck with it?

10 DR. LAWLESS: I would argue that
11 is totally different, actually. I think one
12 is a judgment call in terms of medical
13 treatment and the other is a whoops or a
14 reason for change. So I think it is apples
15 and oranges.

16 CO-CHAIR CONWAY: Well, let's see.
17 We had Lisa and Charlotte up before. Lisa.

18 MS. MCGIFFERT: Well I just agree
19 with all this discussion about intentionality.
20 But I also and maybe I am naive but I hear
21 from patients who have had a surgery years
22 before and something was left in and then they

1 start having problems later. And so when I
2 hear this talk about well you know it's not
3 really going to be a problem, you know, it
4 makes me wonder from the consumer perspective
5 do we really know if it is going to be a
6 problem. Do we know it is never going to be
7 a problem? And really what this is getting at
8 is did you intentionally mean to leave it in
9 there or not? And to me that is a measure
10 somewhat of quality on the part of the surgeon
11 or the surgical team as to whether they
12 actually are able to follow through with their
13 intent, knowing that in some cases the
14 actually intentional treatment is going to be
15 a certain way. But I just think that we don't
16 really know what happens to all those things
17 that are left in because I would guess that
18 most surgeons never get that kind of feedback
19 years later. And the patients that come to us
20 say they spent years trying to figure out what
21 it was and then finally somebody diagnosed it.

22 CO-CHAIR CONWAY: Rich.

1 DR. WHITE: So what I am hearing
2 is we need two codes. Right? We need to put
3 both in the numerator but like you said, pull
4 them apart. So who would go to the CDC and
5 ask for a new code? I mean, is that -- We
6 will just put that as a rider on this vote.
7 I mean, it seems to solve the problem.

8 DR. ROMANO: Well, we've done that
9 sort of thing before and we could certainly do
10 that again. Obviously we would go with the
11 argument that has been discussed here. How
12 that affects the timing, I'm not sure. I
13 mean, obviously we could withdraw this
14 indicator and then re-propose it after such
15 codes are established. Or you could have
16 provisional. I don't know. I will defer to
17 NQF staff what this means to the vote.

18 As far as the paper, yes, I mean I
19 think that I agree with Jason's reading
20 basically they reviewed 72 cases. To be
21 precise, 56 of them were confirmed as
22 correctly coded but of those five were

1 retained sponges and the rest were catheters,
2 screws, drains, etcetera, that broke off
3 during procedures. So at least on the
4 pediatric side, that is the bulk of it. On
5 the adult side, it appears to be more evenly
6 split based on the VA data.

7 CO-CHAIR CONWAY: Iona.

8 MS. THRAEN: So earlier, this is
9 another PSI measure. Have you disclosed the
10 predictive value for these two measures and
11 then if there is any activity going on to
12 improve them? Because I think historically
13 these measures have had the same problems the
14 other PSI measures have had.

15 DR. WEINGART: I think it is --

16 MS. THRAEN: Is it? I missed it
17 then.

18 DR. WEINGART: Page ten.

19 MS. THRAEN: What's the -- mine is
20 --

21 DR. WEINGART: It looks like 45
22 percent on the -- Sorry about that.

1 Page ten in both and it says for
2 0363, which is the adult one, it says PPV at
3 45 percent was reported. Yes, and then on the
4 pediatric one, PPV 63 percent and then it says
5 better than the PPV estimates for the adults.

6 MS. THRAEN: So I will ask the
7 group, is this acceptable since the other one
8 was bumped up to 80?

9 CO-CHAIR CONWAY: Good question.

10 MS. THRAEN: And I guess present
11 on admission, is the story the same for this
12 one in terms of if you include present on
13 admission it would improve the predictability?

14 DR. ROMANO: That's correct. I
15 think because these studies were done before
16 present on admission information was
17 available. So I think that is addressed in
18 the adult submission, if you look at Section
19 2(b)(2)(3) of the adult submission.

20 Right, so in the study by Chen at
21 al., the PPV was 45 percent but adjusting for
22 the availability of POA data, the estimated

1 PPV would be 66 percent.

2 CO-CHAIR CONWAY: Okay, Patricia.

3 DR. QUIGLEY: Thank you. I have a
4 question. And my question is related to
5 because this is a count for cases, for all the
6 physicians who have presented, the scenarios
7 that you have presented, would you all list
8 them as a secondary diagnosis on the problem
9 list as a foreign body left behind, whether it
10 was a needle tip or the packing in the liver?
11 Would they all be listed as a diagnosis, a
12 secondary diagnosis? I mean, that is what the
13 numerator is.

14 Yes? I'm seeing yes and no.

15 DR. ADELMAN: I thought it wasn't
16 our coding. It is the coders generating the
17 bill for the hospital. That is what they work
18 off, not what the physicians code. is that
19 right?

20 DR. ROMANO: They work off all-
21 physician documentation. So not necessarily
22 just the problem list but also the operative

1 note and so forth.

2 DR. CLARKE: It would definitely
3 be documented, say in the operative note.
4 Wouldn't you say, Susan?

5 DR. MOFFATT-BRUCE: Absolutely but
6 because it would be a result of your primary
7 diagnosis and that is where the coders would
8 get the information for the most part is from
9 the operative note or the brief operative
10 note.

11 CO-CHAIR CONWAY: Okay. Is your
12 card up?

13 DR. ADELMAN: If this does get
14 approved, I would urge that for me it is what
15 I am mostly concerned about is that the name
16 is confusing, that people read foreign body
17 left in during procedure and they
18 automatically presume it is 100 percent the
19 unintended. And if there is a way to change
20 the name to make it clearer or put an asterisk
21 and explain that it is actually a mixture and
22 the majority are knowingly left in or

1 intended.

2 It is confusing because it is not
3 like you put an artificial hip because that
4 would be really intended. So it is like
5 unintentional but knowingly left behind.

6 So I will let you figure out the
7 new name but I don't like this name.

8 DR. ROMANO: May I suggest we
9 could defer. Should we defer?

10 DR. MOFFATT-BRUCE: This is an
11 important indicator.

12 MS. BOSSLEY: Well I think if you
13 are willing I think we can rename it and it be
14 done. But I think the question is on the
15 code, which was something that was discussed,
16 and Patrick you know this better than I do,
17 I'm not sure how quickly that code can be
18 approved and then implemented. And I think
19 this could be something if you are willing, I
20 would probably say if you passed this measure,
21 we can strongly recommend that ARQH go back,
22 ask for two codes and then at the next time,

1 at the time of maintenance, we would see that
2 come forward or sooner. They can bring it
3 sooner but at that point for sure.

4 Because I don't know who ICD-10 is
5 going to impact all of this, too.

6 DR. ROMANO: Yes, it would likely
7 be they are trying to make minimal changes
8 before ICD-10-CM implementation. So it would
9 likely be October 2013. And so then it is the
10 committee's recommendation about whether to
11 withdraw endorsement of the indicator until
12 that time or whether to continue endorsement
13 urging ARQH to proceed along those lines.

14 CO-CHAIR CONWAY: Susan.

15 DR. MOFFATT-BRUCE: I think that
16 our individual institutions and the coders are
17 probably more advanced in this than we
18 actually are in their definitions. But I just
19 looked through my PSIs for this year and I
20 know that we had intended retained foreign
21 bodies and yet they are not coding them.

22 So I think that they are ahead of

1 us. We just need to formalize that. So I
2 would be in favor of endorsing this with the
3 caveat that it should be changed going forward
4 to reflect intended and unintended retained
5 foreign bodies.

6 CO-CHAIR CONWAY: Okay, Patricia
7 and then Vallire.

8 DR. QUIGLEY: Oh, I'm sorry.

9 CO-CHAIR CONWAY: Okay, Vallire.

10 DR. HOOPER: I wonder if we are
11 going to change the code to add intended if we
12 need to explore adding a denominator. It just
13 seems like that number is going to be large
14 and I think that we are going to need some
15 public education and that, you know, and I
16 don't know how do you explain that from a
17 risk-benefit analysis it was safer to leave
18 that little needle in as opposed to dig around
19 and spend another hour or two hours under
20 anesthesia to retrieve it. And so I don't
21 know how to deal with that.

22 DR. MOFFATT-BRUCE: And that is

1 part of the algorithm that would have to be
2 developed based on this particular new code
3 that that be appropriate risk-benefit ratio
4 was explored that perhaps additional
5 consultation and disclosure to the patient has
6 been made. Those are the things that would
7 absolutely have to be part of that process.

8 DR. HOOPER: Thank you.

9 MS. MCGIFFERT: I think this is a
10 really slippery slope and it could be used as
11 a loophole to document everything in this way.
12 And to me the issue is not -- It sounds like
13 you are talking about using a new kind of code
14 for the situation you just described.
15 Something is there; it is going to be too
16 difficult to get out.

17 DR. MOFFATT-BRUCE: Right. The
18 risk is higher.

19 MS. MCGIFFERT: But that is still
20 an unintended foreign object left in the body
21 that shouldn't have happened.

22 DR. MOFFATT-BRUCE: It wasn't

1 planned.

2 MS. MCGIFFERT: It did happen. It
3 shouldn't have happened but it did happen and
4 it is more danger to try to dig it out but it
5 did happen. And to me, you know, what this
6 discussion is about is trying to figure out
7 how to carve something up because it didn't
8 cause significant harm at the time that it
9 happened or there was a risk benefit to it.
10 And that is not what this -- This is not -- My
11 understanding is that this measure isn't a
12 foreign body left during the procedure that
13 caused significant harm. This is foreign body
14 left during the procedure. Right? I mean,
15 there isn't a -- That is what this is
16 measuring. Did something unintentional
17 happen? And if not, there is nothing in here
18 about whether or not it caused harm.

19 I mean, it is just like when you
20 document infections. We don't say well we
21 aren't going to count that infection because
22 it didn't really cause serious disability or

1 harm. We count all the infections. And so I
2 think in some cases, the measures are looking
3 at serious harm. In this case, my
4 understanding is that is not what this measure
5 looks like. And the unintentional act, the
6 unintentional thing did happen during that
7 procedure and that we are really going down a
8 dangerous path if we start trying to carve it
9 and say well it's okay if it is this and not
10 that and if it is that but not that. You
11 know, it just seems like we are going to
12 neutralize working on this issue.

13 And frankly, it seems like there
14 is way too many of these happening.

15 CO-CHAIR CONWAY: Okay, the left
16 side of the room is weighing in. Can we just
17 start at the end of the table and move on,
18 starting with John?

19 DR. CLARKE: Yes. So I don't
20 think anyone wants to disregard these events.
21 I think the reason for two codings is that
22 there is two solutions to these events. If I

1 am not counting properly and I leave a sponge
2 behind, there is a solution to that problem.
3 If I have a drill bit break off, it is an
4 entirely different kind of solution.

5 So I think that the fact that we
6 want to code these differently is not the same
7 as to say we want to exonerate people from the
8 fact that this happened. And in fact the FDA
9 is all over these events because the FDA
10 actually has the ability to go to the
11 manufacturers and say we are seeing too much
12 of this. But if it is retaining sponges, they
13 are not going to go to the manufacturer and
14 say there is too much of this. They are going
15 to come to us as clinicians and say there is
16 too much of this.

17 DR. MOFFATT-BRUCE: Well I guess I
18 would just say as a clinician you know, when
19 you do a root cause analysis on this you can
20 figure out if it is this camp or that camp
21 when you are figuring out how to improve it.
22 And what I heard being discussed was I heard

1 someone talk about it, we are going to have to
2 really explain it to consumers like this is
3 okay but this isn't. And if you are not using
4 it to change the information to go to the
5 public, it seems to me that intelligent people
6 within the healthcare community who do root
7 cause analysis can figure out which camp it
8 falls into in order to take the corrective
9 action. If it is a faulty device that is
10 falling apart, then that is something
11 different, I agree, than leaving too many
12 sponges in. But that is -- I don't think you
13 have to change the measure to figure out what
14 the response is.

15 DR. CLARKE: Well I do see it as
16 different because if I am going to -- any
17 diagnosis you make only has to be specific
18 enough to determine a treatment. So when you
19 go to the doctor with a sore throat, the
20 doctor doesn't care whether it is
21 Cocksackievirus or echovirus because the doctor
22 is going to treat it the same way. But if it

1 is cytomegalovirus versus HIV, then the doctor
2 is going to be very concerned about which it
3 is because he is going to treat it
4 differently.

5 And I think that the same is true
6 here. We want a diagnostic parameter which is
7 appropriate for the action that we are going
8 to take in terms of responding to that. So
9 for me, it becomes very useful to say even for
10 instance where we had the incident with the
11 wrong side surgery before, there is a big
12 difference between a wrong implant intraocular
13 lens and other wrong side surgery events doing
14 an arthroscopy on the wrong knee because the
15 solutions for correcting the intraocular
16 implant are different than the solutions for
17 operating on the wrong knee.

18 So I want that diagnostics to be
19 specific enough to distinguish those. And
20 that is why I want, why I am advocating for
21 two separate codes because I am going to be
22 looking at those buckets differently in terms

1 of how to solve those problems.

2 CO-CHAIR CONWAY: Vallire.

3 DR. HOOPER: Well and I think
4 really am just echoing what John says in that
5 one is a process issue. When the count is
6 incorrect and you leave something in, that is
7 a process issue. When -- it is getting late -
8 - a drill bit breaks off or the clip falls
9 out, and I am not a surgeon but just coming
10 from a PACU and occasionally in the OR
11 perspective, that is more of a device issue.
12 And I think it is very important that we
13 separate because the solutions are how you are
14 going to remedy that are different. And so I
15 think that is --

16 MS. MCGIFFERT: So I think what
17 you are arguing is even a third code that goes
18 to the medical device falling apart code. And
19 I think that is, I mean that is what you are
20 arguing for. What you just said is real
21 different from what John was saying that the
22 needle that was dropped and is too much

1 trouble, is too difficult to find and might
2 cause more harm to find, and so let's add
3 another code about the medical device falling
4 apart. I think that would be a great code to
5 put on the table.

6 DR. CLARKE: I think you are
7 correct. The unretrieved device fragment, for
8 the most part, we are looking at device
9 failures. It is true that some of them are
10 very small needles. But in fact what we are
11 really looking at and what the FDA is looking
12 at is these things that represent a failure of
13 the device to function properly with undue
14 consequences to the patient.

15 CO-CHAIR CONWAY: Carol.

16 DR. KEMPER: Kind of along the
17 same lines. I agree with Lisa that I think
18 both are very concerning and we want to
19 capture those because there are different
20 solutions but we want to be able to address
21 both of them.

22 I think by differentiating it and

1 having it a little bit clearer measure,
2 though, I think it will be easier to drive
3 change but it also might make it more likely
4 that people will report. Because if it is
5 clear which camp it falls in, I think people
6 would be more likely to feel comfortable
7 reporting that information.

8 CO-CHAIR CONWAY: And Charlotte.

9 DR. ALEXANDER: I like your
10 comment because I am sitting there thinking
11 that if I have a drill bit that breaks off in
12 the bone, I can get it out but I make a great
13 big hole in the bone to do it. And the
14 patient is at greater risk of a fracture from
15 that great big stresserizer. And if I know I
16 am going to get dinged for leaving that drill
17 bit in, am I going to think twice about trying
18 to get it out and maybe cause injury?

19 So some of the choices we say are
20 safer that we have made a calculated decision
21 for the patient's benefit, if we break them
22 up, we actually get to look at those and find

1 out if we are wrong and we can reassess. So
2 that is another argument for splitting them
3 out. I think we can get good patient quality
4 and safety information from splitting them out
5 and that is not to make an excuse but I think
6 it may be the better way to report it.

7 MS. MCGIFFERT: So you would
8 support another code that is connected to the
9 faulty device?

10 DR. ALEXANDER: Well connected
11 with the decision to not correct the problem,
12 whether that is taking out the needle that is
13 a microscopic needle, or whether it is taking
14 out the broken drill bit, or it is searching
15 for if the clip has fallen down into the
16 abdomen is going to take two hours --

17 MS. MCGIFFERT: So you don't see
18 -- I guess what I am trying wrap my head
19 around is you guys are just seeing two buckets
20 and I am seeing multiple buckets. Because if
21 really what you are trying to get to is what
22 is the cause and what is the solution, there

1 would be multiple buckets. But basically you
2 are seeing it as if it is a faulty device and
3 because it is a faulty device, digging around
4 to get it is going to put the patient in
5 danger and you are not going to do it, then
6 you want that to be all in one bucket, as well
7 as a needle that gets dropped that isn't
8 responsible for any -- no device fault would
9 go in that same bucket.

10 DR. CLARKE: Well except that we
11 could say that the needle, if for instance as
12 Steve mentioned clips falling out of the clip
13 holder, if every tenth clip is falling out of
14 the clip holder, I would call that a device
15 failure. And if I have a needle that is so
16 small that I can't find it and I know that, I
17 am either going to have some mechanism for
18 holding the hemostat on the other end of it so
19 I can fish it out, or I am going to get a
20 needle holder that isn't going to spring on me
21 so that I accidentally lose the clip.

22 So I think to a certain extent, we

1 are perhaps making this a little too esoteric
2 maybe. I envisioned myself in another NSF
3 conference discussing this very issue.

4 But I think the issue is you want
5 diagnostics which are going to be related to
6 actions. And we need, I think at least more
7 than one category because there is at least
8 more than one action.

9 DR. ALEXANDER: And Lisa --

10 CO-CHAIR CONWAY: Let me --

11 DR. ALEXANDER: I'm sorry.

12 CO-CHAIR CONWAY: Go ahead.

13 DR. ALEXANDER: The one last thing
14 is that not everything that fails do we decide
15 to leave in. If I am doing a scope and I have
16 got something that breaks off in the joint, I
17 have to get that out. There is no choice on
18 that. That is going to be a problem. So even
19 if I have to open the joint when I am doing
20 it.

21 CO-CHAIR CONWAY: Let me try and
22 pull all this together and Patrick you let me

1 know if you would disagree with anything.

2 I am hearing one easy and one
3 complicated thing. One is there is a
4 suggestion that we embrace a name change that
5 clarifies what this is. And you said you
6 agreed to that. And I think we can leave that
7 with the staff and we will see that name
8 change surface in the report that will get a
9 chance to edit.

10 The other is a lot more
11 complicated in maybe clarifying what is
12 happening when something is left in. And
13 there is at least four different issues at
14 play here; intended left in, device
15 malfunction, unintended left in, important and
16 not important. There is at least four cells
17 of issues her and I am getting advice maybe
18 from Heidi that, with Patrick's agreement,
19 that if you are interested in pursuing this
20 line of clarifying that you bring it back in
21 the course of maintenance of this measure or
22 sooner, whenever the work can be done because

1 it involves more than just AHRQ in clarifying
2 that. Is that -- let me just check with
3 Patrick on whether you are accepting all that.

4 DR. ROMANO: I looked up the ICD-
5 10-CM codes in the course of this discussion
6 and there is good news and bad news.

7 (Laughter.)

8 DR. ROMANO: So, the good news is
9 ICD-10-CM does have a specific set of codes
10 for retained foreign body fragments. And it
11 specifically distinguishes, for example, metal
12 fragments from plastic fragments and other
13 types of fragments.

14 The bad news is that those are
15 separated and excluded from the code for
16 accidentally leaving a foreign body. So in
17 other words, if somebody says that they are
18 accidentally leaving in a foreign body, then
19 they are not supposed to describe the type of
20 fragment that was left in, in the case of a
21 foreign body fragment.

22 So this is something -- So at last

1 the code structure exists but what is needed
2 is some perhaps better instructions about how
3 for coders how to use the combinations of
4 codes rather than currently the instructions
5 are excludes. So if you use this one and
6 don't use that one, and if you use that one
7 don't use the other one. So we might
8 encourage coders to actually use them together
9 in the case of a retained fragment of a drill
10 bit or a drain or something of that type.

11 So but as far as the timing of all
12 this, I have to defer to the committee and to
13 the staff because there is a certain timing
14 that we will have to go that probably won't
15 happen until 2013.

16 CO-CHAIR CONWAY: I don't want to
17 over-interpret people's comments but I don't
18 think there is a sense in the room that we
19 want to lose this measure. I think all of
20 that was suggestions on perfecting the measure
21 as rapidly as you could do that. Is that --
22 correct me if I misinterpret it.

1 So there is a lot of pressure on
2 you, Patrick, for future work.

3 DR. ROMANO: As long as AHRQ
4 continues to support this work, no matter how
5 the committee votes, we will certainly come
6 back with a re-specified version of this
7 indicator at the appropriate time.

8 CO-CHAIR CONWAY: Is that all
9 right? And you captured all that?

10 MS. BOSSLEY: I got it.

11 CO-CHAIR CONWAY: Okay, are we
12 ready to vote on this measure? I'm sorry,
13 Charlotte, did you have your thing up? No.

14 MS. MCGIFFERT: Okay, could you
15 clarify again what it is -- Could you clarify
16 are we supposed to vote with the changes that
17 you are asking him to do? And he doesn't know
18 if he can do them yet.

19 CO-CHAIR CONWAY: Well, yes, I
20 mean the intention is AHRQ would try to follow
21 up and perfect this measure in the way that
22 was described here. They agree with that.

1 If you don't have trust in that,
2 we could reject it now.

3 MS. BOSSLEY: Right. I mean I think
4 you have to vote on what you have before you
5 because you don't know what the final codes
6 will be and how that will be, the algorithm
7 will work, etcetera. So I think it is what
8 you have. So you need to vote on that. So
9 you vote assuming there is a total change that
10 you find acceptable because I think, again I
11 don't see that being a huge issue.

12 What we would then do is also in
13 everything we write up and then in the future
14 when this measure comes up for maintenance put
15 forward the recommendations of this committee,
16 to be sure that it is before that committee
17 that reviews it, that they are aware of the
18 issues, and see how AHRQ has been able to
19 address that or not.

20 MS. MCGIFFERT: Can I ask one more
21 clarifying question? You said the four
22 categories that you were saying. What were

1 the other two? You weren't suggesting to add
2 the level of harm that was done or not.
3 Right?

4 CO-CHAIR CONWAY: No.

5 DR. LAWLESS: Okay, thanks.

6 CO-CHAIR CONWAY: Just it was
7 associated with devices, it had to do with the
8 intentionality or the need of the surgeon to
9 leave some things in like sponges and livers.
10 It had to do with whether it was an
11 insignificant micro needle that was left in or
12 a significant. They seem to be the four
13 cells. There might be more.

14 MS. PROBST: If we just accepted
15 it, renewed it from 2008, when would it come
16 up again for review? Is it every two years?

17 MS. BOSSLEY: Every three years.

18 MS. PROBST: Every three years.

19 MS. BOSSLEY: But keep in mind, if
20 they are able to do this earlier than that,
21 they can bring it back during an annual update
22 or at any point and we would just do an ad hoc

1 review. So you are guaranteed three years but
2 you may get it sooner.

3 CO-CHAIR CONWAY: And now that I
4 look at this, if the lack of clarity is so
5 serious, maybe we should vote it down, if it
6 is misleading, or are all these comments
7 needed in the future to perfect an important
8 measure.

9 Okay, so are we ready?

10 DR. ROMANO: I mean, what I would
11 say is that if you vote this down on
12 importance, then AHRQ probably won't come back
13 because then the message isn't an important
14 area for them to get involved in.

15 If you vote it down on scientific
16 acceptability, then we would try to come back
17 with a more scientifically acceptable.

18 CO-CHAIR CONWAY: And if we vote
19 it up, you are going to work to continue to
20 perfect it.

21 DR. ROMANO: Right. And if you
22 voted it up, then we would continue to use it

1 and work to perfect it, absolutely.

2 CO-CHAIR CONWAY: Jessica.

3 MS. WEBER: Importance to measure
4 and report. Are all three subcriteria met:
5 high impact, performance gap, evidence?

6 We need one more vote. Janet?

7 DR. NAGAMINE: Yes.

8 MS. WEBER: All right, 22 yes.

9 Scientific acceptability of
10 measure properties, reliability and validity.
11 It is a yes/no question.

12 Janet?

13 DR. NAGAMINE: No.

14 MS. WEBER: Fifteen yes, seven no.

15 Usability: high, moderate, low,
16 insufficient. We need one more vote. Janet?

17 DR. NAGAMINE: Moderate.

18 MS. WEBER: Two high; 12 moderate;
19 eight low.

20 Feasibility: high, moderate, low,
21 insufficient. We need two more votes. Janet?

22 DR. NAGAMINE: We're on usability?

1 MS. WEBER: Feasibility.

2 DR. NAGAMINE: Feasibility.

3 Moderate.

4 MS. WEBER: Six high, 11 moderate,
5 five low.

6 Overall suitability for
7 endorsement. Does the measure meet all of the
8 NQF criteria for endorsement? We need one
9 more vote. Janet?

10 DR. NAGAMINE: Just to clarify, we
11 are voting as is. Correct?

12 MS. WEBER: As is.

13 DR. NAGAMINE: No.

14 MS. WEBER: With the name change.

15 DR. NAGAMINE: I'm sorry. What?

16 MS. WEBER: The name change to
17 make it more clear.

18 DR. NAGAMINE: I would still say
19 no.

20 MS. WEBER: Okay, 17 yes, four no.

21 CO-CHAIR CONWAY: Okay, thank you.

22 PARTICIPANT: Okay, wait. Stop.

1 CO-CHAIR CONWAY: Yes.

2 PARTICIPANT: Did we do the
3 pediatric one already?

4 MS. WEBER: No.

5 PARTICIPANT: Were we voting on
6 both of these or just one?

7 MS. BOSSLEY: So I guess one of
8 the questions I would have to everyone is
9 would your votes change for the other one?

10 (Chorus of noes.)

11 MS. BOSSLEY: Then if everyone
12 agrees, we will just move those over and apply
13 them.

14 CO-CHAIR CONWAY: All right. So,
15 next do we want to open to the public? Jason
16 are you still with us?

17 OPERATOR: Yes, sir.

18 CO-CHAIR CONWAY: Could you open
19 the lines?

20 OPERATOR: Thank you. Once again,
21 if you would like to ask a question, please
22 press *1. Again that is *1 to ask a question.

1 (No response.)

2 OPERATOR: Again, that is *1.

3 CO-CHAIR CONWAY: All right. Next
4 why don't we get a quick recap of what just
5 happened today?

6 CO-CHAIR CIPRIANO: Well just
7 first of all, a big thank you to everyone for
8 your excellent participation. We have
9 completed 16 of the 25 measures that are on
10 our agenda for this meeting. So I think we
11 can feel very good about that. We approved
12 11, rejected three, deferred one, and had one
13 withdrawn.

14 We also have taken specific notes
15 about a number of follow-up items, some
16 specific to measures but some general areas,
17 such as harmonization of timelines;
18 harmonization of reporting; longitudinal
19 measures that cross settings and have multiple
20 measurement periods; the issue of reliability
21 and validity with measures that only collect
22 accounts; the move to more outcome measures

1 and asking the question of how measures
2 improve quality; and then again any specific
3 additions that we have directed the measure
4 developers.

5 So I think we have accomplished a
6 great deal and we thank you for that.

7 CO-CHAIR CONWAY: Okay, start at
8 nine tomorrow. If there is anybody interested
9 in huddling for dinner together or something
10 we can get together in the back of the room.

11 For people who are new to this
12 panel, I think this is my third one, panel
13 where I have had a similar experience, the
14 work is never 100 percent satisfying because
15 this isn't easy. So don't go home feeling
16 bad. It is very complicated stuff.

17 MS. WEBER: And please give back,
18 your voting devices. I will hand them out
19 again tomorrow.

20 (Whereupon, at 5:25 p.m., the
21 foregoing meeting was adjourned to reconvene
22 at 9:00 a.m. on Friday, December 16, 2011.)

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In the matter of: Patient Safety Complications

Before: NQF

Date: 12-15-11

Place: Washington, DC

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