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

C-O-N-T-E-N-T-S

C-O-N-T-E-N-T-S

C-O-N-T-E-N-T-S

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

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

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

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

I guess my interesting facet is I

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

(Laughter.)

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

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

(Laughter.)

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

Thank you.

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

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

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

MEMBER MICHALEK: Good morning, everybody.

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

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

(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.

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

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

(Laughter.)

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

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

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

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

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

MEMBER WANG: Hi. Good morning, everyone.

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

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

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

MEMBER QUIGLEY: Thank you.

Good morning, everyone.

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

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

(Laughter.)

So, we are absolutely engaged in

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

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

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

(Laughter.)

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

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

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

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

(Laughter.)

MEMBER SMITH: Good morning.

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

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

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

(Laughter.)

MEMBER ALEXANDER: Good morning.

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

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

(Laughter.)

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

MEMBER MOFFATT-BRUCE: Good morning.

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

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

MEMBER THRAEN: Good morning.

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

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

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

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

Thank you.

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

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

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

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

(Laughter.)

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

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

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

MEMBER NAGAMINE: Sure. Good morning, everyone.

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

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

involved in their National Quality and Safety Initiatives as well.

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

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

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

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

(Laughter.)

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

MS. SLOSBURG: Good morning.

I'm Donna Slosburg with the ASC Quality Collaboration.

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

MS. KRUSENOSKI: Good morning.

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

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

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

I used to drive a fire truck.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

So, should we start with the Chairs? Yes.

CO-CHAIR CONWAY: I have none to report.

CO-CHAIR CIPRIANO: I have none to report.

MEMBER LAWLESS: None to report.

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

MEMBER ADELMAN: None to report.

MEMBER SIEGGREEN: I have nothing to report.

MEMBER MICHALEK: Nothing to report.

MEMBER PROBST: Nothing to report.

MEMBER McGIFFERT: Nothing to report except that I am a shameless advocate for consumers. That will become evident.

(Laughter.)

MEMBER WHITE: I have no relevant disclosures.

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

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

MEMBER WANG: I have nothing to report.

MEMBER QUIGLEY: I have nothing to report.

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

MEMBER KEMPER: I have nothing to

report.

MEMBER SMITH: Nothing to report.

MEMBER ADELMAN: Nothing to report.

MEMBER MOFFATT-BRUCE: I have nothing to report.

MEMBER THRAEN: Nothing here.

MS. BOSSLEY: Janet?

MEMBER NAGAMINE: No disclosures.

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

(No response.)

Usually it's no. That's fine. Okay. Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

(No response.)

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

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

CO-CHAIR CIPRIANO: Okay. So, we are going to start with the VTE measures. And, Heidi, I think what you said, we would first ask our measure developer?

MS. BOSSLEY: Yes.

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

Maybe we will start with No. 0371.

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

(No response.)

Okay. We won't worry about that.

All right, go ahead, please.

DR. BRATZLER: Good morning.

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

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

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

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

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

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

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

CO-CHAIR CIPRIANO: Okay. Thank you.

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

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

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

MEMBER McGIFFERT: Who me?

CO-CHAIR CIPRIANO: No.

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

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

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

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

CO-CHAIR CIPRIANO: Of this group of measures?

MEMBER McGIFFERT: Yes.

CO-CHAIR CIPRIANO: The six measures?

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

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

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

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

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

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

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

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

started talking, really addressing the usability.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

comparable between hospitals.

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

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

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

CO-CHAIR CIPRIANO: John?

MEMBER CLARKE: When I looked at

the process measures, I am not enthusiastic about process measures that are authority-based or opinion-based, consensus-based. But if a process measure has an evidence-based relationship with an outcome, I think it is perfectly valid to have a process measure. And in fact, I would argue that in some instances where the outcomes, presumably, if they follow practice are negligible, I mean, that is, there is no adverse events, then you really only have the process measures as an indication of whether people, in fact, are providing best practice or just being lucky.

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

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

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

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

MS. BOSSLEY: Yes. Please go ahead.

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

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

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

Thank you.

CO-CHAIR CIPRIANO: Okay. Thank you.

In the back, from the Joint Commission.

DR. BRATZLER: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR CIPRIANO: Iona?

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

CO-CHAIR CIPRIANO: Okay.

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

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

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

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

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

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

MS. BOSSLEY: Right. So, first of

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

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

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

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

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

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

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

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

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

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

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

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

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

(No response.)

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

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

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

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

Is there evidence to support? Yes.

I have to switch back and forth here.

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

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

electronically?

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

So, there is a little variability in that section.

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

Richard?

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

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

So, I would like a little clarification.

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

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

VTE. It has just not been clinically-validated.

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

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

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

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

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

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

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

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

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

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

DR. BRATZLER: That's true.

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

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

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

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

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

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

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

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

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

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

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

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

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

So, Pat, let me go ahead with you.

MEMBER QUIGLEY: Thank you, Pam.

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

I actually had rated this as

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

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

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

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

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

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

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

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

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

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

MEMBER QUIGLEY: Yes.

CO-CHAIR CIPRIANO: Okay.

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

So, thank you.

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

MEMBER QUIGLEY: Thank you.

CO-CHAIR CIPRIANO: Okay. Lisa?

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

And so, I am wondering if we have

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

DR. BRATZLER: No, it's not.

MEMBER McGIFFERT: No, it's not?

DR. BRATZLER: No, it's not.

MEMBER McGIFFERT: Okay.

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

MEMBER McGIFFERT: Okay.

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

MEMBER McGIFFERT: Okay.

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

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

MEMBER ADELMAN: Thanks.

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

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

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

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

CO-CHAIR CIPRIANO: Okay. Thank you.

Vallire?

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

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

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

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

Thank you.

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

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

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

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

So, we took the position that

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

CO-CHAIR CIPRIANO: Okay. Thank you.

Jason Adelman again.

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

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

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

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

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

CO-CHAIR CIPRIANO: Janet, go ahead.

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

make sense to keep track of how we are doing? Absolutely.

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

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

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

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

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

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

So, those were our big comments on this.

CO-CHAIR CIPRIANO: Okay. Thank you.

Richard? And then Lisa.

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

are whether or not someone gets it.

Lisa just brought up the list. And it is acceptable just to pull on a set of TED hose, and you are giving acceptable prophylaxis, even to your high-risk patient, which, to my way of looking at it, there is no evidence.

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

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

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

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

CO-CHAIR CIPRIANO: Lisa?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MEMBER WEINGART: Thanks.

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

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

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

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

My understanding is that it is not

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

Is that correct?

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

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

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

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

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

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

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

CO-CHAIR CIPRIANO: Carol?

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

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

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

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

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

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

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

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

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

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

reporting.

Am I answering your question?

MEMBER MOORES: You are.

MS. BOSSLEY: Yes.

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

Lisa, is yours a clarifying question?

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

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

that voluntarily submit this data already.

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

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

MEMBER MICHALEK: Which numbers?

CO-CHAIR CONWAY: They are 0376 and 0450.

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

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

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

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

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

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

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

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

CO-CHAIR CIPRIANO: Okay. Thank you.

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

MEMBER QUIGLEY: A point of information?

CO-CHAIR CIPRIANO: Go ahead.

MEMBER QUIGLEY: May I ask a question?

CO-CHAIR CIPRIANO: Microphone, please.

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

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

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

Thank you.

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

the committees that review the measures.

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

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

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

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

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

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

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

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

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

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

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

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

Steve?

MEMBER LAWLESS: You may have

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

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

So, Ann looks like she wants to say something.

MS. WATT: How could you tell?

(Laughter.)

Hi. I'm Ann from the Joint Commission.

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

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

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

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

(No response.)

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

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

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

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

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

Point it here at the voting.

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

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

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

MEMBER NAGAMINE: Okay. Thanks.

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

go ahead and try this.

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

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

MS. WEBER: It is just a test.

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

(Whereupon, a test vote was taken.)

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

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

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

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

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

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

So, give Jessica just a second on this.

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

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

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

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

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

(Whereupon, a vote was taken.)

MS. WEBER: We need one more vote. Hit Send.

Okay. We have 20.

CO-CHAIR CIPRIANO: Janet?

MEMBER NAGAMINE: Yes.

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

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

(Whereupon, a vote was taken.)

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

MEMBER NAGAMINE: Yes.

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

The summary of votes is 17 yes, 4 no.

Usability?

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

(Whereupon, a vote was taken.)

MS. WEBER: Janet?

MEMBER NAGAMINE: I would say mod.

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

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

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

(Whereupon, a vote was taken.)

MS. BOSSLEY: Janet?

MEMBER NAGAMINE: Mod.

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

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

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

(Whereupon, a vote was taken.)

MS. BOSSLEY: Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Okay. Try casting

your votes again. Three more votes needed.

Okay. Seventeen yes, 4 no.

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

(Laughter.)

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

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

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

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

All right.

MEMBER NAGAMINE: Heidi, this is --

CO-CHAIR CIPRIANO: Is that Janet?

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

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

MEMBER NAGAMINE: Okay. Thank

you.

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

MEMBER NAGAMINE: All right. Thanks.

CO-CHAIR CIPRIANO: Sure. Thank you.

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

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

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

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

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

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

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

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

CO-CHAIR CIPRIANO: Lisa?

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

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

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

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

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

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

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

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

CO-CHAIR CIPRIANO: Any others? Steve?

MEMBER LAWLESS: When you are

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

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

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

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

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

not the ICU?

MEMBER LAWLESS: But on the day of admission --

MS. WATT: Yes?

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

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

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

Are we ready to do the voting on 0372 then?

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

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

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: Yes.

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

Okay. Twenty-one yes.

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

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Twenty-one yes.

Usability?

(Whereupon, a vote was taken.)

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

MEMBER NAGAMINE: Mod.

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

Feasibility?

(Whereupon, a vote was taken.)

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

MEMBER NAGAMINE: Mod.

MS. BOSSLEY: Okay.

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

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

(Whereupon, a vote was taken.)

MS. BOSSLEY: Janet?

MEMBER NAGAMINE: Yes.

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

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

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

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

MEMBER NAGAMINE: All right. Thanks.

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

MS. WATT: I can tell you that we

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

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

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

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

And so, the measure looks at

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

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

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

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

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

CO-CHAIR CIPRIANO: Thank you very much.

Questions for Lisa or comments or clarifications from the group?

Richard?

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

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

performance measure also.

CO-CHAIR CIPRIANO: Richard?

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

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

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

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

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

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

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

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

MEMBER NAGAMINE: This is Janet.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MEMBER NAGAMINE: I wanted to add

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

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

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

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

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

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

Because I am a bit concerned about

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

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

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

CO-CHAIR CIPRIANO: Okay. So, we

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

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

MEMBER McGIFFERT: Yes, I do.

CO-CHAIR CIPRIANO: Okay.

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

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

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

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

MEMBER McGIFFERT: I mean, it seems like that is what they are recommending, but it is not really clear, as we are voting, that that is what we are voting for.

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

MEMBER McGIFFERT: Okay. Great. Thanks.

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

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

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

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

MEMBER McGIFFERT: That was in there?

DR. BRATZLER: -- public reporting

to the VTE measure set.

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

CO-CHAIR CIPRIANO: Richard, please.

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

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

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

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

CO-CHAIR CIPRIANO: Steve? Sorry.

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

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

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

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

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

MEMBER LAWLESS: Okay.

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

(No response.)

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

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

Any other comments/questions before we vote?

(No response.)

Okay. Jessica, please.

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

(Whereupon, a vote was taken.)

MS. BOSSLEY: Janet?

MEMBER NAGAMINE: Moderate.

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

MEMBER NAGAMINE: Oh, I'm sorry.

MS. BOSSLEY: On importance.

MEMBER NAGAMINE: I would say yes.

MS. BOSSLEY: Okay.

MS. WEBER: Twenty yes, 1 no.

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

(Whereupon, a vote was taken.)

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

MEMBER NAGAMINE: I would say no.

MS. BOSSLEY: Okay.

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

Eighteen yes, 3 no.

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

(Whereupon, a vote was taken.)

MS. BOSSLEY: And Janet?

MEMBER NAGAMINE: I would say low.

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

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

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: Low.

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

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

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: No.

MS. WEBER: Eighteen yes, 3 no.

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

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

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

(Whereupon, the foregoing matter

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

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

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

(No response.)

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

(Laughter.)

Come on.

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

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

MEMBER MOORES: -- discussions

that you had.

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

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

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

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

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

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

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

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

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

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

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

Do we have a comment from the Joint Commission?

DR. BRATZLER: Of course, the

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

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

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

CO-CHAIR CONWAY: Okay. Thank you.

And any questions from the panel?

Richard, you can go first.

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

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

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

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

yet, we did an absolutely horrible job.

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

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

CO-CHAIR CONWAY: Okay. Thank you.

Jason? And then Iona.

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

value and then a change in dosing.

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

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

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

better than I.

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

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

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

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

DR. BRATZLER: No, all the cases

are measured at the patient level.

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

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

CO-CHAIR CONWAY: Iona?

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

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

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

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

MEMBER THRAEN: Well, I guess,

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

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

CO-CHAIR CONWAY: Okay. Thank you.

Christina?

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

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

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

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

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

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

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

re-, retooled in using the QDM format.

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

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

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

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

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

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

CO-CHAIR CONWAY: Okay. Christina?

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

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

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

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

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

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

MEMBER WHITE: My question to the

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR CONWAY: Lisa?

MEMBER MOORES: Yes, I would say

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

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

And I was just wondering, Dale, if

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

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

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

CO-CHAIR CONWAY: So, since it has

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

You're back now?

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

CO-CHAIR CONWAY: Christina?

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

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

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

MEMBER NAGAMINE: Yes.

CO-CHAIR CONWAY: Yes.

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

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

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

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

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

CO-CHAIR CONWAY: Thank you.

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

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

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

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

(Laughter.)

Is that correct?

DR. BRATZLER: Yes. Well, I --

CO-CHAIR CONWAY: That's okay.

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

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

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

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: (Telephonic interference).

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

MEMBER NAGAMINE: No.

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

MS. WEBER: Ten yes, 11 no.

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

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

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

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

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

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

slamdunk.

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

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

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

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: No.

MS. WEBER: Seven yes, 14 no.

MS. BOSSLEY: These are always the fun ones.

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

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

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

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: I would say low.

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

MEMBER NAGAMINE: Low.

MS. WEBER: Okay. Thank you.

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

Feasibility?

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: Low.

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

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

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: No.

MS. WEBER: Four yes, 17 no.

CO-CHAIR CONWAY: Okay. Thank you.

Moving on to 0375, this is venous thromoboembolism warfarin therapy discharge instructions.

Could we hear from, 0375 --

MEMBER SIEGGREEN: Me.

CO-CHAIR CONWAY: Mary? Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CDC just released their report

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

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

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

drug events occur because of this one medication.

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

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

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

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

MEMBER QUIGLEY: Oh, thank you so much.

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

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

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

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

Thank you.

MEMBER HOOPER: And I concur with Patricia.

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

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

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

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

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

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

being asked to be maintained in its current form?

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

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

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

So, it is more than just checking

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

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

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

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

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

And there are still gaps, big gaps.

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

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

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

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

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

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

MEMBER THRAEN: Go ahead.

CO-CHAIR CONWAY: Go ahead, Janet.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the proper way to educate in the right language.

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR CONWAY: Vallire?

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

And in this measure, I have yet to

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

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

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

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

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

CO-CHAIR CONWAY: Steve and then Saul.

MEMBER NAGAMINE: This is Janet.

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

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

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

(Laughter.)

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

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

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

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

So, that's it.

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

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

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

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

Thank you.

CO-CHAIR CONWAY: Okay. Thank you.

Any other comments? Janet, any parting comments?

(No response.)

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

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

(Whereupon, a vote was taken.)

Try voting again. One more vote needed.

Janet?

MEMBER NAGAMINE: Moderate.

MS. WEBER: It's yes or no.

MEMBER NAGAMINE: Oh, I'm sorry.

Oh, that's tough.

Yes.

MS. WEBER: Ten yes, 11 no.

CO-CHAIR CONWAY: All right. Next?

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

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

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

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: No.

MS. WEBER: Four yes, 17 no.

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

MEMBER McGIFFERT: I think the other one that someone raised was that they are provided through some kind of oral communication with the written language, with a written document.

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

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

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

CO-CHAIR CONWAY: Iona?

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

CO-CHAIR CONWAY: Patricia? Okay. Sorry. All right, Jason?

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

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

MEMBER NAGAMINE: This is Janet. I have a comment.

CO-CHAIR CONWAY: Yes, go ahead, Janet.

MEMBER NAGAMINE: Tagging onto what Iona said about ultimately affecting outcomes, and after having studied this in our system, we actually concluded that, despite the rigorous education that patients get, it impacted the outcome less than we had hoped.

And where we directed our focus was getting better at determining who should be on warfarin and really calculating upfront the risk/benefit ratio better, so that the outcomes would be impacted.

CO-CHAIR CONWAY: Let me ask Heidi's question in a different way. Of the people who voted no -- I want you to raise your hand -- if the Joint Commission further specified the kind of education, how many people would change their vote?

It is undefined. I mean, if they did all the things that were requested, language, oral discussion, and whatnot, to the education process, how many no votes would that change? Raise your hand.

(Show of hands.)

MS. BOSSLEY: In an informal vote, that makes it 8 yes and 13 no -- I haven't had enough coffee -- 13 no. So, it is still, again, the informal does not pass scientific acceptability.

MEMBER PROBST: It seems to be such an important issue in terms of patients coming back, care transitions. You know, I have had family members that -- fortunately, I was a nurse -- but they got no education about that they had congestive heart failure or were going home on warfarin. And when I asked about it, they said, "Well, we didn't expect them to live." I said, "Well, they did live," you know, and "so they need the education."

(Laughter.)

And so, it really needs to happen. So, I am just worried that at this point in time, if we don't support the measure, what kind of message -- I mean, I am just thinking about being on the Purchaser Committee and trying to explain to people why the Steering Committee didn't think education was important enough to keep a measure there.

So, I know that it is not perfect. And I also know that, if you keep passing a

non-perfect measure, there is no incentive to get it perfect. But it seems something that is pretty counterintuitive.

CO-CHAIR CONWAY: Let me just clarify. I don't think anybody here said education wasn't important. So, for you and Iona that feel bad, this is about feasibility and scientific validity.

MEMBER McGIFFERT: And I think it would be really good if we could send that message out, that we feel that it is essential and that this is not a vote against education, but it is a vote against inadequate education.

CO-CHAIR CONWAY: We also don't have a measure to hold people accountable for that that is scientifically valid.

MS. WATT: Can you hear me now? I feel like a commercial.

You know, you are coming through loud and clear. And you are not telling us anything that we don't know and haven't thought about. What we don't know how to do

-- and this is what I am asking your help, and I am sincerely asking your help -- how do we make a measure for education at the inpatient level of care that would address the issues that you bring up?

I mean, we are stymied, to be perfectly honest with you. If you could make measure that it would meet your threshold for meeting these criteria, what would it say? How would it look? Gladly, we will write it. I just don't know how.

CO-CHAIR CONWAY: I think we have some volunteers.

(Laughter.)

We will go around this way, Richard first.

MEMBER WHITE: You would have to have a validated educational material shown, when given to the patient in their language, improved outcomes. And no one has done all that research, but, I mean, that is what you would like. Then, you say -- it is like

nomogram -- then, you would say, "Yes, we applied this and taught this, which is a validated tool. We don't know if they really learned it." But, I mean, no one has developed --

MS. WATT: Well, there is no validated tool.

MEMBER WHITE: Yes, right. I know.

MS. WATT: That's the problem.

MEMBER WHITE: I know, that's the problem.

MS. WATT: And so, are performance measures to remain silent on this very, very important issue of education because nobody has made validated tools? You know, that doesn't feel right, either.

CO-CHAIR CONWAY: John and then Vallire.

MEMBER NAGAMINE: My hand is up, Bill.

CO-CHAIR CONWAY: Okay.

MEMBER CLARKE: The Joint Commission might want to consider something very radical, since this is ultimately an outcome measure. And that is to make sure that the patient has adequately demonstrated an understanding of what is going on. That is, that they actually have responded in writing to questions about what they should do under what circumstances.

MS. WATT: Post-test-type stuff?

MEMBER WHITE: I can't get my medical students to answer them right.

CO-CHAIR CONWAY: Right. Order in the house.

Vallire and then Janet and then Jim.

MEMBER HOOPER: I guess no one disagrees that education is important, but there are so many components to education. I mean, I agree, John, a post-test would be great. But now bedside nurses can barely get everything they need to get done to take care

of that patient and keep them alive from one shift to another.

And education occurs in every patient contact that is no formal education, nor is it always documented. I mean, every time you walk in that room, there is some component of patient and/or family education, and it is not always going to be documented.

I don't think education is your problem. I think you have got to get to the outcome and drill down on the problems with the outcome that will then guide you to the process problems.

As a long-time bedside nurse, to say, "Well, now only have I now got to make sure I get back and check my 20 checks in the electronic chart, but I have also got to complete a post-test for the patient" is just beyond capacity. I mean, it is just is.

So, I just really think that education is important, but it is not the focus of a performance measure. It has got to

be an outcome.

MS. WATT: But the outcome occurs after the hospitalization.

CO-CHAIR CONWAY: Okay. Let me point out something to the panel members. The staff do a very good job of capturing the rich nature of this discussion, and the report that comes out of this will not be a simple yes/no vote. It will contain some of this discussion of the rationale, and you get to see a draft of the report, right, before we release it? So, it will be sent around to you.

So, a lot of the rationale behind these votes is included in the report. So, you are not going to go public with a vote against patient education.

Stephen? And then, we will get on this side of the table.

MEMBER LAWLESS: Thank you for that clarification, Mr. Chairman. I don't like minimum security prisons.

(Laughter.)

For the Joint Commission, if you want an idea, a 24-hour post-discharge phone call to clarify how well these guidelines have actually been done or the instructions have been followed up or followed through, as a suggestion. It is not going to impact my vote. But if you want a suggestion, that is one I will give you.

CO-CHAIR CONWAY: Janet, you have something to say? Janet?

MEMBER NAGAMINE: Yes. So, stepping back, I think the intent of this measure is to reduce events on warfarin. And after having studied this, I think we also have to look much more closely at who we put on warfarin because what we found was that the ones who had bleeding events were the ones that were older, had dementia, fall risk, et cetera.

And so, you can focus on education. But I also want to throw out there and the question which I really appreciate is,

what do we do about this problem?

I think we need to look closely at the risk/benefit ratio. So, if mom is 92 and has dementia and is falling every day and has A-Fib with a 5 percent risk of stroke per year, what does that do for her versus her risk of bleeding? And I think we can't just talk about education without looking at the people we are putting on warfarin as well.

CO-CHAIR CONWAY: Okay. Thank you.

Mary, and then Louise.

MEMBER SIEGGREEN: I agree with Janet. I think sometimes it the clinician's judgment call.

But I wanted to back up to some statements about the patient education. And having a patient sign something that they have received the education or that they understand it doesn't mean that there is going to be any followthrough. And we see this, I see this over and over again when I ask the patients in

the clinic, "Nobody ever told you about smoking and what a problem it was, right?" And they can rattle off every single problem there is with smoking, and, yet, they are still smoking. So, for some reason, that hasn't hit them.

I think it is the same thing with any education. If you don't know what the little key is that is going to make this person or influence this person's behavior, then it is very difficult. You can't ensure that, again, because I told you have learned or because I have told you you are going to change your behavior.

So, I think adding more things for the healthcare provider to do just makes more work for the healthcare provider, but it is not necessarily going to get us to the outcomes that we want. So, maybe looking at that patient who is, quote/unquote -- I hate this word -- "non-compliant" is not the person who belongs on Coumadin or warfarin.

CO-CHAIR CONWAY: Richard?

MEMBER WHITE: Yes, we are doing a VTE measure and not an A-Fib measure. So, we are moving discussion into a whole different realm about the indications.

So, these people are at very high risk for recurrence right after they are put on anticoagulation. So, they have got to be on warfarin or one of these new anticoagulants, once it is FDA-approved.

So, this whole discussion about appropriateness doesn't apply to the VTE group. They really have to be on this anticoagulation for at least three months.

MEMBER NAGAMINE: That's true. Thank you. Risk/benefit is there.

CO-CHAIR CONWAY: Patricia, is your card up?

MEMBER QUIGLEY: Thank you.

My question is related to process. I wondered if we could finish the voting process, and then maybe have some open dialog

with the Joint Commission, so we could help them with what they are asking.

CO-CHAIR CONWAY: Sure. We are done voting, and we are in open dialog.

MEMBER QUIGLEY: Oh, so we have voted? We are not having to go through all the rest, as we have done before?

MS. BOSSLEY: Right.

MEMBER QUIGLEY: Oh, okay.

MS. BOSSLEY: So, importance and scientific acceptability are must-pass. So, it passed, well, came close to passing importance, which is why we went on to scientific acceptability. It, I think, clearly, did not pass scientific acceptability.

MEMBER QUIGLEY: Oh, thank you.

CO-CHAIR CONWAY: Okay. Iona?

MEMBER THRAEN: And this is just feedback to the Joint Commission. I don't know if there are equivalent measures associated with other kinds of chronic

diseases like diabetes and asthma in terms of the educational process or the intervention process, in terms of getting patients up-to-speed with their disease and the use of their medications, et cetera, et cetera, that could be adapted or adopted in this arena that might be useful.

CO-CHAIR CONWAY: Okay. Carol?

MEMBER KEMPER: Just one other comment to what Iona said. I am more familiar on the pediatric side, obviously. And so, for me, asthma is the core measures that we use. There is a very similar measure as to this one in the asthma core measures.

And what we have found is we have done a lot to make sure that our medical record, that it is very easy for people to check those off. But in some research that has been done across freestanding children's hospitals, we found that there has not been any impact in that or in correlation with then return to the hospital.

So, I think we are still trying to figure out -- I just want to reiterate; it goes back to what Mary said -- we have got to figure out how to do the education, and we don't know that yet.

And so, it makes us feel good that we can check that off, but it shouldn't because we are still not seeing that we are creating the impact that we want to.

CO-CHAIR CONWAY: Okay. Thank you for that rich discussion, which will get captured in the report.

All right. We are on to Measure 0376. This is an outcome measure, incidence of potentially preventable venous thromboembolism.

DR. BRATZLER: I would like to make a comment for the discussion. We actually do not consider this an outcome measure.

We had a long discussion with our Technical Expert Panel about this when we came

up with it. We actually considered this a process measure. Some people called it an intermediate outcome, but it really focuses on whether patients -- the denominator population are those patients who develop hospital-acquired VTE events. And the process is, did they receive prophylaxis or not? If they received prophylaxis, even if they got the event, we consider it not preventable.

So, what you are trying to define here is a group of patients who got a hospital-acquired VTE event who did not receive prophylaxis. It says something about that process. It also says something about the adequacy of the hospital's risk-assessment profile, because if you have a lot of patients getting VTE events that did not receive prophylaxis, it may reflect the fact that you are not giving a prophylaxis to high-risk patients.

So, we actually don't consider it an outcome measure. It is really focused on

did they receive prophylaxis or not? Were they given the chance to prevent the event?

CO-CHAIR CONWAY: Good. Thanks for that clarification.

And, Saul?

MEMBER WEINGART: So, thank you.

So, the measure is, as you said a minute ago, kind of a look-back. We look at the denominator of folks who had hospital-acquired VTEs and then look back and see either they had prophylaxis, and it is not ordered, but it actually looks like it is supposed to be received.

And the criteria is also met if there is a reason stated for exclusion. In other words, if the patient declines or if it is thought not to be appropriate. So, there is a risk assessment built into it, and it prevents the organization from being dinged on that one.

And then, there were a number of other exclusions, high length of stay, comfort

measures only, somebody in a clinical trial, or the DVT or PE was present on admission.

So, the group discussed it a bit, and we had a couple of observations that I thought I would share with the group.

First, there was a discussion about whether present on admission was easily or not easily ascertained. I think there was a sense that we are getting increasingly good at doing this, or at least having the medical decoders document this in the medical record.

I think there is some question about whether a VTE diagnosed in the first two or days or so maybe was there on admission, but wasn't picked up at the time of admission. So, I think there is a little bit of an ambiguity in that respect.

As we have discussed multiple times today, there is some component of risk assessment built in. In other words, you could exclude an individual for whom anticoagulation was not appropriate. But when

summing up individuals over the course of a hospital, if you have an oncology population, an orthopedic population, a population with high thrombophilia, this may result in sort of failure to account for those differences across institutions or services.

The staff identified in the measure the need to identify what an episode of care entailed. I think the measure assumes that this is an admission. It does sort of beg this question of whether time at risk is a vulnerability that ought to be taken into account. In other words, if you have a long length of stay, you are more at risk of an event, and failure to anticoagulate or to prophylax in some way might be overrepresented in groups that have longer time at risk. On the other hand, we don't do this routinely for the other measures. So, it is just something I think to bear in mind.

Another thing which came up was a question of the adequacy of prophylaxis. This

is an issue we discussed early on about whether mechanical prophylaxis is acceptable, and I don't want to belabor that now.

The other two things I thought I would mention is it doesn't assess whether the anticoagulation is adequate. In other words, they might be on warfarin, but it might not be therapeutic. So, that is not taken into account.

And then, finally, this is a measure where we need to acknowledge that there is a certain amount of treatment failure. Even with patients who are appropriately prophylaxed, they might still develop an in-hospital event.

So, all in all, I think there are some issues with the measure and there are with any measure. My own view on it is that I think it is a pretty interesting way to get at whether practices are in place at the institution. And it is tied to perhaps a harder measure that is closer to outcome than

we are used to, and that these concerns and reservations I think are something that we ought to discuss and think about, but don't necessarily mean it is not a valid and important measure for us to consider.

Oh, I didn't go over the rankings. You can't actually see the rankings. Mostly good.

DR. BRATZLER: I did want to comment on one thing you said, and that is treatment failures. That is actually why we developed the measure the way we did, because we recognize that, even with appropriate prophylaxis, some patients will get events, but those cases pass because they got appropriate prophylaxis or they got prophylaxis. So, the measure really is looking at a patient who develops a hospital-acquired event and got nothing.

CO-CHAIR CONWAY: Okay. Questions from the panel members or comments?

MEMBER NAGAMINE: I just had one

comment about present on admission. The other thing we discussed in our subgroup was there are patients who leave the hospital and come back within a day or two with a DVT or PE. And although it probably originated in the previous admission, this population would not be captured in the preventable VTE group. And I believe Richard sent around an article that estimated that that would be about 30 percent of patients, if I am not mistaken.

Richard, could you comment on that?

MEMBER WHITE: There was a paper presented at ASH last week, American Society of Hematology, "Root Cause Analysis of Failure of Prophylaxis in Hospitalized Medical Patients". And so, they isolated these cases, and it wasn't strictly on ICD-9 codes. It was out of England. So, they had a different way of finding them.

And when they looked, there was all sorts of failures. I think 25 to 30

percent got no prophylaxis, 15 percent got prophylaxis but not all the time, 10 percent didn't get the right dose. So, you see all sorts of failures in there. And I think 20 percent to 25 percent got perfect prophylaxis and still got a VTE.

So, there's all sorts of ways things can fail. It just showed the complexity. It has taken this author a year and a half of combing through these charts to get this quality data on several hundred patients. So, it was a big effort. But it just shows you the complexity of analysis.

CO-CHAIR CONWAY: So, you said, was this 30 percent of admitted DVT cases had --

MEMBER WHITE: No. Thirty percent of hospital-acquired VTE cases in retrospect got, I think 30 percent got appropriate prophylaxis during the entirety at the right dose. And then, there was 20 percent who didn't get any prophylaxis whatsoever, and a

lot of other stuff in between.

DR. BRATZLER: And I wanted to comment on the issue about the readmission. Actually, I do think that is a key issue, that a patient may have not gotten prophylaxis during a first stay, went home, developed a VTE, and comes back into the hospital. We wouldn't capture those because it would have been present on admission.

But, again, because there is no way to know that the patient is going to be admitted to the same hospital the second time, there is no way for us to account for that in this performance measure. So, we have to look at the episode of one acute care event.

MEMBER WHITE: Who is in the denominator? How do you identify these patients? Is this ICD-9 discharge VTE POA? No?

DR. BRATZLER: Yes. Yes, they have to have a discharge diagnosis of a VTE.

MEMBER WHITE: It is not another

assay of hospital-acquired? It is coded --

DR. BRATZLER: It has to be confirmed. The diagnosis has to be confirmed by a test.

MEMBER WHITE: And it is in the administrative data?

DR. BRATZLER: Right. So, there has to be administrative data that they had the event, but, also, then, they look at the chart to make sure that there was a confirmation test of the event.

MEMBER NAGAMINE: My understanding is that with HAI there is a way to link it to a prior admission. So, if you were to define a short period of time, would that be workable? Just a question.

DR. BRATZLER: So, I guess you could ask the question whether they had been recently in the hospital. The problem is the hospital that is capturing this data has no influence over, may not have any influence over the previous stay. So, it could have

occurred in a previous hospitalization, but the hospital that is reporting this measure can't be held accountable for something that happened in the prior -- particularly if it was a different hospital. So, that is the challenge.

MEMBER NAGAMINE: Right. And how do they handle that in HAI?

DR. BRATZLER: I'm not sure.

MEMBER THRAEN: Sorry. That is for CMS Medicare patients. And so, they are looking at the billing for individual patients. So, if they are showing up in the hospital within their 30-day readmission, or whatever the case might be, associated with a healthcare-acquired infection, then that is sort of how it plays itself out from a billing perspective for Medicare.

MEMBER SIEGGREEN: What if they don't show up in the hospital, but they get treated for a urinary tract infection in a physician's office post-hospitalization?

MEMBER THRAEN: Right now, it is the hospital level.

CO-CHAIR CONWAY: Okay. Jason?

MEMBER ADELMAN: I'm confused a bit by the process measure versus outcome measure. I mean, I understand what you said.

Well, first, I should ask, is the intention to report just the rate or the numerator and denominator and then calculating the rate? Because, you know, if you are going to report the numerator and denominator, then it is both an outcome measure and a process measure, right? Because once you give out the denominator, you are giving out -- the next measure we are going to discuss is the AHRQ PSI on DVTs. Also, if we are going to be, by doing through charts, giving out the denominator, that might be a more accurate way than simply using the AHRQ PSI. So, that denominator is an outcome.

I have a second part to that question, but maybe I will pause.

DR. BRATZLER: I think I understand your question. So, I can't speak to Joint Commission, but for the Hospital Compare, actually, you can download a database that has the numerator and denominator, but the rate typically is what is actually reported.

MEMBER ADELMAN: So, then, in the patient safety world, we often talk about not really looking at the outcome when judging a provider, for example. Like take Saul is at Dana-Farber and I am at a general medical hospital. And so, there's a lot of oncology patients. So, we could have the exact same level of compliance with the very first measure we discussed, VTE prophylaxis. But because you are using an outcome as the denominator, his rate will seem worse than mine.

DR. BRATZLER: No, no. So, that is why it is reported as a rate, because you both have equal opportunity to determine, when

a patient comes into your hospital, whether or not they are at risk for VTE events.

Now, I would agree that the oncology hospital would likely have more events. But I would also expect that an oncology hospital would assess that their patients are at greater risk and would put more of them on VTE prophylaxis. So, the measure only reports the proportion of patients who didn't get prophylaxis who had an event.

So, the whole conversation, when we were talking about this measure early on, focused on behavioral health, where we excluded behavioral health from the first measure because no good data. And that is one place in the hospital where you sometimes find truly fully ambulatory patients. But it doesn't mean that all of those patients are not at some risk for VTE.

And if you in this sixth measure start to see patients who are having hospital-

acquired events and aren't getting prophylaxis, then you can start to assess, well, is my risk assessment at the time of admission missing patients that I ought to be prophylaxing?

So, you are absolutely right that the rate of events, the number of events would vary. We would expect it to vary between hospitals. But that is not what the measure is. It is, if a patient had an event, did they receive prophylaxis or have that documented contraindication to prophylaxis?

MEMBER ADELMAN: I understand, but I don't totally agree with -- I can have a medicine patient, he can have an oncology patient that both meet indications for DVT prophylaxis. And we can both not -- you know, so based on the risk stratification, we can both not give the prophylaxis. His patient will be more likely to have an outcome. So, we both failed on that first measure. So, you would see a gap between the very first measure

we reported this morning and this one, where I will do worse on the earlier one and better on this one.

DR. BRATZLER: See, I think you are actually making my point, though, that this is almost a proxy measure of the effectiveness of the hospital's risk assessment protocol. Because I would expect Saul's risk assessments to consistently show relatively high risk for VTE events. And so, I would expect their risk assessment to have many more patients getting prophylaxis than your general medical patients.

So, I mean, that's why I say it somewhat reflects how good the hospital's risk assessment is for patients. Because if they have high-risk patients and they are not giving prophylaxis, then the number of patients who have an event that didn't get prophylaxis is going to be higher.

MEMBER WEINGART: But I think Jason's point is that treatment failures are

likely to be higher in certain groups than others, even if you do the risk assessment appropriately. I think you acknowledged that.

DR. BRATZLER: Right, right.

MEMBER WEINGART: Yes.

DR. BRATZLER: So, treatment failures, though, pass the measure as long as they got prophylaxis. By definition, if they were a treatment failure, they got prophylaxis.

CO-CHAIR CONWAY: Okay. Lisa?

MEMBER McGIFFERT: I wanted to go back to the issue of whether you would report the numerator and the denominator. Did I hear you correctly that you would not? You would only report the rate? And if that is the case, I think I would like to have a discussion about whether we should always have the components of what went into the rate, I think is very important to be part of this. And especially in this kind of situation where one of the elements of the rate could actually

be an outcome measure, we should seriously consider that.

MS. WATT: The answer to the question is that this measure is publicly reported on the Joint Commission's website quality check. And what is reported on those screens is the overall rate.

Now, just as with Hospital Compare, there is the capability, if people want to download the entire dataset to do their own analysis, or whatever, they can do that. That is not a real transparent process. I mean, when you are looking at the web page, you are seeing a rate.

MEMBER McGIFFERT: So, the rate, all the data is available for download if someone wanted to get it on the Joint Commission page?

DR. BRATZLER: On Hospital Compare. On Hospital Compare. You can't get it at --

MEMBER McGIFFERT: On the Hospital

Compare? Well, you know, Hospital Compare, for example, is not going to include the numerator and denominator for infections. And we, frankly, see a big problem with that, and I hope that that is not a trend that we can expect.

But, you know, I think it is really important to have all the elements that go into that rate available to the public in some form.

DR. BRATZLER: I can't speak to the infections, but I know for most of the process measures on Hospital Compare you can download at the hospital level the numerator and denominator, not the patient-level data, but the numerator --

MEMBER McGIFFERT: "You" meaning me? Okay.

DR. BRATZLER: "You" meaning you.

CO-CHAIR CONWAY: All right. Richard and then Patricia.

MEMBER WHITE: So, the

denominator, this includes all of the events picked up by PSI-12, postop, medical, everybody in the hospital?

MS. WATT: This measure looks at patients within ICD-9 principal or other diagnosis code of VTE.

MEMBER WHITE: It shouldn't look at principal. That's why they came in the hospital.

MS. WATT: Sorry, sorry, sorry. My error. Secondary, other --

MEMBER WHITE: With the flag POA no?

MS. WATT: Correct.

DR. BRATZLER: And the "and" is there also has to be a test confirming the diagnosis in the chart.

MEMBER WHITE: Right. Okay. So, a couple of little questions.

So, if you screened a patient for asymptomatic and found it, if it was coded, it would be included --

DR. BRATZLER: It could be included, yes.

MEMBER WHITE: -- but it is not a symptomatic event? It happened to get screened, right?

DR. BRATZLER: Correct.

MEMBER WHITE: And you also -- just real nitpicking -- so, you put in 45387 so you could get an upper extremity thoracic vein, and you excluded all the other upper extremities and you put in a couple of non-specific codes that are not upper extremity or lower extremity or anything, 45389 and 453.9. So, you've got some real non-specific codes in there that might be excluded.

DR. BRATZLER: Right. So, we have checked with Patrick about some of the --

MEMBER WHITE: Clean it up, yes.

DR. BRATZLER: Yes. I know the PSI-12, I think it is 12, has been updated, and we have been looking at some of those codes also.

MEMBER WHITE: So, it will include all of the postoperative as well as the medical though?

DR. BRATZLER: Yes.

MEMBER QUIGLEY: Thank you.

My question is directed towards Jason. Jason, I was wondering, are you always going to do it as a way of risk-adjusting? Because I know in the stratification details it says that there is no risk adjustment or risk stratification. I didn't know if you were asking if there could be a way to do that. Were you looking for that?

MEMBER ADELMAN: No, not exactly. I was just confused about the denominator. Like we have the first measure where we are looking at documentation of DVT prophylaxis over everybody, and then the next one, documentation over just people with VTE. And it just seems the first one is more reliable.

Like I could ask Dr. Clarke about, if we measured on marking the site of every

case in OR and then have another measure of marking the site only when there is wrong site surgeries, and we often just move away from like judging, when there happens to be a bad outcome, that is when we judge. We try to look at everybody whether there is a bad outcome or not.

So, I don't see the point of having both of these measures. And the first measure seems like a more reliable one. That was the point I was trying to make.

DR. BRATZLER: I guess I would just argue that, when we would talk about this particular performance measure, it gets back to some of the discussion we had about VTE-1 where there were questions about the lack of validated risk adjustment protocols. And it also reflected the fact that the feeling of our Committee was that the majority of hospitalized patients are at risk of VTE events. In this day and age, most people have risk factors.

And so, the sense was that, if your rate of potentially preventable events was high, that you are probably not adequately risk-assessing your population and you need to focus on those that are developing VTE.

MS. WATT: You know, it really is a mechanism for hospitals to use to perform that quality improvement assessment. Okay. So, now we have this. Why? It helps to drill down, I think.

CO-CHAIR CONWAY: Iona?

MEMBER THRAEN: So, Richard confused me. And I am going to raise the question of, quote, "harmonization". You used the PSI-12 measure as a reference to this measure?

MEMBER WHITE: No, I know the PSI-12 pulls out all that administrative data on patients who go for surgery.

MEMBER THRAEN: Okay.

MEMBER WHITE: So, the coder or the software, or whatever is done, they are

pulling it out on medical patients as well. In other words, we are going to look at all the VTEs that develop in the hospital, essentially. There might be some subtle difference in codes.

I was just trying to see if this measure, how much it overlaps with PSI-12. It takes all the PSI-12 cases and you have to go look to see if they got adequate prophylaxis. So, I was just trying to clarify if it is that or just medical patients.

MEMBER THRAEN: So, the PSI only looks at those that have VTE?

MEMBER WHITE: No. Those that have a major operating room procedure and then develop VTE.

MEMBER THRAEN: And the VTE?

MEMBER WHITE: Right.

MEMBER THRAEN: And this looks at, of those that had the VTEs globally --

MEMBER WHITE: Yes, no matter what.

MEMBER THRAEN: -- who got prophylaxis?

DR. BRATZLER: Did they get prophylaxis, which is --

MEMBER THRAEN: So, they are related, but not the same?

DR. BRATZLER: Right.

MEMBER THRAEN: All right. That's all I needed.

CO-CHAIR CONWAY: Any further questions or discussion?

(No response.)

Janet, do you have anything?

MEMBER NAGAMINE: No. Thank you.

CO-CHAIR CONWAY: Okay. Shall we move on to voting? Jessica?

MS. WEBER: All right. Importance to measure and report, high impact, performance gap, and evidence. It's a yes/no question.

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Twenty yes, 2 no.

We have a new panel member.

Scientific acceptability of measure properties, reliability and validity. It's a yes/no question.

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: Can you come back to me? I need to look up what I put here. Hang on.

MS. WEBER: Sure.

Twenty yes, 1 no.

Janet, would you like to add yours? Or we can come back to you later.

MEMBER NAGAMINE: I put yes.

MS. WEBER: Okay. Twenty-one yes, 1 no.

Usability, high, moderate, low, or insufficient.

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: Mod.

MS. WEBER: Seven high, 14 moderate, 1 low.

Feasibility? It is a high, moderate, low, insufficient.

(Whereupon, a vote was taken.)

One more vote needed. Go ahead and cast your votes again.

Janet?

MEMBER NAGAMINE: Moderate.

MS. WEBER: Seven high, 13 moderate, 2 low.

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

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Twenty yes, 2 no.

MEMBER WHITE: Can I make one more comment to add to it? This gets kind of nitpicky, but we did a big chart review of a

lot of medical cases that were coded this way. It is really confusing when the diagnosis is made on hospital day one or two. No one can decide if it was present on admission or not.

So, the only thing I would say is I would like them to do the retrospective review of the cases that developed in the hospital after hospital day three. In fact, for the Joint Commission, if you go 24 hours, you still pass their test for starting prophylaxis and you get events occurring.

It is just very confusing. I don't know if it is worth the time of the hospital reviewing the cases that developed on hospital day one or two. So, that is the comment I will make.

CO-CHAIR CONWAY: Okay. Thank you.

We are at kind of a decision point here. Measure 0503 has been withdrawn. We can explain that later. And that leaves us with one VTE measure. Should we push on or

should we break for lunch? Push on? Okay, right.

Jean, would you introduce yourself?

MEMBER DE LEON: Jean de Leon. I am a wound care specialist at Baylor in Dallas.

CO-CHAIR CONWAY: Great, great.

And to the Joint Commission that is packing up and getting ready to leave, thank you very much for your participation this morning.

So, next will be Measure 0450, postop pulmonary embolism or DVT rate from AHRQ. And our reviewer was Jason.

Jason?

MEMBER ADELMAN: Yes. So, I should mention that when we went around I didn't say anything interesting about myself. There really is nothing interesting about me except that I have two very cute girls.

(Laughter.)

Okay. So, we had a phone call beforehand. Since the call, I think everybody here got an email that evidence was added based on the questions that we asked during our call about the evidence around the validity.

Our group I think all agreed, and you can see in the votes there, that this is a high-impact measure. It is really an outcome measure just looking at DVTs in postop patients and VTEs, and that there is a performance gap.

I believe that the software is reliable in pulling from the coding data information, but there is a question of the accuracy of the coding and, ultimately, the validity of the measure.

And so, last night these additional references came out. So, I pulled them and I emailed everybody. And I am just going over them because I think they are important.

So, there were four articles sent. And I have found one or two others. I will just summarize very briefly.

One of them is in review, so I couldn't pull. But the three, each one of them discussed the positive predictive value of the tool.

There was the one by Kyle Farney at the VA. It is called "Validity of Selective Patient Safety Indicators". This was a study published in 2011, but had data from 2003 to 2007. It actually looked at three PSIs, and this being one of the three. And for this particular PSI, they looked at 112 records, and the positive predictive value was 43 percent.

Another study by White, et al., in 2009, this was using UHC hospitals. The title of the article was "How Valid Is the ICD-9 CM-based AHRQ Patient Safety Indicator for Postop VTEs?"

And there, they looked at 121

cases, about the same. And the positive predictive value was 48 percent, about the same.

Then, one study was under review, as I mentioned. The last study was Henderson, 2009, 112 cases, about the same. This time the positive predictive value was 54 percent. So, you are talking about high forties to low fifties.

There was another article that I found that wasn't sent which actually was published by -- the authors were from AHRQ. It was in the Joint Commission Journal in 2007. Jim Battles was one of the authors.

In that study, the positive predictive value was 29 percent. So, you are looking at 29 percent up to 54 percent, average in the forties. So, to me, that really puts into question the validity of the measure, that the positive predictive value is really like 50 percent, just barely.

Second, another point I wanted to

make was that in one of the studies that was given to us, one at the VA, there were three PSIs in that study. The positive predictive value for iatrogenic pneumothorax was 73 percent and for accidental punctures was 85 percent.

And I just want to point out that this varying positive predictive value, we will see reports of all the AHRQ PSIs and you will see numbers. But if you were to correct for positive predictive values, one of them you would have to take 40 percent of the measures, the ones we are talking about. For accidental puncture, it would be 85 percent. And so, it is, to me, hard to interpret because there's such varying positive predictive values for the different PSIs.

And finally, the reason why I was asking the question from the Joint Commission about if the denominator would be published, because there was mention in the instructions about related competing measures. So, here we

have another measure that is up for discussion that is going to rely on chart reviews and other mechanisms, more reliable mechanisms, I think, to find the amount of VTEs. And it seems to me that perhaps we should favor that over something that has a positive predictive value in the high forties.

That is pretty much my comments.

CO-CHAIR CONWAY: Thanks, Jason.

Is AHRQ here for any comments?

DR. ROMANO: Hello. This is Patrick Romano.

Yes, so we have been through quite a saga with this indicator. So, let me try to give you a little bit of historical perspective.

So, we did collaborate with both the University Health System Consortium and the VA, as well as with the network of hospitals that joined AHRQ's Pilot Project to undertake the three studies described that generated positive predictive values,

basically in the high forties.

So, we obviously undertook kind of a careful examination to see what was going on there and what was the explanation for these false-positives. We found that the two most important explanations were that some patients came in with VTE that was present on admission. And second was that some patients had upper extremity thrombosis or superficial thrombosis that were getting labeled as VTE by the indicator because the codes, the ICD-9 codes, were non-specific. The codes for thrombosis were less precise than the codes for thrombophlebitis. And so, people prefer to use the codes for thrombosis, and they were defaulting to the non-specific codes.

So, what we did in response to that was two things. One is that we incorporated the present-on-admission information into the specification of the indicator now, so that those are excluded. And second, we petitioned the ICD-9 CM

Coordination and Maintenance Committee to change the codes actually for thrombosis, so that there are now separate codes for upper extremity thrombosis and superficial thrombosis, and also, to separate the codes for acute thrombosis and chronic thrombosis.

So, that change was just implemented in October of 2009, right? So, we have only one study now that has looked at this systematically since that coding change was implemented. And that was the additional reference that was under review.

In that study, we did two things. One is we worked with UHC again to look at a sample of patients who had total knee arthroplasty. They wanted to focus on patients who were known to be at high risk. And this was part of a case control study looking at potentially modifiable risk factors for those events. But, in the course of that, we basically found that the PPV in that population was 99 percent now after POA and

the new coding.

We also looked at a separate group of seven hospitals that volunteered to look at all their surgical cases. In those hospitals, using the new specification, the PPV was 81 percent.

So, basically, from those two studies, we have seen what we expected, which was a substantial improvement in the positive predictive value as a result of the combination of using POA information and the new codes.

So, that is what we are basically coming back to, to say that I think that we have made an effort to address that problem through working with the Coordination and Maintenance Committee for ICD-9-CM, with the coding community, and with, obviously, the state health data agencies that are now increasing collecting POA information.

CO-CHAIR CONWAY: Thank you.

DR. ROMANO: I might add just one

other point which is interesting from the study, which is under review, which is that we looked at modifiable risk factors because it was sort of a matched-case control methodology where we match cases in each hospital with controls.

And one of the things that we found was that controlling for age and gender and obesity, and so forth, risk factors for these events, all of these patients which were total knee patients, all these patients had some form of prophylaxis that was SCIP-compliant. But three risk factors, bilateral total knee as opposed to unilateral, odds ratio of 4.2; receiving pharmacologic prophylaxis instead of just mechanical prophylaxis, according to recommended doses, odds ratio of 0.5, and ambulation on or before the second postoperative day, odds ratio of 0.3.

So, these are the kinds of opportunities for improvement that we are

trying to identify and encourage hospitals to look for.

MEMBER ADELMAN: If I may, I would question I guess everybody, should we wait before affirming this request for the new request to be published and to be scrutinized, where we get a chance to see the methods and see the "N's" and everything else? Or is it acceptable to act on the data that was just given, you know, knowing that we haven't really scrutinized any of the research? I don't know the answer, but I would put that out to everyone.

CO-CHAIR CONWAY: Okay. Good question.

We are open for questions and comments.

Richard and then Saul.

MEMBER WHITE: I have two. One is I think Dr. Romano should make a comment or two about the fact that for the PSI-12 one of the unique aspects of that measure is it is

possible to get a really sick patient and they would be in the hospital for two weeks before they have surgery, right? And they get a DVT before the surgery. So, some of the loss of predictive value is that they didn't pick up the fact that it was a preoperative VTE.

So, the thing he brought up is something that I have been thinking about. Perhaps we could get two outputs from the PSI. One is a measure for everyone who got surgery on hospital day zero or one, all the elective cases, in which case I think it is going to even have higher predictive value, and then a total, you know, the PSI for all-comers, which is going to include some people in the hospital for 60 days who had to have a laparotomy or a test lump extraction on the 35th day but had a VTE on day seven, had surgery on day 35.

The real good numbers came out of the total knee. So, if we have to force them to have surgery early, then the PSI is

probably going to be an even better predictor. So, that report might be even better, I think, than the ones where you've got these super-sick patients.

The second comment is we have just finished an audit of the new codes for medical VTE. In other words, we have got all these new codes. We only look at the DVTs and PEs. And we look to see whether the ones that are in the hospital, medical patients, POA no, had it.

And again, the answer is it is very good, but if it fails in the medical patient, it fails with the people who are diagnosed on hospital day zero, one, or two, because, again, I think I mentioned that earlier. It is very confusing whether it was really new in the hospital or not.

So, some of these administrative cuts having to do with when the diagnosis is made or when surgery is made might improve the predictive value.

CO-CHAIR CONWAY: Great.

Saul?

MEMBER WEINGART: Yes. So, to Jason's point, I think the Committee is in an awkward position because the overwhelming weight of scientific evidence suggests that the measure may not meet our criteria. On the other hand, Dr. Romano describes some promising research that is just over the horizon, although, clearly, the results are excellent, but in a narrow population.

So, that would also make it a little bit awkward for us. So, I think it is in awkward. In some ways, I wonder if the wisest thing might be to defer a vote rather than to sort of repudiate the measure or to endorse it, but rather to postpone it.

MS. BOSSLEY: I think my one question is, how soon is the review coming out? I mean, that will help us decide, I think.

Patrick, do you have any idea on

that?

DR. ROMANO: Well, both of these papers are under review currently. I think that we do have the ability to share at least an abstract of the information with the Committee.

I mean, many of you are as familiar about journal policies as I am. Generally, journals do allow sharing of information with publicly-constituted bodies of this type. So, we will have to explore that a little bit further, but I am sure that we could create some redacted version of the documents that we could share with the Committee.

MEMBER WEINGART: To what extent do you think that the knee replacement population makes the results look better or worse than they would in a more general surgical population?

DR. ROMANO: I think certainly the knee replacement population makes the results

look better. So, I trust the 81 percent that I cited from seven general hospitals much more than the 99 percent, simply because the total knee patients are kind of selected to be relatively healthy patients when they are coming in for elective surgery.

By the way, to one of Jason's points, I don't want to be accused of covering up anything, the paper by Battles, it showed the lower PPV around 29 percent. I do have a copy of that.

The reason we didn't include that is because they did not specifically address the PSI. In other words, the PSI logic has certain exclusions that raise the PPV; whereas, they just purely looked at the underlying codes.

CO-CHAIR CONWAY: On this issue of having review of that data, we do have a Phase 2 set of measures to review. We could, if you will let us --

MS. BOSSLEY: We could or we can

at least huddle with John and Patrick. I don't want to jinx you, but you may not get through all your measures today and tomorrow.

(Laughter.)

So, if you don't, you will have at least one more conference call, and you may actually have one measure that we are still talking to the developers on whether they have full testing information to provide to you.

we may be able to come back to you and have a very brief call, not like the last safety project, I promise, and entertain this. So, if you want to, I think it would be helpful to talk through this measure all the way through. But if you want to hold any decisions until we get to touch base with AHRQ and figure out, is it Phase 2 or is it in a couple of weeks, a month, we can go from there.

CO-CHAIR CONWAY: So, why don't we see if there are other issues to get on the table? I think John had his card up, and then

we will come back this way.

MEMBER CLARKE: This is just a general comment that has to do with the patient safety indicators and the predictive value. And it illustrates the tension of using these patient safety indicators.

That is that my understanding is that patient safety indicators were developed in order for an institution to capture their patient safety adverse events. As such, they tried to cast a wide net in order to capture all the events. And when you want to capture all the positives, you inevitably have to capture more false-positives.

So, it is inherent that these patient safety indicators, because of why they were designed, are going to have lower positive predictive values than something else that could be developed in a "never event" kind of mentality where you were inarguable about what was inside the net.

I think the problem comes from the

fact that these patient safety indicators are now being used by secondary agencies as indicators of safety. I think that is where some of this tension lies.

But it is inevitable that they are not going to have positive predictive values of 98 or 99 percent. In fact, as a researcher, I would be concerned if they did because I would wonder how many things were outside the net that we weren't seeing.

CO-CHAIR CONWAY: Louise and then Iona.

MEMBER PROBST: I might be naive, but it seems to me, if it is not supposed to happen, I really am not as concerned about predictive value. I need to kind of have you explain more to me. If I don't want to have an infection, if it is zero tolerance and I don't want to have a DVT, I understand some of them are going to happen, but if you get too high of a predictive value, I think I would be concerned that the measure is not appropriate.

So, help me understand why this is a problem.

MEMBER CLARKE: In fact, you want to capture all the events. So, you say something like, if the patient has a positive BQ scan, we count them. Well, you are not going to get every patient with a DVT. So, then, you say, well, everyone who has an abnormal finding on chest x-rays consistent with DVT. Well, you are going to capture more, but you also are going to capture some people who didn't have DVTs. So, the wider you go in order to get every patient who has the event, the more false leads you have to follow up in the process.

CO-CHAIR CONWAY: Iona?

MEMBER THRAEN: Okay. So, I am stepping outside of the conversation and going in a different direction. There was a recent publication in April that looked at the AHRQ PSIs, the voluntary reporting of sentinel events, and the IHI global triggers, and the

evidence associated with that comparison.

So, my question back to you is that this is a claims-based, an administrative claims-based approach. Is there an equivalent IHI global trigger or clinically-based approach that would get us closer to where we want to go in terms of sensitivity and specificity that we ought to be considering in light of this measure as well?

DR. ROMANO: Well, the paper that you are referring to I think was really focused on the fact that the AHRQ PSIs really just pick out a very selective subset of events. And so, if you really want to understand the full spectrum of patient safety and patient experiences in hospitals, you really need a much wider set of events.

And the gaping hole, for example, is with medication errors and problems related to medication errors, which aren't addressed in our PSIs at all. So, that is a valid concern looking at the indicators of the set.

I think our strategy has been to focus on specific types of events where there are felt to be opportunities for improvement and perhaps greater actionability, and where we also have the ability to identify the accuracy of the data, to improve the accuracy of the data, and so forth.

So, I think that the argument that we would make is that, for a clear clinical diagnosis like postoperative venous thromoboembolism, where there is specific treatment that follows from specific diagnostic tests, the ICD-9-CM-coded data should give us what we need to know. And if it doesn't, then it is because either the coders aren't doing it right or because the codes aren't precise enough.

So, we fixed the latter problem. The former problem is an ongoing process of education.

But I guess I would sort of throw the question back to you. Like is it

necessary to have a completely sort of parallel process for collecting data when coders are already supposed to be going through the record finding diagnoses just like this that affect the treatment of patients in a hospital?

That is what we are striving for, is to use administrative data in creative ways where we can get not to 100 percent, but to an acceptable range of 80 percent or 85 percent or so. I think that is what we have seen in terms of the sensitivity of the indicators. The two most recent studies showed 87 percent and 95 percent sensitivity. So, again, we are missing a few of these events, but probably not enough to really make a big difference.

CO-CHAIR CONWAY: Okay. Steve and then Saul.

MEMBER LAWLESS: Yes, just a question for the people from AHRQ again. My preference with me would be, instead of just seeing an abstract, I mean the publication you

are talking about in print, the abstract, you know, it is kind of like looking at the National Enquirer headline and then you buy it.

(Laughter.)

And so, I would say that your judgment, if it is going to be that impactful. to wait until the article comes back. If it is not that impactful, then it doesn't really make a difference. But I would leave it to your judgment. But the abstract wouldn't do it. It would either be get an early release or not at all.

MEMBER WEINGART: So, I want to respond to two quick comments that were made, and then Patrick's comment about the use of administrative data for quality measurement.

I mean, I think one of the important points we have learned from using these indicators is that we need to code better. And if we code better, then we will get better measures. And I don't see the

chart review as an alternative, but as a complementary way of getting at this information.

To the question about PPVs, I mean, I think my first project ever was to work on the validation of PSIs. And Patrick is nodding because he tortured us over this for quite a long period of time.

(Laughter.)

And the initial concept was, to John's point, that we wanted to use this for case finding. You know, if the PPV is 20 percent, well, that means I don't have to review 100 charts; I only need to review a smaller number because I know it will be enriched in these events that I am looking for.

And I think that is kind of a well-heeled and well-established use for these things. The thing that people have been concerned about is, can it also be used as a quality measure to compare across hospitals?

And that is an area that Patrick has made a lot of his career investigating.

And so, I think there are two separate uses for this. One of the concerns is, if the PPVs are low and the sensitivities are low, then maybe it is not a very accurate measure, and hospital performance is being inaccurately presented. And perhaps we shouldn't be promoting the use of a tool that does this.

On the other hand, the value for finding cases that you think are potentially problematic for peer review, and so forth, that is I think well-established.

Equal time?

(Laughter.)

DR. ROMANO: I will recognize Saul's seminal contributions to the literature in this area with Lisa Iezzoni.

(Laughter.)

Really, their work on the complication screening program inspired the

development of the patient safety indicators. And so, I think what AHRQ tried to do was to build on the best of their findings and try to work on further specifications to improve the performance of the indicators and to get them out to a wider audience to stimulate improvements in coding. So, I agree with Saul.

CO-CHAIR CONWAY: John, is your card up?

MEMBER CLARKE: It was for my previous comment. If there's no other comments, how about we consider deferring this?

MEMBER THRAEN: I just have one quick clarification question. So, in light of the new research that you just discussed, the present-on-admission question to help with the predictive value, is that included in this measure as it is currently being proposed?

DR. ROMANO: Yes, it is, yes, as well as the changes in the coding

specification that we discussed, the exclusion of non-specific codes.

The issue that Dr. White raised that has not been addressed, because I think honestly there is some controversy about it, is there is a subset of patients, probably 10 to 20 percent of the false-positives, that we are labeling as false-positives, but they really did have a hospital-acquired VTE, but it was before the surgery. And some of those patients came in with a hip fracture, and they were left to sit around in a hospital for a week without prophylaxis. And they got a DVT. Big surprise.

Other patients had some kind of a complicated course with trauma and ended up having to go back to the OR after two weeks. In those cases, we might want to hold the hospital harmless for the fact that the patient got a DVT.

So, it is a little bit of a complicated situation with those hospital-

acquired, but preop thrombosis. Those are still in at this point.

CO-CHAIR CONWAY: We have had three or four requests to defer this. Would there be anybody here opposed to deferring this to our second phase of work?

Okay. Jason?

MEMBER ADELMAN: I just have one last question for Patrick. Today and tomorrow, there is a lot of PSIs and PDIs that we will be discussing. Saul and John made these points about the difference between the net for finding cases and then using it as a tool to evaluate hospitals.

And just looking at some of the references, the positive predictive values are all over the place. It seemed from what you said, the high forties was not acceptable and 80 percent now is acceptable.

What do you use? Like you could leave the tool today as is and not come here and ask to make it an official NQF-endorsed

measure. What do you consider a positive predictive value or sensitivity/specificity that gets to the level of where we can actually judge hospitals?

DR. ROMANO: Well, ultimately, I am going to say that that is a policy decision which is for the National Quality Forum and its Steering Committees and CSAC to make.

What we are trying to do is to present the information, to improve the indicators to present the information. There is certainly a lot of demand from stakeholders, especially in the purchaser community and the consumer community, to get these kind of indicators out there. But, ultimately, it is your call what the right threshold is.

CO-CHAIR CONWAY: So, if we defer, one thing I would like to ask the original Workgroup on VTE if you will be the people that will agree to review the additional data?

And then, two, we would have to

get some agreement on what data we would like to see. Is the request that it be more than an abstract? Is that acceptable?

DR. ROMANO: Absolutely. Thank you.

CO-CHAIR CONWAY: Okay.

DR. ROMANO: I will confer with staff about the circumstances under which we can share that information.

CO-CHAIR CONWAY: Okay.

And then, Richard?

MEMBER WHITE: I am not sure totally it should be focused on the positive predictive value because I think for reporting the key issue is risk adjustment, right? You've got a hospital that takes on the tough cases, and, okay, you've got better PPV. You get a higher rate, right? It's got a good positive, you've got it, but now you have got to risk-adjust appropriately.

Does AHRQ have any data from any hospitals where they have a high observed-to-expected to kind of find out whether or not

the excess cases were much more difficult, impossible to predict? Is there any feedback on the public reporting part of it, which has to do with the risk adjustment that is done on this administrative data?

DR. ROMANO: Very good question. I don't know if -- I think Jeff Geppert, who leads our analytic work, is on mute.

MS. BOSSLEY: Operator Jason? Operator, can you see if Jeff Geppert is on the line?

OPERATOR: Absolutely.

MS. BOSSLEY: And open his line, too.

DR. ROMANO: In the meantime, I will say that the risk-adjustment model that is used for this includes a set of age coefficients, a set of coefficients for modified DRGs, basically, the type of surgery that the patient is having, the body system in which the surgery occurred, and about 18 or 20 different comorbid conditions that may

increase or decrease the risks of the overall C statistic which measures the determination of the model is 0.745, which is about average for these kinds of outcome measures.

To get to your question, I don't think we have any specific information about the performance of the risk-adjustment model across different hospitals. It is an interesting question, more difficult to organize those kinds of studies. I would certainly be interested in collaborating with --

CO-CHAIR CONWAY: Here's a suggestion: I would suggest this line of discussion will occupy us most of this afternoon, since we are doing PSIs and PDIs this afternoon. So, we may want to kick that down the road a little bit.

So, it sounds like, do we need to formally vote on deferring?

MS. BOSSLEY: No.

CO-CHAIR CONWAY: Okay. It looks

like there is support for deferring.

The 0503, Heidi could explain what happened there. The American College of Emergency Physicians pulled that out.

MS. BOSSLEY: Right. So, several of the measures that are under consideration have first been reviewed within -- I'm sorry, clearly, I haven't had enough coffee today. Several of the measures were reviewed where they had met all the criteria with the exception of two, reliability and validity. They had not yet tested the measure.

This was one of them. You will have several others. What we had done was incorporated them into full maintenance because they got into the three-year review.

Emergency Physicians are in the process of testing this measure now. So, we want to give them a little more time to bring that data back to you. So, that measure we will just move to Phase 2. It is in the summer. And then, you will be reviewing it at

that point.

CO-CHAIR CONWAY: Do we need to go to public comment?

MS. BOSSLEY: That would be good.

CO-CHAIR CONWAY: Jason, the operator Jason?

Where did he go?

MS. BOSSLEY: I don't know.

Is there anyone in the room who has any public comment?

(No response.)

Well, we will have another period as well. So, hopefully, Jason comes back.

CO-CHAIR CONWAY: So, lunch, that sounds good to me, Heidi.

(Laughter.)

MS. BOSSLEY: So, lunch is outside.

CO-CHAIR CONWAY: All right. Let's break for lunch.

(Whereupon, the foregoing matter went off the record at 1:11 p.m. and resumed at 1:40 p.m.)

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

1:40 p.m.

CO-CHAIR CIPRIANO: Okay. One of the things that several of you have asked, if we could describe the remaining work for this group following this meeting, which will span into next summer and fall. Heidi is going to go over that.

There was a little bit of information in the original slide deck for the orientation for the Committee. So, you may have seen something a while ago.

So, Heidi is going to walk through that, which, again, is sort of an expanded timetable. It includes not only our work, but then the subsequent approvals that occur as part of that.

MS. BOSSLEY: Okay. So, I am first just going to talk about this phase. So, we divided this project into two phases, in part, because of the number of measures we knew we had just undergoing maintenance.

Safety is one of our biggest groupings of measures in our portfolio.

So, we are currently in the screening and evaluation piece, which is what you are doing today and what you will do on perhaps one conference call after this.

What Andrew, Jesse, Jessica, and myself will do in the next few weeks is take all of your discussion and your votes and write up a report. And it is a very technical report now where it discusses the overarching issues that you have discussed.

I think we will have some on the outcome and process links. There's a few things you have talked about even just from this morning that I know we will pull out into broader, more overarching discussion points.

Then, we will actually have a table for each of the measures that will show your ratings of each criteria and the rationale as to why you went about voting the way you did. So, all your conversation here

today is what we are taking notes on furiously, and we will try to summarize.

That will come back to you to look at. We may have a conference call, depending on where we are with everything, where we are with the measure you just deferred, where we are with the one measure we have that we are talking to developers on whether they have tested or not.

If you get through every measure here, you may actually not have any conference calls after this. And we may just write up your report and then have you review it, and we will go out for a 30-day public and member comment.

So, typically, with the comments, we will get anywhere from 150 to 200 to 300 comments. We will, as staff, take that to create themes out of it, have you look at every individual comment as well as the major themes.

And then, you may revisit the

recommendations you just made today, and you may be swayed by the comments that you receive that you want to change your recommendation. Either you will or will not recommend a measure, that kind of thing. You may actually add more gap areas because that is the other part we would like you to identify. If not today, we will definitely do it over email. You started doing it just even in your discussions.

All those comments are then taken along with the report and your recommendations to our Consensus Standards Approval Committee. Pam sits on that group.

Their responsibility is to make sure, No. 1, you follow the process and the criteria; to make sure that the recommendations you are making fit within the parameters of where they think the portfolio should head. And then, all of that goes -- I'm sorry, I misspoke.

So, it goes out for comment and

then it goes out for member vote. That, plus everything else, goes to the CSAC.

And then, it goes to the Board for ratification. Then, we have a 30-day appeals process, where any individual can actually come back and say they would like the CSAC and the Board to revisit a decision that was made on the measure endorsed.

So, that is the timeline we have got on this phase. We are basically going to replicate that same thing with Phase 2. So, we will schedule another meeting with you, not in June. I don't know what month we will go into. Well, we had June marked. So, we will look at what date we are going to pick.

And that phase is looking at, do you remember what topic areas, Andrew?

MR. LYZENGA: We have falls and pressure ulcers sort of grouping -- I'm sorry -- falls and pressure ulcers as sort of a group of measures; a group of mortality measures, the AHRQ mortality indicators.

I am trying to think of what --

MS. BOSSLEY: We will get to the list to you.

MR. LYZENGA: Yes, I will get the list.

MS. BOSSLEY: I have lost track.

Phase 2, and that is in the second round.

MR. LYZENGA: Oh, HAI measures as well. I think those are the three main groups.

MS. BOSSLEY: Okay. And so, you will go through the same process. We will divide you into Workgroups. We will have you then come as a group together, make your final recommendations, and then it follows through the process.

The timeline on that one right now is that we would have a call for measures starting in January. Well, actually, I don't know if we will do a call for measures because we already did one.

We may have a few new measures come in that we know need to be done, given all the federal programs out there.

Submission would be due by sometime in March. And then, we would have you meet, let's say it is May or June, and then go through the same process. So, that is kind of the timeline we are looking at and the next steps.

Does that make sense?

CO-CHAIR CIPRIANO: Any questions at this point?

Jim?

MEMBER SMITH: As a novice in this process, I just want to thank the Chairs and the staff for both that review that I needed, but also getting to this point. It has been very informative, and thank you.

CO-CHAIR CIPRIANO: Thank you.

I think the other thing is that, with more lead time with the second phase of work, it won't feel quite as much of a sprint

trying to get everything together.

Okay. What we thought would help for looking at Workgroup C's measures is you see the way they are organized on the agenda, the first four do deal with PDIs and PSIs. We thought it might be beneficial to have a general discussion about that prior to the detailed discussion of each of the measures.

And so, we would invite -- Patrick, are you chewing -- we would invite you to help introduce that discussion.

DR. ROMANO: Right. So, the rest of the measures that we will be talking about this afternoon and tomorrow from AHRQ are in the realm of what you might call procedure-related mishaps. They obviously reflect different types of mishaps. Accidental punctures, lacerations is an obvious generally surgical mishap, as well as foreign body. We will be talking tomorrow, I think, about transfusion reactions which are a transfusion-related mishap.

So, each of these events has sort of a clearer component of preventability, if you will. And some of them are more common.

APLR, PSI-15, which we will be talking about shortly, is relatively common. But transfusion reactions and foreign bodies after procedures are very rare, very rare.

So, I think it raises some questions that started to come up in the discussion this morning about what is the role of these measures and how should these types of measures be used.

The accidental puncture or laceration measures and the iatrogenic pneumothorax measures are reported as risk-adjusted rates, recognizing that different patients have different risk factors that put that at higher or lower risk of these events. And that is incorporated into the risk adjustment.

But foreign body and transfusion reaction are so rare that they are reported as

counts rather than as rates. And most hospitals actually have zero. And the hospitals that have one or more generally only have one during any given reporting period.

So, this is a very different type of measure, and I just wanted to kind of put this on the table initially. Those measures, in particular, are not really designed for comparative evaluation of hospital performance. They are submitted, they were submitted in the spirit of encouraging transparency.

So, as NQF's perspectives have evolved, there may be a need to sort of have more of a discussion about whether those types of measures should still be NQF-endorsed. But the principle is that, for those measures, we are not reporting rates; we are reporting counts of events.

And we are suggesting that it should be in the public domain to foster open discussion and debate about what happened and

how to prevent those events in the future. But it is not intended for direct comparison of different providers.

So, I don't know, John, if you want to add anything to that. But I just wanted to kind of lay out that framework before we get into the discussion of these specific measures.

CO-CHAIR CIPRIANO: Thank you very much.

Saul?

DR. ROMANO: Saul was going to comment on the pediatric ones. And, of course, the issues, the pediatric ones are designed in parallel with the adult ones, but the pediatric ones are generally even rarer than the adult equivalents. So, the issues of reliability and difficulty of measuring and comparing hospital performance and ranking hospitals are even more pressing for the pediatric versions.

CO-CHAIR CIPRIANO: John?

MEMBER CLARKE: We discussed this in our group. I support the comments that were just made.

There are basically two kinds of events. One that you could envision, even with the best care you might get an adverse outcome. And obviously, those are risk-adjusted and are only really properly interpreted if there is a risk adjustment.

There are some things which the NQF has called serious reportable events, but which stem from the concept they should never happen, that should never happen under any circumstances. And under those premises, they need to be risk-adjusted because there's no one who is at risk. You might argue that someone who is obese is at risk for a retained foreign object, but that is not going to alleviate you from the responsibility of not having a retained foreign object, even in that patient.

And there is a second sequelae

that comes from that. That is this idea of rates. We discussed this as well.

When you have an event that should never happen, the issue is, did it happen or did it not happen? And so, a rate is kind of irrelevant because the only acceptable rate is zero. Whereas, if an event is something like an infection that could happen, then you are just trying to drive the rate down, and you need to have some kind of risk-adjusted rate.

The other reason for having this, there are two other implications of having a rate. One is that, if you talk about a rate and you are trying to drop the rate down, it is not axiomatic that the correct rate is zero; whereas, if you have a number and you are trying to drive the number down, the logical conclusion is that the correct number is zero. You are actually trying to achieve zero.

And with these rare events, as Patrick mentioned, the other implication is,

if you have a rate that is in the order of 1 in 5,000 which is a retained foreign object, or 1 in 10,000, which is a wrong site block, if you want to prove that your rate has dropped significantly, I am going to say 1 in 10,000 to 1 in 20,000, you need so many cases that the rate becomes irrelevant because I can't provide any statistical validity to a change in the rate from 1 in 30,000 to 1 in 80,000. We don't have enough denominator to do that.

So, I am all in favor of these events that should not happen to anybody being numerical rather than risk-adjusted rates.

MEMBER THRAEN: And then, a third issue that came up in our group was the idea of why there were separate pediatric measures for the same problem, and why it wasn't a combined measure with stratification.

CO-CHAIR CIPRIANO: And, Patrick, is that something that you guys will answer?

DR. ROMANO: Well, in some sense

it is a labeling issue. You know, it is really when we originally designed some of the patient safety indicators based on the work that Saul and his mentor did years ago at Harvard, they included both adults and children. But, then, stakeholders said to us, well, you know, "We are particularly interested in children" or "We are particularly interested in adults." And so, we separated the indicators, and AHRQ supported a particular process to develop pediatric indicators where we convened a whole separate set of clinical panels with pediatricians and obstetricians, and so forth, to focus on pediatric indicators.

So, to some extent, it is an artifact of the process by which stakeholders requested a separate set of pediatric indicators, and then we convened separate clinical panels to review and endorse some of those indicators.

MEMBER THRAEN: Because you went

through a separate process, are there inherent differences between the adult versus the pediatric version?

DR. ROMANO: The major differences for these indicators, for the ones that are risk-adjusted, is that the risk-adjustment models are different, and they incorporate different factors, as you might expect.

MEMBER THRAEN: Okay. All right.

DR. ROMANO: So, the comorbidities that apply to adults don't apply to children. We don't have too many kids with diabetes, but we have a lot of kids who have congenital heart disease or congenital anomalies.

But, you know, this is open for discussion certainly. So, I think that there would be a possibility of consolidating these indicators, but it is just not the process by which they were established.

CO-CHAIR CIPRIANO: Charlotte?

MEMBER ALEXANDER: Your comments about the low numbers and wishing to report as

a pure number, as we are looking at quality and trying to understand if we are improving our process and what the value is for quality reporting, it is helpful for me to know where I came from and where I am today, and where I might go tomorrow.

And so, the talk as I heard it in our discussion was partly to ask for a rate or some way that we could trend, that we could get a grasp on where we are on and is this reporting doing us any good, or are we just reporting to be reporting.

DR. ROMANO: Well, I think what we do is within an individual organization you can't really trend these. In other words, you can look and say: "Okay, well, we have been event-free for two years and that's great. We're on the right track, and, hopefully, we will stay event-free for more years to come." But you can't trend it in a statistical sense.

On the other hand, we can trend at the population level. And so, there is, I

think, in some of the forms there is some data about these events. Most of these events have sort of dropped from 10 to 20 percent overall over the past five or six years. And we hope that they would continue to drop further.

So, that is the level, I think, at which we can do trending for the population to see if we are driving improvement in the overall healthcare system.

CO-CHAIR CIPRIANO: Vallire?

MEMBER HOOPER: I will tag onto what Charlotte said. I think, as a group, we were somewhat split on count versus rate. Because, while statistically you would need a large set of numbers, from a consumer perspective, if you are looking at a general region, I think it is very important to know, was it 1 in 1,000 cases; was it 1 in 10,000 cases. You know, trending types of cases with wrong site surgery, there are certain procedures that are more prone to wrong site/wrong procedure as opposed to other

areas.

So, I think that while we appreciate the statistical issues related to trending up and down, that at the same time there were a good number of us that would still like to see a numerator and a denominator, and particularly at the regional and local level. So that the healthcare consumer can truly look at these numbers and make some decisions.

CO-CHAIR CIPRIANO: And I guess, Patrick, a question back to you, then, is, what we are hearing is, does AHRQ -- because I don't know -- does AHRQ do that kind of rollup and, if so, where do you report that now? Because, again, it would be non-specific to the measure, because the measure is coming forward as an institutional report, versus what aggregation can AHRQ do in order to satisfy that need?

DR. ROMANO: Yes, I think most of, if not all, of these measures have area-level

versions. So, if you go to the qualityindicators.ahrq.gov website, you will see that there is an area-level version of these indicators, which is generally designed for application to counties or states, although it could be applied to smaller areas as well.

And there are also some comparative benchmarking data that are available on the AHRQ website and through the HCUPnet utility which would allow you to look at the trends over time in a particular area.

CO-CHAIR CIPRIANO: Thank you.

And so, I think maybe what is also inherent in the discussion is that, with subsequent reviews of these measures, those regional and national trends would be reviewed, again, to look at whether or not the measure should be continued.

Does that make sense, I mean, if the group had that discussion? In other words, would we need to keep the measure? If,

in fact, this national/regional rate were dropping so dramatically that it was no longer an issue, which would be the only way we would know, should those data be part of the review, subsequent reviews?

Okay. So, let me see, we have -- is it Tracy? Yes. And, John, is yours still up as well? Okay. And then, Susan. Then, we will come over here.

MEMBER NAGAMINE: And my hand is up.

CO-CHAIR CIPRIANO: Okay.

MEMBER WANG: I appreciate the discussion on the rate versus count because that is one of the challenges I had when I was looking through these measurement sets.

I think, as a consumer, also as a non-clinician in this group, I appreciate information being reported, whether it was count or rate. But I wanted some guidance from NQF regarding, when we are evaluating the measures, if it is a count, so for me, it does

not pass some of these scientific reliability/validity testing, if I use these rigid criteria, most likely we are not going to be able to endorse this metric.

So, discussing this metric, I wanted some guidance on how we should be evaluating this.

MS. BOSSLEY: That is a good question. I think it would be helpful if we actually get into it and talk about the scientific acceptability of one of the measures. Because that issue of whether you could actually evaluate the measure on reliability and validity based on a count versus rate, I don't know that I have ever heard a committee debate that. In part, you are just looking at how that measure is constructed and the data that they provide based on it.

But let me ask -- I don't want to put Karen on the spot, but -- go ahead.

CO-CHAIR CIPRIANO: Well, Steve,

you're going to address this point? Go ahead.

MEMBER LAWLESS: No, I was just thinking in terms of the count versus the -- you have such a low number. It is a sentinel event or it is a "never event". And you treat it as that and you make it public as that, and try to create something that looks like is there a rate on top of that, just something that shouldn't happen.

I think there are forums for that piece. I don't necessarily see the public understanding of, if you have one and you stand out, and there's a graph and everybody is zero and you have one, it gives an impression that is not really there.

CO-CHAIR CIPRIANO: Okay. Susan, Jason, Lisa, and John, and then I would like to move to the measure. Oh, I'm sorry, who's on the phone? Janet.

MEMBER MOFFATT-BRUCE: One of the things our group actually discussed at length was, while these are "never events" and the

counts are reasonable, it is a fairly small group that we are actually looking at here. These measures speak to general surgery patients, which I can assure you this happens in every type of surgical patient.

So, is there a consideration for making this a much broader and, therefore, probably more scientifically-valid measure, whether or not it is a rate or a count, to more applicable surgical procedures?

DR. ROMANO: I don't think that is quite correct. I mean, these measures, the foreign body measures apply to almost any hospitalized adults. The accidental puncture/laceration measures have fairly limited exclusions for certain types of surgery, and so forth, transfusions.

MEMBER MOFFATT-BRUCE: But I think we need some clarification. Perhaps I am not reading the -- when I look at "subjects/topics areas", it says surgery, general surgery.

DR. ROMANO: Oh, that is just some

boxes that we have to check off on the NQF form.

(Laughter.)

MS. BOSSLEY: We can go back and revisit where boxes should or should not be checked.

MEMBER MOFFATT-BRUCE: Because that was part of our discussion in the group.

MS. BOSSLEY: Yes. So, we allow developers to pretty much select whatever they would like to say this measure applies to because it helps with the search engine that we have that, once it is endorsed, people can find it.

But what we are finding is that, by allowing that broad categorization, you are getting probably more than you want. So, I think we need to revisit whether it probably makes sense to include it or not.

DR. ROMANO: In general, it should be interpreted as general, not general surgery.

MEMBER MOFFATT-BRUCE: I am in absolute agreement with you, absolutely.

CO-CHAIR CIPRIANO: Okay. Good point. We can come back to that.

Jason?

MEMBER ADELMAN: So, talking generally about the PSIs and PDIs and sort of bringing it back to the conversation earlier, all of these measures, to me, they are different than the others that we have discussed and the others that we have reviewed.

The ones that rely on chart review, I feel like there is a lot less, I will call it false accusations. Like, for example, at our institution we find that we have five pneumothorax. And then, we look and three of the five weren't pneumothorax at all; it was just miscoding, and it doesn't feel good.

Then, people dismiss the whole AHRQ PSI tool as not valid. And also, they

are upset by it because the tool is accusing us of doing things that we didn't do.

I understand that there are validity issues in some of the other tools -- maybe because of lack of charting, something was missed -- but not as much of these false accusations. There is probably a better term for that. And because the numbers are so small, they feel very real.

I had asked earlier Patrick, and he deferred back to us about, what would be a good positive predictive value? And he deferred to us. And I would almost ask NQF, like we are physicians and nurses and patient safety experts, but it is almost like a statistics question. Like I want my statistician back from the medical school to come and ask him this question.

I know you weigh-in in a very formal way on what makes good evidence. I feel like 40 percent of a positive predictive value was generally accepted as bad, and 80

percent seems to Patrick to maybe be okay. And what if it was 65 percent? Then, where would we be? And am I the right person to judge that?

And so, perhaps NQF could help because it crosses all these measures. They seem very different than everything else.

I guess that is what I wanted to say.

MS. BOSSLEY: Sure. So, I may go see if our resident methodologist can come up to help with this because I am in no way -- I am a nurse. I didn't quite study this as much.

But I will tell you, we had the Testing Task Force take a look at our criteria last year. They struggled with, is there a way to provide even more guidance on what C statistic, what statistic, what would you be looking for? And they felt that they couldn't do that. They couldn't give you an absolute.

So, it is to a certain extent at

the discretion of the Committee on what you feel is appropriate. That is how you do your ranking of the reliability and the validity.

You may rank your reliability low because of the results you see. You may also rank the validity low. And if those are low, then you would actually not move the measures forward.

What they have done, and AHRQ can talk more about their testing because I went and looked at it. I didn't want to answer the previous question because I hadn't looked at it in a while.

We allow testing at either the data element level, so individual data elements, or at the measure score level. And that is what they have done, which is look at the counts, the data, across and done a signal-to-noise ratio on it, and provided back, I think it was kappa statistics on it. I will have look again because I have lost track.

You need to look at that and determine whether you feel that it is sufficient to support the measure as it is specified. If you need additional assistance, though, we are happy to ask our staff to take a look at it who have more expertise in this or have an outside consultant take a look at it. So, that is something I think you just need to let us know.

But we haven't yet felt comfortable giving a hard-and-fast because it does depend on the measure, the level of measurement you are talking about, the amount of patients you are looking at. There's no many variables, they couldn't come out with a specific. So, it is a little vague intentionally, and I'm sorry about that, but yes.

Does that help?

CO-CHAIR CIPRIANO: Okay. Lisa?

MEMBER McGIFFERT: I wanted to weigh-in on the rate-versus-number issue. I

think that we should always try to give as much information as possible in different ways because every consumer looks at things differently. Some people look at pictures, and some people look at numbers. And some people want to know all the background stuff, and some people just want stars. So, that is always a factor.

But I think I agree that with these "never events" the number is absolutely essential, and the rates are pretty meaningless to consumers because it is such a weird rate.

But I also agree with you that there needs to be some context. That can be bed size of the hospitals. It could be some of the states arrange the information by type of hospital. So, you put all the trauma centers together and you put all the rural hospitals together. And so, there are lots of different ways to do that.

You know, I was on another NQF

committee on frameworks, on how to present information. And I know I advocated to get that in there. I am not sure that it made it. But I think that that is the kind of advice that should go along with this. But putting it in context by size of hospital might be a slight bit of difference than putting it in a rate, you know.

CO-CHAIR CIPRIANO: Okay. John?

MEMBER CLARKE: I just wanted to follow on this rate business. As Patrick mentioned, in a hospital which either does or doesn't have an event, a rate is really irrelevant. At the national level, the only difference between a rate and a number is that you have also collected the denominator.

The only issue is when it comes to comparison. And my concern about comparison is that people will make false comparisons if they compare, say, Minnesota with Pennsylvania, for example, false comparisons because our definitions are different. Diane

Rydrych at Minnesota just has done a survey of all the state reporting in every state of wrong site surgery, and every state has a different definition of what wrong site surgery is.

And then, in addition to that, if our rate is 1 in 30,000 and her rate is 1 in 60,000, is that different? The average person on the street would conclude it is, when, in fact, there may be no statistical difference between the two at all.

I also would like to address Jason's comments and maybe steer the Committee in a different direction. Because the predictive value of a positive test is not an indicator of the test. It is a combination of the indicator of the test, the sensitivity and specificity of the test, and the prevalence of the problem in the population. And you can change the predictive value of a positive test by doing nothing to the test but just changing the population being tested.

If you want a parameter of the test itself, you use the ratio of the sensitivity true-positive rate and the false-positive rate, which is called the likelihood ratio. So, if you want to get into a measurement as to what is the correct number to cut off, it wouldn't be a number based on the predictive value of a positive test. It would be a number based on the ratio between true-positives and false-positives, which is called the likelihood ratio. And that would be the correct parameter to use to evaluate what you are doing.

CO-CHAIR CIPRIANO: Okay. Thank you.

Iona?

MEMBER THRAEN: So, along the same lines -- and this may be too far out there, and I will appreciate being pushed back into the box, if it is appropriate -- one of the things I am struggling with, and maybe it is my need for a little bit more concreteness in

context, as people have described, and, again, we are in the maintenance phase of these measures. So, the assumption, operating assumption, is that the sponsors have collected data with these measures in some fashion or another.

And for purposes of understanding how these measures translate into information, it would be helpful -- and I don't want more work; I don't want more information -- but it would be helpful to see what that data looks like. Because we are trying to do is we are trying to move towards knowledge.

And if the way in which it is currently constructed yields some way of presenting information, and we look at that information and it doesn't make any sense, doesn't give real value, it helps for me, anyway, to bring that contextual framework to these measures that we are looking at in the abstract.

CO-CHAIR CIPRIANO: Patrick, did

you want to respond at all?

DR. ROMANO: I will just wait until we get into the individual measures.

CO-CHAIR CIPRIANO: Okay. Janet?

MEMBER NAGAMINE: Yes, my question about the general group is about added value. Given the small numbers -- and I am assuming these are all reportable events that will have had a root-cause analysis done, and that the Joint Commission will have aggregate data -- it seems that there is sort of a mechanism to address these events.

And so, I guess I am just kind of generally wondering, what would be the added value of reporting them, particularly if these rates or numbers may or may not make sense to people, and they may or may not be accurate? Like someone mentioned the five pneumothoraces. It feels bad, but they didn't actually really even happen.

And so, I guess that is my question going into this.

CO-CHAIR CIPRIANO: Well, I think in general terms, any Joint Commission reporting process would be completely separate from what the use of this measure is. And so, it does not really play into our deliberations.

MEMBER NAGAMINE: So, I guess what I am saying is, what is the added value of doing this? Because what we want to do is make sure that we address these problem areas, and it seems to me that they may be addressed already in a different venue.

CO-CHAIR CIPRIANO: While I think we would agree, I think that is beyond the scope of our work to say something --

MEMBER CLARKE: May I comment on that?

CO-CHAIR CIPRIANO: -- is being done.

MEMBER CLARKE: I think one value, Janet, is that the NQF provides consistency. For instance, in Pennsylvania we rely heavily

on the NQF definitions of wrong site surgery and retained foreign object, and so on and so forth.

And I think to the extent that the NQF can develop a process that is nationally embraced, it helps the various states who are charged with monitoring these events. And so, I see a consistency as a useful byproduct of these kind of deliberations.

MEMBER NAGAMINE: Got it. Thank you. Thanks.

CO-CHAIR CIPRIANO: Carol?

MEMBER KEMPER: Just for a point of clarification, for the Joint Commission it is not required to even report a sentinel event to them, as long as you are using the process that they establish. So, it is certainly they wouldn't be capturing all of these.

CO-CHAIR CIPRIANO: Okay. Thank you.

We would like to move into the

actual measures. We will probably not get through the four measures that we have been talking about within the context because we are going to need to take a break on those from 2:30 to 3:30 because we are going to lose Patrick for that time of discussion.

But let's go ahead and start with Measure 0344.

And, Charlotte, I think that's -- no, I'm sorry, that's not you. Steve has 0344.

MEMBER LAWLESS: I have nothing to add to the entire discussion. We can move on to the next measure.

(Laughter.)

Measure 0344 is a pediatric measure, obviously, accidental puncture or laceration rate. The numerator is present at discharge -- this is using administrative data -- that have had a coded, ICD-9 coded, accidental cut, puncture, perforation, or laceration during a procedure in a secondary

diagnostic field. The denominator is all surgical and medical discharges under age 18 in specific DRGs. They do exclude in this normal newborns, the very, very low-birth-weight babies, and probably due to the powerful orthopedic lobby, complex spinal cases in orthopedics. I don't understand why they would be excluded, except they are probably so bloody anyway that nobody could tell.

But, anyway, that was the measure. What was striking was that the rates or the incidences were very low. They are a percentage of a thousand cases across the board.

I think some of the numbers they are actually quoting are actually even outdated from the newer data that has been published.

And the risk adjustment, there is some risk in terms of type, you know, teaching hospital, non-teaching hospital, age,

whatever. But some major risk factors are not in the risk adjustment. And that is by specialty, whether it is a pediatric specialist doing it or an adult specialist, non-pediatric-trained person doing it versus a pediatric surgical person doing it; body part, which makes an impact. If you are doing belly surgery on someone versus you are doing retinal surgery, the only difference is visibility as it is occurring.

Whether the child has had a prior surgery or not; you dealing with small cavities, and that was not put into it. So, a prior condition would be was that cavity entered prior to that, and that would be a risk factor, or type of procedure.

And again, pediatric hospital versus non-pediatric hospital.

The measure itself has been reported for years. So, there is NACHRI and the CHC hospitals have been getting this data for years. They have been collecting it. It

has been out there. It has been low rates. So, it is not surprising or it is not new.

However, what has been new is that there is a group, a pediatric offshoot of the National Surgical Quality Improvement Program, or the NSQIP program, that actually is now for pediatrics. It is up to about 45 to 50 of the pediatric specialists across the country looking at this type of thing.

And their rates by specials vary dramatically. They do their reviews not based on administrative data; they do their reviews by direct case reviews and 30-day followups.

I don't have the rates in front of me, but the rates do vary from zero to a very, very small percentage. And I think they are all from NSQ.

So, there is a newer group looking at this in a lot more scrutiny than the historic by administrative coding because you do rely on administrative coding on the practitioner saying, "Whoops, I hit the

vessel," and they may or may not done that. So, there are some concerns along those lines.

And then, if you look, I think somebody pointed it out -- I think John Clarke brought it up -- if you look at the number needed to treat to see a real difference among groups, the number needed to treat starts getting into the thousands. And so, going from a .007 to a .002, we will find that most institutions it gets to be, well, where is the real difference here and where is the variability?

And then, the final thing I would mention is that -- and I couldn't get this from NSQ -- was whether things like central lines and putting in central lines, where from personal experience, because I am a pediatric intensivist, you do tend to lacerate vessels sometimes putting in central lines. That causes a big problem whether that would be considered a secondary or not. Or during a cardiac catheterization, the same thing

happens, or during a chest tube placement you may have blood, which by nature is hitting a blood vessel. So, I don't know if they are included or not.

So, not a new measure in itself, it has been reported, so it is not a surprise. But I think from a standardization, I think there has been some refinement since this data was actually captured and numerous sources of data which may be able to be brought into this.

CO-CHAIR CIPRIANO: Patrick, would you like to comment on 0344? Specifically, if you could address an option for different data reporting, I mean rather than using only claims data?

DR. ROMANO: Oh, okay. Well, in general terms, of course, all of the AHRQ indicators were originally designed to be used with administrative data. That was the genesis of the program, was that people wanted to -- there was a demand for indicators that

could be applied to administrative data. And so, AHRQ responded to that demand.

Now in the last couple of years, we have seen that some states are beginning to add more data elements to their administrative datasets. And of course, as users transition to electronic health record systems, they have additional data that is available to them internally.

So, we have done some pilot work, for example, incorporating laboratory data into the design, particularly for the risk adjustment of selected indicators. So, that is a trend for the future.

And I will encourage John to say something about AHRQ's priorities for development and evolution of the measures.

Just to address a couple of technical comments, so the risk adjustment, because these are rare events, that limits the number of parameters that you can estimate in a risk-adjustment model. And so, this risk-

adjustment model has a C statistic of 0.93, which is actually a very high C statistic. And it is driven largely by the body system that was operated on. So, certain body systems, of course, have much higher risk than others.

And it is driven by a marker, an indicator, of basically the number of procedures, and whether it was a diagnostic or therapeutic procedure. Obviously, therapeutic procedures are higher risk than diagnostic procedures. Patients who had multiple procedures are at higher risks than patients who had a single procedure. So, that is part of the risk-adjustment model.

But, of course, it can't account for anything prior to the index hospitalization. That is an inherent limitation of using these kinds of data.

But the overall C statistic is 0.93, which is quite, quite good for these types of models.

The point about there's no question that there is some heterogeneity in this type of an outcome indicator. So, there is a mixture of different types of lacerations and punctures. And, yes, the physician documents that they punctured the carotid artery and that they had to do something, they had to have a nurse at the bedside for six hours to tamp down the bleeding, then that could be certainly captured.

On the other hand, if it was just sort of routine bleeding in the course of a chest tube insertion, for example, that typically would not be coded because there wouldn't be any defined anatomic structure that was punctured or lacerated. So, generally, in order to kick in this code, there would have to be documentation that a specific structure was punctured or lacerated.

Ideally, there may be a separate code to indicate what specific structure that is. But the coding rules don't require the

use of both of those codes. So, that is why we haven't been able to incorporate that into the logic.

So, I think that is the technical comments. Let me defer to John on the AHRQ priorities.

MR. BOTT: Well, we are actually in the throes of defining what our priorities will be measure development and measure refinement over the next few years at this given time. So, it is hard to comment on that specifically.

But I would just echo what Patrick said about AHRQ is anxious to adopt other data sources wherever possible and exploring some of those avenues in the most immediate -- in fact, we just wrapped up a project which looked very promising, which was incorporating lab values in the outcome measures for a number of the PSIs. And that looked very promising to pursue that work in the future. We seem to be fairly likely to continue that

work.

CO-CHAIR CIPRIANO: Okay. Great. Thank you.

Comments or questions from the Committee?

MEMBER CLARKE: I have a question.

CO-CHAIR CIPRIANO: John. Sorry.

MEMBER CLARKE: Well, two comments and two questions. The one comment is a general comment. And that is, as a surgeon, I don't think the critical issue in accidental perforations and lacerations is accidentally perforating or lacerating something. I think the critical issue is not detecting it and fixing it right away.

The critical issue comes when you do something and you don't realize you have done it, and then you get a complication as a result of it. If I nick the bowel and I sew it up with a stitch, I am not going to get a bad result. But I don't realize that I nicked the bowel and I don't sew it up or I sew it up

a day later, then I am going to get into big trouble. And that is true for the adult version as well.

There is a comment in this particular thing proposing that there needs to be a minimum pediatric threshold in which to apply this standard. I would like to stand against that concept, at least in the aggregate.

It seems to me in things that are volume-related like pediatric surgery, where, presumably, greater volume means greater expertise, to only look at the high-volume places is to miss one of the really critical factors.

And I can understand that you might not want to look critically at a single hospital that only does one colon Hirschsprung pullthrough a year, but you certainly want to look very critically at all the hospitals that fall into that group as an aggregate.

So, I would be against having some

kind of minimum volume threshold and something that is minimally volume-dependent.

And then, I have two questions, and they have to do with the exclusion of the low-birth-weight babies, which I assume was only related to the fact that it is such a rare event, and the exclusion of newborns. Now I could understand that a newborn, you would think that a newborn baby popping out and going home would not be subject to accidental perforations and lacerations, but you would be surprised, if it is a cesarean section, they often -- not often -- but they occasionally get nicked in the process of doing the cesarean section. We have a number of reports in our database of babies who have been accidentally cut, developed a skin laceration as a result of having been delivered by C-section.

MS. BOSSLEY: Could you use your microphone, please, Vallire. Vallire, microphone, please.

MEMBER CLARKE: You could call it anything you want, but it happens.

MEMBER HOOPER: I'm sorry, my question was, would that fall under the adult measure or the pediatric measure because, technically, it is an adult surgery? I know this sounds crass, but the nick of the baby would be no different than nicking another body part, a bowel.

DR. ROMANO: Actually, if I could address, it is fairly simple to answer. If falls under a completely different -- it is a perinatal indicator, and it falls under the birth trauma indicator, which was evaluated and discussed by the Perinatal Steering Committee earlier this month. And that was a separate discussion.

So, normal newborns are excluded because they basically add noise without adding much information. At some hospitals, it is a very large percentage of their total volume. Of course, those patients are

extremely low-risk, absent birth trauma. So, they really just add noise.

The very low-birth-weight infants, less than 500 grams, are excluded across the board from most of these indicators, just because hospitals -- well, they are just obviously a very different type of clinical situation, and you are close to the limits of liability there on some of those. Infants may be allowed to die shortly after birth, especially under 400. So, that is a fairly extreme cutoff for birth weight. But we do keep the ones that are over 500 grams.

CO-CHAIR CIPRIANO: Okay. Steve?

MEMBER LAWLESS: Yes, I'm going back to AHRQ in a second.

The question I think was, the administrative data versus the American College of Surgery has now defined or growing together as consensus for both their adults and pediatric worlds what the definition is laceration is, how they are defining it.

That data source is like a lab. I would actually reach out to them and say, "Guys, let's be consistent here." They are using it now for their maintenance and certifications, other things. So, it adds a little better consistency in terms of the definition.

The other is to Mr. Clarke's feeling, going with your rates versus individualities. Having one or two events a year, but having them in someone who has only done one of these procedures a year is entirely different from one of these events a year happening in someone who does 50 of these or 100 of these a year.

So, I think one of the bigger things which I would also agree don't exclude is -- don't put in a minimum threshold and do sort it out by pediatric versus adult and level of experience somehow, because I think that is what a big key of this whole thing is, versus the people who report all the time.

CO-CHAIR CIPRIANO: Could you comment on the minimum threshold?

DR. ROMANO: So, two quick responses. So, I think the threshold issue may be a misunderstanding. Where are you seeing that in the document? The top of page 13?

MEMBER CLARKE: "This problem could be minimized by focusing on public reporting of this indicator on hospitals that meet a minimum pediatric volume threshold or by incorporating" --

DR. ROMANO: Oh, could it be minimized by focusing public reporting? So, that is not --

MEMBER CLARKE: That is my point. I mean, if you say only pediatric hospitals of more than 200 beds are going to be evaluated, then a hospital of 200 beds is doing to look bad compared to another hospital of 200 beds, when they are both highly superior to any other hospital in the country.

DR. ROMANO: No, that is a good point, but it is nothing intrinsic to the design of the indicator. It is just an issue that people have to confront in the field when they apply the indicator and figuring out how to apply it, and if they want to do public reporting, how to do that. But it is nothing about the design of the indicator that would impose a threshold.

The other question that I wanted to -- oh, yes, the American College of Surgeons. So, we welcome opportunities to work with others in the field to clarify these definitions and to develop more precise definitions. Because coders come to us and say, "Well, I don't really know what this is. The surgeons tell us it is this, but, then, in some other hospitals surgeons tell us it is something else."

And so, we will get to foreign bodies later. But through the foreign body process, actually, there has been quite a bit

of discussion with the surgical community, through the SRE process that NQF has led. It has led to some consensus about even something as narrow as when surgery ends. It turns out to be a fairly critical question.

So, I think we would welcome the opportunity, and we have the mechanism to go back to the Coordination and Maintenance Committee and say, "Well, hey, we should change the code." We're also looking forward to ICD-10-CM implementation in October 2013, and these codes will become more specific in ICD-10-CM.

So, there is an opportunity definitely to make the codes line up better with surgeons' understanding of the events that should be captured. But, fundamentally, this is about public use data as opposed to private registry data. So, we want to harmonize but still retain the focus on public use data.

CO-CHAIR CIPRIANO: Okay. Any

others? Oh, Jason, okay.

MEMBER ADELMAN: John made a comment before which I appreciated, but I didn't totally get the punchline. It was when you talked about the difference between a laceration that you can correct immediately with one stitch versus one that goes unnoticed and leads to a real adverse event.

It made me think of another indicator that we are talking about later, the retained foreign bodies. Just the name retained foreign bodies immediately makes me think of somebody left a sponge in.

And when I read some of the articles, I realized that very few of those are actually like a sponge that was accidentally left in. Many of them are intentional microneedles that I have heard surgeons tell me -- the point I am trying to make is it seems to be in both these indicators, from what you said about the lacerations and another one, that there is a

mixture between things that surgeons will generally think are benign versus things that are really bad, and where that mixture is is unclear. It puts into question the meaning of the information.

There is 153 retained foreign bodies. I just don't know how much are --

MEMBER CLARKE: Yes, I think it is important to clarify the difference, although your point is excellent, which is that there are benign misadventures and there are malignant misadventures. I think the undetected accidental perforation versus the immediately-recognized one is an example of that.

But the other thing we are talking about, though, there is a very important difference between a retained foreign object which is unintentionally left behind and what they call, or what the FDA calls an "unretrieved device fragment". So, for instance, you are drilling into the femur.

You break the end of the drill off. You realize that the end of the drill is broken off, and you make a medical decision at that moment in time, do I want to dig that out of the head of the femur? And your answer is, no, I don't; it is more benign to leave it in. That is, by most definitions in my understanding, is not called a retained foreign object; it is called an "unretrieved device fragment".

MEMBER ADELMAN: In these indicators, it is a retained foreign object. What you just called the unretrieved --

MEMBER CLARKE: Not by the definitions I have been using.

MEMBER ADELMAN: Oh, I am misunderstanding what I read.

DR. ROMANO: Maybe we can stay on --

MEMBER ADELMAN: I only bring it up because it just seems that sometimes we are stuck by what we can do instead of what we

really want to do. And because of that, we are just trying to make the best of something that seems less than ideal. And it is just two parallel examples of a code will indicate a laceration. Whether it is meaningful or not, they don't tell us. And so, we just have to list them all. And that was the point I was trying to make.

DR. ROMANO: Right. Well, I think that is an important point, and the Committee needs to recognize that. We are very upfront about that. In fact, in the paper that we cite related to the adult indicator, which was led by my colleague Garth Etter, we reported 91 percent PPV overall for the adult indicator, 226 of 249 events, but 56 of the true-positives, 24 percent of the true-positives were of the nature that John described. They were minor mishaps that would either fix themselves or were caught immediately. So, you might say that those events are not clinically-consequential.

But that comes with the bath water, so to speak. You have to decide whether catching those mishaps, how bad is that, to include that in the overall basket?

CO-CHAIR CIPRIANO: Okay. Vallire? And then, I think let me just see if we are ready to make a conclusion on this one.

MEMBER HOOPER: Going back to John's comment regarding the difference between recognizing an accidental puncture or laceration and doing something about it versus truly from a PACU perspective, from a recovery room nurse perspective, when you see the truly sick patient, it is the patient who got discharged from the PACU 24 hours ago and looked fine, and then 24 or 48 hours later they had a lacerated bowel and they come back septic.

So, I am looking at this summary of evidence and high impact, and it talks about the high cost and increased length of stay. But I wonder if that data is related

to, as John was saying, the laceration that was caught and remedied at the time that it occurred versus the accidental puncture or laceration that is not detected.

And so, I guess what am wondering is, is this measure truly sensitive to what is adversely impacting the patient outcome? And I think is the undetected laceration or puncture typically more so than the detected laceration or puncture.

MEMBER CLARKE: Well, yes and no. There is no question, if you stick a trocar in the bowel and you don't recognize it, you are in big trouble. However, I can think of some counter-examples whereby, for instance, you lift a little retina off the eye and then you sew it back on right away, but you still have a worse result than if you had never lifted it off altogether. Or, in general surgery, if you cut the common duct and recognize it right away, you still wish you had not cut the common duct. I don't mind nicking a bowel; I

would object strenuously to cutting the common duct in half.

(Laughter.)

CO-CHAIR CIPRIANO: Okay. Well, what we have before us is Measure 0344, though, which is an accidental puncture or laceration rate in pediatrics. And so, I think you have pretty much had a chance to explore the issues related to how this measure is constructed and what information it does yield.

So, are we ready to vote?

Janet, any questions, any comments from you?

MEMBER NAGAMINE: No. Thanks.

CO-CHAIR CIPRIANO: Okay. Jessica?

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

(Whereupon, a vote was taken.)

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

NQF criteria for endorsement?

(Whereupon, a vote was taken.)

Nineteen yes, 2 no.

CO-CHAIR CIPRIANO: Okay. John, the next measure.

MEMBER CLARKE: I think we can keep this short. The adult recommendations follow the pediatric. There are fewer exclusions for, say, the neonates and the underweight babies, et cetera.

Almost everything that we could have said about this we have said about the pediatric. So, I don't think there is anything that I can add to the discussion.

CO-CHAIR CIPRIANO: So, are there any additional comments or questions? Or are you ready to vote?

(No response.)

Okay. We are voting on 0345, accidental puncture or laceration rate, which is adults.

MS. WEBER: We will need a moment

to upload the voting.

CO-CHAIR CIPRIANO: Okay. Janet, are you back on yet?

MEMBER NAGAMINE: I am. Sorry. I managed to disconnect myself.

CO-CHAIR CIPRIANO: That's okay.

MS. WEBER: Okay. Importance to measure and report, high impact, performance gap, and evidence. It is a yes/no question.

(Whereupon, a vote was taken.)

We need two more votes. Try casting it again.

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Twenty yes, 2 no.

Scientific acceptability of measure properties, reliability and validity. It is a yes/no.

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Twenty yes, 2 no.

Usability? High, moderate, low, or insufficient.

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: High.

MS. WEBER: Three high, 16 moderate, 3 low.

Feasibility? High, moderate, low, or insufficient.

(Whereupon, a vote was taken.)

We need one more vote.

Janet?

MEMBER NAGAMINE: High.

MS. WEBER: Nine high, 11 moderate, 2 low.

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

(Whereupon, a vote was taken.)

We need one more vote.

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Twenty yes, 2 no.

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

What we will do is move to two additional measures and hold off right now on the foreign body measures. Okay? So, we can come back to those when Patrick rejoins us.

So, we are going to move to 0263 and 0267, but let's do 0267 first, for those of you that are tracking in an electronic file since it is in the same Workgroup.

So, 0267, we have Iona.

This is wrong site, wrong side, wrong patient, wrong procedure, wrong implant.

MEMBER THRAEN: Okay. Thank you.

First of all, this is an Ambulatory-Surgical-Center-sponsored indicator. And many of the issues we have already talked about relevant to this particular one -- one is the use of a rate versus a count. The sponsor is proposing a rate, and they identify in their data, in

their information, that the rate of surgeries involving wrong site, dah-dah-dah-dah-dah, range from a minimum of 0.00 percent to a maximum of 0.31 percent, mean rate of 0.00 percent, standard deviation of 0.02 percent, median rate of 0.00 percent.

So, the conversation we had in our discussion was, again, the idea of the rate versus the count. I would add to that that the seriously-reportable events of wrong site surgeries that apply to hospitals tends to be a count measure, and that I know that historically -- I don't know how strong it is currently because hospitals seem to be buying up ambulatory surgical centers, but at least in my community there is sort of a competition that goes on between ambulatory surgical centers and hospitals. And using a rate in one sector and a count in another sector creates an uneven situation environmental context for trying to judge outcomes. So, that is one of the issues.

Another question that was raised was whether or not the universal protocol process really is decreasing these wrong site surgeries. One of the comments by Dr. Clarke was that, well, if it is done right, yes. However, it goes back to that question we had earlier about implementation issues in terms of how you actually improve care.

And then, some of the Workgroup members expressed an interest in seeing that the measure is stratified by procedure. Again, this has been proposed by ambulatory surgical centers. In my local area in the State of Utah, the Association is reporting that many of the wrong site surgeries are related to eye surgeries, eye procedures, and that in the other worlds this is a very small occurring incident, but it does have more of an occurrence in those areas. So, stratification by procedure would make some sense due to that.

However, the developer responded

it was not feasible to do this at this time. Likely, it will become more feasible as the measure starts being implemented and reported out as part of the CMS mandatory reporting program.

Which, then, raises another question on the reference to the CMS mandatory reporting program, how is CMS asking for this to be reported? Are they asking, again, from a count perspective or from a rate perspective or are they using an ICD-9 code? So, that might be something the developer might want to respond to.

CO-CHAIR CIPRIANO: Okay. Our measure developers, if you would just remind us of your names?

MS. SLOSBURG: Can you hear me? Can you hear me? Okay.

I am Donna Slosburg, and I am with the ASC Quality Collaboration. And this is Dr. David Shapiro. On the phone, Operator, I think we have Kim Wood, M.D., and Susan White.

So, if I can't answer the technical questions, one of them, hopefully, will.

We just wanted for just a brief second to tell you all, I know NQF is very familiar with us because we have six NQF-endorsed measures, but because of the varied experience in the room, we just wanted to kind of give you all a brief overall about the industry and about the Collaboration and how we came about.

Basically, the Collaboration was formed in 2006, and our stakeholders include accrediting bodies, professional organizations and associations. We have basically done all of this work voluntarily.

Currently, we were just informed, No. 1, that there is going to be quality reporting, as Iona alluded to, starting October 1st, 2012. So, all of the data we have is from approximately, and depending on the quarter, 1300 to 1500 ASCs across the

country that are reporting data from 49 states. And this data is aggregated up. So, we do report a numerator and a denominator.

However, to answer your question about, is it going to be a count with CMS, the specifications guide is not going to be out until the second quarter of 2012 to start reporting October 1st, 2012. We understand that it is going to be a claims-based reporting on Medicare patients, but I don't have all of the details.

MEMBER THRAEN: To me, that raises a problem, claims-based, because wrong site surgeries don't really have an ICD-9 claims associated with it, which is why you have a manual reporting system for wrong site surgeries.

MS. SLOSBURG: They are in the process of actually -- and, Kim or Susan, if you are out there, if the operator could open up their lines -- but I am going to let David --

DR. SHAPIRO: I think the answer to your question -- we are in a transition period. CMS just issued a final rule at the beginning of last month which contemplates their starting to collect data next year, next calendar year 2012.

Five of the currently-endorsed measures that you all have endorsed for us in the past, and they include the two that we are discussing with you all today. So, I think you are clearly asking some great questions.

As Donna mentioned, we don't have all of the data. We are engaged with CMS in trying to help them through exactly how they are going to get this data.

But what it appears that they are going to do is have this on our claims. So that they will initiate some kind of code on each claim that will reflect the absence or presence of either or all of these five seriously-reportable events. We don't have the exact data codes yet, and we also don't

have the experience with CMS to answer your other question, which is how they are actually going to report this data.

But we certainly do agree that harmonization is something that we strive for. We think this is an important measure, and we hope that, going forward, that CMS understands that this is something that we should be using in a harmonized fashion between all healthcare settings that deliver surgical care of the comparable type. So, we absolutely agree with your comment.

MS. SLOSBURG: Back to the question about procedure-specific, we don't have that data right now because, again, this is a total voluntary reporting, the data we have. However, we are all in the process of working on a registry. If that registry gets accomplished, which is our goal, then we certainly could be able to take the data from the wrong site surgeries and slice and dice it by demographics, by procedure, by state, for

those that are reporting in the registry.

DR. SHAPIRO: I think that answers the question.

CO-CHAIR CIPRIANO: Okay. Questions or comments from the Committee?

Lisa?

MEMBER McGIFFERT: I just want to clarify that what we are voting on is a measure that is presented as a rate and not as a number, right?

DR. SHAPIRO: Right. We have been reporting it, we have been doing it, we have been reporting these for the last several years, actually, since the NQF endorsement, on a publicly-accessible website that any of us or anybody, any consumer can look at.

And we have been reporting them as a rate to harmonize with the way that reporting is done in other situations. But we do have the aggregated data to be able to give the actual number. And it is easy to calculate the number back from the rate by

knowing the amount of participating centers that gave us the data.

But I think the main point in that is, as we go through this transition where these become part of the CMS reporting requirements, that our data is going to be really subsumed by the CMS data, which will be certainly much more robust and have much more participating centers that are represented. And they also will not be represented the same way we have been able to, had to do it, in an aggregated manner, but they will be represented individually, as they submit those claims back to CMS on the 1500s.

MEMBER McGIFFERT: But the hospital presentation is by number, not rate, correct?

MS. SLOSBURG: Can I clarify or can NQF clarify for the group? To my knowledge, wrong site is a serious reportable event, but there is no inpatient, hospital, wrong site, endorsed measure, correct?

MS. BOSSLEY: I looked to be sure that my memory was correct, and that is correct.

MS. SLOSBURG: So, I want to make sure that everybody understands. I mean, we want to harmonize, but there is no inpatient wrong site measure. There is serious reportable event for wrong site, but not a wrong site endorsed quality measure.

I don't know if that is more confusing or less confusing. And we wanted to make that point.

MEMBER McGIFFERT: My memory is that CMS doesn't count it. They just say, "It shouldn't happen. We're not going to pay for it," period.

MEMBER THRAEN: Except that in the provider preventable conditions that has just been released, wrong site surgery is not a claims-based access. The wrong site surgery has been held out as OPPC, Other Provider Preventable Condition, that has a manual

reporting system associated with it. So, we are back to the idea of hand-counting and manually reporting to CMS on those, specifically those wrong site surgery events.

MS. SLOSBURG: And again, the implementation guide is not out yet. But the information we are getting is verbally, what we are hearing from CMS. So, until it is final, just I don't want to guess incorrectly.

CO-CHAIR CIPRIANO: Okay. John and then Saul.

MEMBER CLARKE: A couple of comments about this. Unfortunately, I have become the world expert in this topic without ever having done one.

We have collected now 466 wrong site events in Pennsylvania over seven and a half years. We have worked in close collaboration with New York, and particularly Diane Rydrych in Minnesota, who has done a terrific job.

There are about 19 states that

require reporting of serious reportable events as patient safety measures in their states. And all of those, of course, require the reporting of wrong site surgery. So that there is a mechanism in almost half the states for reporting wrong site surgery, and some of them are easily available on the web and some of them are not. But they all report in terms of numbers.

So, while I don't think it should affect our assessment of this, I would advocate in terms of reporting out your results as a number, to be concordant with the way the hospitals, who, quite honestly, have a much larger volume and, therefore, have many more of these events.

When it comes to another parameter that has to do with rates, however, it is how you measure these. In a couple of instances, in subdivisions -- so, we have gotten so many cases, we can tell you there were 50 wrong level spinal cases, there are 19 stents in the

wrong ureter, and there is 1 wrong site cardiac case, and no wrong site upper abdominal general surgical cases, and lots of knees and lots of eyes.

But just taking the ureter as an example, in Pennsylvania we have about 80,000 ureteral stents done a year -- or excuse me -- in eight years. We have about 10,000 a year. But some of those are bilateral stents. So, you are not going to get a wrong side in a bilateral stent. And so, if you just take a simple number of stents inserted, then you get the wrong number. If you take the number of patients who have stents inserted, you get a wrong number. And so, without tweaking the denominator, you can get slightly aberrant results, so another reason for this very rare event just going with the whole numbers.

But the fact that I think that this should be on a case base rather than a rate base doesn't mean we can't get the case numbers out of the rate. So, I don't think

that should preclude us from looking at this standard.

MEMBER WEINGART: Yes, I completely agree with Dr. Clarke's comments and the idea that Minnesota, Pennsylvania, New York, Massachusetts have very carefully specified the definitions of these events in order to exclude the trivial ones.

I think the first one in Minnesota encountered, when they turned on their SRE reporting law, was a resident looking in the bladder, going up the wrong ureter, realizing it, coming out, looking at the correct one. There was no harm. There was no injury. And yet, it was publicly reportable. So, I think it is very important to harmonize and align those.

I am assuming that by wrong site that also includes wrong level for spinal issues.

I think the last thing I wanted to ask you about was the validation piece of this

because the documentation we received suggests that the validation process involved sharing a tool with a bunch of clinicians, who then kind of looked it over and assessed the case validity. So, I wonder if there is kind of more to it, to make sure that what we are measuring is actually what happened.

That also begs this question, if you go to a claims-based reporting system, then we don't have any evidence on which to assess the validity of the measurement and would be hard-pressed to endorse an approach that has been trialed yet.

MS. SLOSBURG: Is Susan on the line? Operator, can you open Susan's line?

MS. WHITE: I am. I am, Donna. I'm here.

So, reliability was certainly tested. The face validity was tested by sharing the measure with a panel of experts and having them rate on the Likert scale. And the reliability was tested with centers

actually or ASCs actually going back and reviewing to check to make sure that wrong sites were properly identified. That was based on a smaller sample of the centers, 21 of them in this case.

MS. BOSSLEY: Just quickly, what you have put forward to us, though, is just a measure with the data source of paper records right now, correct, not the claims?

MS. SLOSBURG: Correct.

MS. WHITE: Right. So, I mean --

MS. BOSSLEY: Right. And so, I just want to clarify that, if they did come back to us with new specifications, we would take a look at that, then, if it warrants a review.

MS. SLOSBURG: And that would be with the annual update, right, Heidi?

MS. BOSSLEY: Yes, we would take care of it that way.

So, I would just put that -- that is a future potential expansion but not right

now.

MS. WHITE: Right. Donna mentioned that CMS is going to have measures that will come into play, and we will want to work for harmonization.

But, right now, we are not proposing a claims-based measure.

CO-CHAIR CIPRIANO: Okay. Vallire and then Bill.

MEMBER HOOPER: Just as a point of clarification, is this measure designed to capture wrong site/wrong side surgery just in freestanding ambulatory surgery centers or is it also designed to capture wrong site/wrong side surgery in outpatients that are done in hospital settings? Or do we know what the CMS measure will look like?

MS. SLOSBURG: Our group, the Quality Collaboration, our experience and expertise is strictly in ambulatory surgery centers. So, what we have put forth is only measures for ambulatory surgery centers. So,

I cannot speak to HOPDs.

DR. SHAPIRO: So, the reporting requirement is going to be mandated for approximately 5300 Medicare-certified ASCs. So, we will be reporting on Medicare patients that have their procedures performed in one of those, not necessarily -- freestanding can sometimes be misleading, but it is really the fact that in most states, actually, there is a separate licensure different from an HOPD. And actually, the billing is quite different, and there are a lot of things that are different that pertain to that. But that is the distinction.

So, at the get-go, when we start reporting this next calendar year, this will just be for the ASCs. But, again, harmonization in the future is something that we very strongly advocate.

CO-CHAIR CONWAY: This is just an aside thought. It is a question to NQF and potentially get a comment on the record.

Do we have any effort underway to harmonize reporting? And what I am looking at here is on an event like this you may have to report to the State if you are in Pennsylvania. If you participate in a PSO, there might be a different form to put that, or the Joint Commission. And then, there is now the potential of CMS wanting you to put information probably on a billing form. That is how they usually operate.

So, I mean, are we working on that?

MS. BOSSLEY: Yes. I mean, we started with, first, the serious reportable events, trying to set definitions that could then be used as individuals develop the measures.

With regard to actual implementation, we continue to try to encourage that those be used. They may be used differently in states. I think that is actually fairly common right now. But the

goal is to be able to have a standard set of definitions that can go from serious reportable events to the safe practices, to the measures. So that you are at least defining and capturing in the same way, yes, that is the goal.

CO-CHAIR CONWAY: But, I mean, you don't usually get into this, but it might even be worth for you to take the leadership one step beyond and get the reporting process, the form, or whatever, standardized as well.

MS. BOSSLEY: Yes.

CO-CHAIR CONWAY: That would help us out in the field a lot.

MS. BOSSLEY: We also are working on the common formats as well for the PSOs with the thought that that is what we are working on as well.

But Dr. Clarke?

MEMBER CLARKE: If I could inject in that, in Pennsylvania we have tried to solve this problem. Many hospitals use an

internal system for reporting adverse events, some kind of risk management system. And we have been mapping to that.

So, probably the correct solution to this problem is Riskmaster or one of those other systems that you use for managing these events are developing templates so they can spit out a report to the FDA, they can spit out a report to Pennsylvania, they can spit out a report to CMS. And that is probably the way it is going to go.

CO-CHAIR CIPRIANO: Okay. Are there any other comments or questions at this point?

Iona?

MEMBER THRAEN: I just wanted to sort of summarize with a comment that was made in our review group, which basically said that they thought that this measure had face validity, but it is a public health issue in terms of "never events" and that, in general, there was support for it, even though it is

one of those, again, one of those rare events, but, again, the focus being the issue of numbers versus rates.

CO-CHAIR CIPRIANO: Okay. Thank you.

All right. We will ask Jessica to walk us through the voting, then. This is on 0267.

MS. WEBER: Importance to measure and report. Are all three subcriteria met, high impact, performance gap, evidence? It is a yes/no question.

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Twenty-two yes.

MEMBER THRAEN: I think that is the first time.

(Laughter.)

MS. WEBER: Scientific acceptability of measure properties, reliability and validity. It is a yes/no

question.

(Whereupon, a vote was taken.)

We need one more vote.

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Twenty-one yes, 1 no.

Usability? High, moderate, low, insufficient.

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: High.

MS. WEBER: Fifteen high, 6 moderate, 1 low.

Feasibility? High, moderate, low, insufficient.

(Whereupon, a vote was taken.)

We need one more vote.

Janet?

MEMBER NAGAMINE: High.

MS. WEBER: Twelve high, 9 moderate.

Overall suitability for

endorsement. Does the measure meet all the NQF criteria for endorsement?

(Whereupon, a vote was taken.)

We need one more vote.

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Twenty-one yes.

CO-CHAIR CIPRIANO: Thank you. I apologize.

Okay. So, we are moving to report Group D, Measure 0263, which is patient burn.

And for that, we do not have the member of the Subcommittee here today. So, if we look at the preliminary voting, this is relatively-consistent with just a little bit of, one vote consistently that is not the same. But, then, feasibility has a number of different variables.

It is under D, Workgroup D. It is under Care Coordination. The summary is in there.

Okay. So, this is the percentage

of ambulatory surgery center admissions experiencing a burn prior to discharge. So, obviously, an intraoperative or episodic unanticipated event of a burn. Okay?

All right. So, this is an outcome measure. Paper records are the source. And it is a rate, is that correct?

Okay. All right, we will ask David and Donna to speak to it.

Are there comments or questions? Are your tents up? John, is yours up also?

Okay. All right. We will start with Vallire. Thank you.

MEMBER HOOPER: Yes, I just have a question. It seems that this is measuring burns prior to discharge. And sometimes we will see blistering or burns that will occur in the ambulatory patient population post-discharge, because you need to remember that that patient may be discharged within one to two hours of the procedure. And so, while this is a needed measure, I am just curious as

to if we are missing issues, if perhaps we should add something about postop followups, as we do routine postop followup calls anyway.

CO-CHAIR CIPRIANO: It may be that, since this is beginning to be a little bit of a consistent concern that the group is very appropriately identifying, which does fall under the continuum of care, care coordination issues, that as we identify situations where we are only recording this measure in a particular setting, that we need to convey the importance across all the measures, that there need to be opportunities to have sort of the next step of the measure that occurs, whether it is at home, whether it is at the followup visit, whether it is in a followup call, or whether it is hospital to other level of care, because I think that is where we don't really have a lot of those measures right now.

And again, that relates to the need for the development of longitudinal

measures with multiple sites that, again, are not in existence right now. So, I think if we could put that in that category as well?

And clarify for us, for any of the measures that you have sponsored, not just these two, it does relate to the episode of in the door/out the door, as opposed to any post-procedure --

DR. SHAPIRO: Exactly. Exactly, and that was as a result of a lot of discussion amongst ourselves in terms of formulating these measures. But we really wanted to make sure that it was under the direct observation for all of, especially the serious reportable events, during their limited stay in the ASC.

And this is an inherent issue with postoperative with ASC patients, is we don't necessarily know what happens to them, even though we do as much arduous followup as we can with patient calls, surveys out to physicians. But we, for the purposes of

starting this measure, at least limited it to their experience within the perioperative time. And it is actually a perioperative measure. It is not just intraop. So, anything that occurred adverse, even the falls that could occur in recovery, so it is from really admission to discharge. And that goes for the other measures that you have endorsed in the past that relate to the status, not this particular measure.

CO-CHAIR CIPRIANO: John?

MEMBER CLARKE: I would like to speak in favor of monitoring this. It is actually more rare than both retained foreign objects and wrong site surgery. However, it has really serious consequences, not only to the patient, but, in fact, in some instances to the rest of the hospital staff in the room and even in the rest of the hospital. So, when they occur, they can be real disasters of the first order.

In our experience, only a small

percentage of them are surface burns due to thermal injury such as an inappropriate Bair Hugger's hot water, and so on and so forth.

So, most of them have to do with the combination of the cautery and free oxygen. Most people don't realize that anything, even fire blankets, will burn in over 50 percent oxygen, and rather rapidly at that.

So, I think that we are capturing most of the events with this.

Again, I would argue, because this is rare and because it varies by type, it would make more sense to just report the number of events. For instance, eye cases, very unlikely that you have free oxygen and electric cautery in the same place at the same time. And so, very low risk of events. Whereas, ENT cases or facial plastic surgery, a very high risk.

And so, if you start comparing places that are eye clinics with classic

surgery clinics, you are going to have a difference just based on the different population and the different risk.

CO-CHAIR CIPRIANO: Carol?

MEMBER KEMPER: My comments are similar to Vallire's, that I was concerned about detection. I am not sure, even within our own institution with same-day surgery that we are even doing a skin assessment on these patients as they leave. And so, certainly there's the cases -- and we have seen those -- where some days later it is recognized.

But I just kind of wondered a little bit about your processes to detect these because I didn't know if like, for example, skin assessment might capture them, some of them, even immediately before they leave.

CO-CHAIR CIPRIANO: Stephen?

MEMBER LAWLESS: Yes, I second what Carol just said about the skin assessment, because most of these are around

the pad or the Foley itself or the pad is where you see the redness. Most of the people burned, there is some irritation or redness that, then, they could to key into, hey, let's look at this and follow this. So, most of them, you kind of know it is happening or there is a good indication that something has happened around there. So, I think that would be a very strong one to probably add to this, the skin integrity, but also around the pad.

CO-CHAIR CIPRIANO: Okay. And just so you know, there is no hospital measure for this as well, inpatient hospital measure.

MEMBER THRAEN: It is an SRE, though?

CO-CHAIR CIPRIANO: Yes. Yes.

Charlotte? And then John again. And, Carol and Vallire, are yours up or down? You're up again? Sorry.

Okay. Charlotte, please.

MEMBER ALEXANDER: Thank you.

I would add to the surgical pad

the tourniquet because our alcoholic prep sometimes goes underneath the tourniquet and can cause burns.

CO-CHAIR CIPRIANO: Okay. John?

MEMBER CLARKE: This would be one where I would actually advocate that we not only get patients who have been set on fire, but just fires in general. I think any fire on the field, the operative field, whether or not it actually harms the patient, is a very dangerous situation.

There are near-misses and there are near-misses. This is one near-miss I don't want to have happen to me in the operating room.

CO-CHAIR CIPRIANO: Vallire?

MEMBER HOOPER: While I agree this measure seems to be focusing a good bit on electrical burns and fire in the surgical field, we do need to be aware of preoperative, intraoperative, and postoperative warming, and particularly on the frail elderly patient.

And this is where that post-discharge followup, because it is somewhat like a sunburn in that sometimes you stay out and it is several hours later that you notice that, oh, I got sunburned.

And what we will see sometimes is that this will occur with particularly some of these elderly patients with very frail skin. So, I think we need to be aware of this outside of just the electrical burn and fire in the surgical field.

MS. SLOSBURG: This is Donna. Can I just comment?

We do have a definition in our measure specific to that, and we do recognize six recognized mechanisms: scalds, contact, fire, chemical, electrical, or radiation.

MEMBER HOOPER: I don't believe that that definition would include forced air.

MS. SLOSBURG: Forced air? Can you give me an example?

MEMBER HOOPER: Bair Hugger.

MS. SLOSBURG: Bair Hugger. Yes, that's a contact.

MEMBER HOOPER: Okay.

MS. SLOSBURG: I mean, our goal is to include all burns.

MEMBER HOOPER: I don't know what you would call it, but I would --

MS. SLOSBURG: To a clinician, it is a contact. I don't know if --

MEMBER HOOPER: Okay. Okay.

MS. SLOSBURG: Dr. Shapiro?

DR. SHAPIRO: Absolutely, it is a contact. And it goes back to the whole issue of the perioperative period that this measure covers. It is that Bair Hugger burn, and does, unfortunately, or packed with warm blankets, occur interoperatively, but also postoperatively.

Although I will say my personal experience with having this happen to patients is there is some recognition of it during the time of admission. Because part of our

definition is causing the tissue injury, and if there is even a minor tissue injury, there is enough time in the postoperative period for that to be recognized. But often, you know, it certainly could; there is always the outlier.

CO-CHAIR CIPRIANO: Okay. Just FYI, this may be part of a risk-adjusted case mix, adjusted, elderly surgery outcome measure. I don't have the details up, but it does come up under fire. So, at some point, we should probably just check for any kind of harmonization with that measure as well, for whatever elderly conditions.

Mary?

MEMBER SIEGGREEN: So, this is strictly thermal and doesn't have anything to do with chemical at all?

DR. SHAPIRO: No. Here, let me read our six. It's scalds, contact, fire, chemical, electrical, or radiation.

MEMBER SIEGGREEN: Okay.

CO-CHAIR CIPRIANO: Okay. Any other comments or questions on this measure?

(No response.)

All right. Jessica, please move us --

MS. WEBER: Importance to measure and report. Are all three subcriteria met, high impact, performance gap, evidence? It is a yes/no question.

(Whereupon, a vote was taken.)

We need two more votes. Go ahead and cast your votes again.

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Twenty-two yes.

Scientific acceptability of measure properties. Are both reliability and validity rated moderate or high? It is a yes/no question.

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Twenty-one yes, 1 no.

Usability? High, moderate, low, insufficient.

(Whereupon, a vote was taken.)

Janet?

MEMBER NAGAMINE: Mod.

MS. WEBER: Seventeen high, 5 moderate.

Feasibility? High, moderate, low, insufficient.

(Whereupon, a vote was taken.)

We need one more vote.

Janet?

MEMBER NAGAMINE: Mod.

MS. WEBER: Eight high, 13 moderate.

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

(Whereupon, a vote was taken.)

You need two more votes.

Janet?

MEMBER NAGAMINE: Yes.

MS. WEBER: Twenty-two yes.

CO-CHAIR CIPRIANO: Okay. All right.

DR. SHAPIRO: Thanks to you all.

CO-CHAIR CIPRIANO: Yes. Thank you, Donna, David, Susan, and Kim. We appreciate it.

MS. SLOSBURG: You're welcome. And thank you all, because we do take your comments very seriously.

I remember when you were talking about fires, that was a very heated, large, long discussion with the Steering Committee regarding fires versus burns.

So, we do listen, and as we go through the annual process, we will take your comments very seriously.

Thank you.

CO-CHAIR CIPRIANO: Okay. Thank you.

All right. I think we will take a

quick break, in hopes that Patrick will be back. And then, we will finish the AHRQ measures, the two on foreign bodies, and then we will move into the other two for this afternoon on monitoring of persistent medications and high-risk meds in the elderly.

So, take 15 minutes.

(Whereupon, the foregoing matter went off the record at 3:29 p.m. and resumed at 3:44 p.m.)

CO-CHAIR CIPRIANO: If everyone could take their seat, Bill is going to go on Measure 0021 and 0022. So if you would locate those. Those are actually in Workgroup A Medication Safety. So if you are opening files, Workgroup A. And we don't have a sponsor to talk to the first one from the committee, so Bill is going to take it away.

CO-CHAIR CONWAY: We do actually.

CO-CHAIR CIPRIANO: Oh, you do? Okay. Did we ask someone? Christina?

CO-CHAIR CONWAY: Christina.

CO-CHAIR CIPRIANO: Okay. Christina will introduce the workgroups work, the topic.

DR. MICHALEK: Okay, so Measure 0021 is looking at annual monitoring for patients on persistent medications. Those medications were defined as ACE Inhibitors or ARBs, dig, diuretics, certain specific anticonvulsants, carbamazepine, phenytoin, phenobarbital, valproic acid.

For the digoxin, diuretics, ACE inhibitors and ARBs, it is going to look at patients who get at least one serum potassium and either a serum creatinine or BUN within the measurement year. The measurement year, as best we could understand was 180-day period of time that they are looking at the patients are on these medications and receive one of those tests. And then for the anticonvulsants, there would be a drug level, a therapeutic drug level.

Our concerns that we had that we

discussed as a group, we wanted some clarification on whether the measure included monitoring for statins. They were mentioned within the measure but not within the description of the measure and we did get clarification that they were excluded. I think they had been included previously.

We also had some question about the rationales to why the medications in particular were chosen. Based on some information that we are aware of in new studies that had come out, you know, these are included as implicated in hospitalizations but not high on the lists. For example warfarin and insulin, patients on those medications, like we discussed previously, are more likely to have return hospitalizations due to being -- factors of being on those medications. So we were unclear why these medications rose to the top in this measure.

Also some of the data that was cited wasn't specific to these drugs. It was

kind of in general one article was specific to levothyroxine which isn't even a drug that is included in the measure. We talked about FDA drug labeling guidelines for these medications. And again, they don't really support what this measure is calling for. There is some talk with some of these medications about monitoring at initiation of therapy. There really isn't anything that talks about, you know, annual monitoring of these items for patients that are on these medications. And it doesn't include any patient over the age of 18. It certainly is not harmful to do it we just had all of those questions as to why these were chosen and why they are included in a measure.

It seems reasonable monitoring for these. But like I said, based on the other medications we know are involved in readmissions, we were unclear as to the importance of having these have their own measure.

CO-CHAIR CONWAY: Okay, thanks, Christina. If the measure developers, if you could introduce yourself and tell us a little bit about your measure and respond to those questions, if you could.

If you keep talking and they turn it on. No, it doesn't do that.

CO-CHAIR CIPRIANO: Is our AV guy there? Maybe we can call on Pat while we are waiting.

CO-CHAIR CONWAY: Yes, they are trying to record this. So Pat, do you have a question?

DR. QUIGLEY: Yes, thank you. I am a member of Group A. And I would just like to say I apologize that my rating is not up there. I had talked with Andrew about this when we had our group conference call because I did really raise this and it is all in there, my feedback is.

But as a group member reviewing this, I had expressed my concerns, especially

related to the evidence. You know, the age group that this is targeting is 18 and older but if you look at the evidence, it is almost similar to 0022, which is for the elderly. All of the evidence for this is predominantly related to the elderly. So the two indicators in and of itself, you know, the supporting evidence or the liability, the validity, all that information is related. It is almost similar.

So that is what I had major concerns about. The evidence in here and how it is supported, the indicator that they were trying to measure. So I did have that also in my notes. So I apologize if they are not up there.

CO-CHAIR CONWAY: Okay, thanks. NCQA.

MR. REHM: Yes, I'm Bob Rehm again, the Assistant Vice President, Performance Measurement. I had a few comments and then I will try to address some questions.

Sorry for being late. The rain held us up a little bit.

CO-CHAIR CONWAY: Bob, move that closer.

MR. REHM: Oh, I'm sorry. Just so you can appreciate the context here, NCQA has been developing measures for about 21 years. I've been with NCQA 11 months. Dawn, what a little over a year?

MS. ALAYON: Almost a year.

MR. REHM: Jeremy has been in Performance Measurement about a year and a half?

MR. GOTTLICH: Two years.

MR. REHM: Two years. And then Erin has been with us two weeks.

So we weren't there when these measures were born and we will try to answer your questions as much as possible.

Again, we appreciate your consideration of these. These measures were developed in 2004 and began being used in our

HEDIS data set in 2005. So they have a very long history and they were endorsed by NQF, as you know, in 2009.

These are quite different than the measures you have been looking at today. These are primarily ambulatory care measures.

CO-CHAIR CIPRIANO: You need the mike up again.

MR. REHM: I'm sorry. -- ambulatory care measures and, in fact, come from a sort of preventive sensibility. Both measures are longstanding and they are both quite stable in terms of their performance and variation.

They are both performing well. The annual monitoring for patients on persistent medications has improved in all quartiles in the three years of the data that you have. And in fact, this goes back to 2005. So the worst performing health trends that report this measure have been improving constantly, as have the highest performing

health plans.

In terms of the use of these medications in the elderly, this has demonstrated significant improvement over the past year. We would imagine, primarily, because of CMS's Stars rating system and the fact that this measure is in that program.

So again, they are both used broadly in public and private programs, including public reporting, pay for performance and accountability initiatives, including NCQA accreditation, CMS Stars, both the public reporting side and the incentive side, CMS PQRS program, IHA's pay for performance program in California, which includes all the health plans there, and NCQA's new ACO accreditation program that was just released a couple of weeks ago.

So I just wanted to share that background information with you.

And the questions are posted where? I am sorry if I -- Are they up on the

screen?

CO-CHAIR CONWAY: Christina, would you want to restate those?

MR. REHM: So the question in particular that was raised was --

DR. MICHALEK: Well, the first question that we had was in parts of the measure it talks about statins and measuring AST and AIT. So that we, everybody received confirmation that that is not part of the measure.

MR. REHM: Correct. When we did the measure development back in 2004, we cast a broader net on the types of drugs we felt might be included. So in our field testing, those were drugs that were included in the field testing.

And it was in the measure in originally and then later as the measure developed, it was pulled out. So that was an error for including it in the submission and our apologizes.

DR. MICHALEK: The other question in general was why these medications. When you look at those medications that are associated with complications, readmissions, these are on the list but they are far lower on the list. Why were these chosen over other medications?

MR. REHM: Right. And again, I wasn't there at the birth. I would speculate that they were because they were both, these were drugs that were highly utilized so we get a fairly significant in and we are able to, from the feasibility side those were the drugs that made sense. I'm not sure why the drugs that were on the original field test in the original measure were moved later on.

Jeremy?

MR. GOTTLICH: This is a measure that looks both for adverse drug effects and therapeutic monitoring and they wanted to, you know, I was talking to some of the people that have been around and might have heard some

more about the measure development and I asked an example of why not warfarin. And so warfarin is something that might require more monitoring within the year. You know, this could be a weekly drug. Really we are looking at drugs that we would want one monitoring event in the one year of measurement.

MR. REHM: So again, this measure like many of our measures aren't addressing all possible issues known and so, again, it is addressing what it is addressing in a funny way. It is not trying to be a comprehensive measure but a measure that again at its origins was attempting to go after drugs that were used quite frequently and were felt that a conservative recommendation would be monitoring annually would be a quality, an area for quality improvement. And the data that we have on performance tends to indicate that.

DR. MICHALEK: The other question that we have is about the measurement and you

talk about that 180-day period. Just if you could clarify for us, because I don't know that we got that clarification on our call, if it is day 181, and that is when they get their level drawn or their potassium, it's out, then they are out? They don't count?

MR. GOTTLICH: No. The main part of the measure is looking for a numerator event within the measurement year. So the numerator event is a monitoring event.

To be in the measure, to be in the eligible population, you just need 180 days that you are on the medication. That could include days in the prior year. So if the medication was dispensed in the year prior to the measurement year, that continues into the measurement year. We count all those days just for your to get in the eligible population. The monitoring event can happen in that 180 days or it can happen a hundred days later.

DR. MICHALEK: And the measurement

year is a calendar year?

MR. GOTTLICH: That is correct.

DR. MICHALEK: Okay.

MR. REHM: Any other questions?

CO-CHAIR CONWAY: Patricia.

DR. QUIGLEY: Thank you. I would again just like to help address that the population, the denominator or the numerator are for people 18 and older. It's the entire adult population. Yet in the directness of evidence to this specific measure, which is on page eight, it says, "This measure seeks to monitor the use of persistent medications in the elderly." You know, all of the content is essentially related to the elderly. And so that was why we had difficulty in our discussion about this indicator, the supporting evidence of what it was really set out to measure because of the rest of the discussion that is in this document was really more specific to the elderly, people 65 and older.

MR. GOTTLICH: I was looking at the measure workups as we developed the measure and for the most part, the evidence available that we could find was for the 65 and older population, which is more vulnerable to adverse drug effects because of polypharmacy.

When we did take it to our panel, I was able to speak to someone from our geriatric panel who was there at measure and is still with our panel. She had said that with these drugs, they still require really therapeutic monitoring for the entire adult population of 18 and older. But I think just getting evidence for that group in therapeutic monitoring was a little more difficult but they felt it was really important to include.

And if you look at the performance rates for the measure, they are actually highest for the Medicare population and lowest for commercial, which means there is more room for improvement in that group.

CO-CHAIR CONWAY: Okay, comments or questions from the panel? John, you were up first.

DR. CLARKE: I need some clarification. Are we measuring -- why are we measuring these things? Are we measuring them because they are most likely to cause patient problems down the line? Are we measuring them because they are the most commonly prescribed drugs? Or are we measuring them because they are the drugs that are most likely to have interactions with other drugs? Or are we measuring them because they are the drugs that are most likely to not be properly monitored? What is our intent here?

MR. REHM: Again, hard to reflect on the original thinking but I would speculate --

DR. CLARKE: Well what is the thinking now?

MR. REHM: I'll tell you what the thinking now is. When we develop a measure,

we are trying to get an index for medication management. And there are many different places you can go there and different measure developers can go into different directions.

I think that these were widely used medications and the labels on these indicate annual monitoring. We are trying to get a measure that captures a health plan's ability to address that to see if they are able to influence that through reminder systems and the variety of tools that they have available to improve what should be done.

I don't think after the To Err is Human Report that medication monitoring was something that was not on the table.

DR. CLARKE: But if we look at this, one thing we are not doing with this, if I am correct, is deciding whether in fact these medicines are being appropriately prescribed. In other words, I'm on thyroid for the rest of my life. So you monitoring whether I am getting my T-4 level but you are

not monitoring whether I can be taken off thyroxin, whether I needed it in the first place, whether I still need to be on it. Right?

MR. REHM: Correct. We are capturing -- This is a fairly humble measure in all fairness, as a lot of our measures are. And compared to the kinds of measures you were looking at earlier today, quite a bit different. And I think that what we are trying to do is ascertain from a kind of a population health level, whether things that are fairly straightforward, are feasible to measure are in fact being done.

Could we add drugs to this class? Certainly. And when we do our reevaluations we are on a different reevaluation cycle than NQF's Call for Measures because we over a hundred measures in play at any given time. And so this is scheduled, I believe, for 2013 or 2012 and that is when we would take a look and see if there are other rug classes or

specific drugs that would be appropriate to add to this that would bring greater weight to bear on the measure. We are quite open to that and happy to take your recommendations as well.

DR. WEINGART: Yes, my comment echoes the others. You know, there are a lot of prevalent drugs that make us worry. And it does feel like this is a dated measure.

And you know in practice the things I worry about are liver function tests on glitazones and EKGs on psychotics and things like that. So it is hard to quarrel that somebody ought to check the potassium once in a while on somebody on a diuretic but it strikes me that there would be more punch in the measure if it was really based on what we perceive the risk to be and what little evidence there is out there on a connection between failure to monitor and adverse events.

I guess I am saying what others have said but just maybe louder.

MR. REHM: Thank you.

DR. MICHALEK: I just want to clarify that this is not recommended in the prescribing information for these drugs. It is not recommended to get these things once a year. I did look that up because I just wanted to see for myself. It is not listed there, although it is reasonable. Okay, it is reasonable to think that you might want to do these things. It just, you know again, and I don't mean to beat it up but to kind of echo what other people are saying, I think it is dated and I think it is light. And I don't know how far we are really going to get from just saying that we want to see that you obtain these once a year.

CO-CHAIR CONWAY: John, is your card up? Okay. Iona.

MS. THRAEN: I'm just going to focus specifically on the anticonvulsant category of drugs because I do know in a previous iteration of our steering committee

there was a focus on epilepsy and the use of anticonvulsants with that group and the performance gaps associated with evaluation and follow-up, etcetera, if you remember that. So I don't know how much that particular subsection actually and I don't even remember if we even approved it. It was a while ago. I don't know that we did, how that subsection relates to that previous measure.

And the evidence that was being presented at that time pretty much said that folks with epilepsy and using these kinds of drugs were not getting evaluated on a regular basis. And so I would just call attention to that subcategory for that reason.

CO-CHAIR CONWAY: Lisa?

DR. MOORES: I just had a similar question along those lines, actually. From a more practical standpoint, when you look at the anticonvulsants that are included in the list, they are ones that you can certainly check a level in and to some degree we target

that. But in reality, for a patient for epilepsy, if they have no symptoms and no seizures, their level is therapeutic. I could check a level and I would do nothing with it if the patient is doing well. So I don't really know what this accomplishes in terms of quality.

MR. REHM: Well if I can, you know many of our measures are in fact you are trying to get to near 100 percent beta blockers after MI, things like that. And we retire measures when their performance gets to that level.

I think in this case we are not trying to -- for people that are being well managed and are in fact not having seizures, then the testing may or may not be relevant. We are not trying to get people to be at 100 percent. A lot of people assume that out of the gate. So I don't think that is necessarily the case here.

And if you look at the performance

on anticonvulsants from the performance data, it is quite a bit, it is a different profile, if you will, than the others. And the others quite often are performing at 85 plus percent as the mean. And you know, the anticonvulsants were quite a bit lower. And I think the reflection is that patients are being managed according to their symptoms and not necessarily by just monitoring them.

DR. MOORES: Yes, and I guess that makes sense but again, for that particular class, what does it mean from a quality standpoint to track that at all? Instead maybe what we should be monitoring is clearly they need a level if they come in with a recurrent seizure. That is where they need to be monitored much more closely. Or they come in with other side effects that you suspect are secondary to the medication.

MR. REHM: And I think your comments reflect the tension between a measure that is targeted, highly targeted to high-risk

individuals and that is a different measurement strategy and approach. And that is not what this measure does. It does what it does. And I think your point about -- I think a lot of our measures you know, around medications, can be taken into several different steps and you can get into very small populations and really try to do a good job of seeing that clinically based care is being delivered. This is a little bit different level of the measurement.

DR. LAWLESS: The reporting of this to what level, zip code, hospital, practitioner, the United States?

MR. REHM: Right. This measure is a health plan related measure. So all the performance data you see are health plans, Medicaid, Medicare, and commercial plans. So probably covering about 126 million lives.

How plans report that, plans use this, for instance in California it would be used in a pay for performance program that

goes to physician level. And I am trying to remember I have it right here. Annual monitoring is in the California program. So it is one component of many in an accountability model. In PQRS, as you know how those measures work, the same is the case.

So by and large you know, on one hand it is a fairly large denominator measure for a health plan. What the health plans do with that or what CMS does with that in terms of Medicare Advantage reporting is really up to them but quite often it does trickle down, if you will, maybe to clinics. And as ACOs develop measure like this could be incorporated into how they operate, whatever rules they happen to be operating in.

CO-CHAIR CONWAY: Iona.

MS. THRAEN: So I just want to get from the pharmacists and abstracted view, or at least reflect back what I think you are saying which this is more, it looks more like it is a shotgun approach to monitoring of

meds. And you don't perceive or see the real justification in the priorities of these particular medications. Is that correct?

DR. MICHALEK: I think there is, we all know there is other medications that are linked more to problems than these are but they are on the list.

It is not unreasonable to get these levels once a year in these patients. I just, from a quality standpoint, taking that one level, saying that this is what the measure, we want you to take one potassium throughout the year, is that really going to affect a quality outcome, as opposed to if somebody comes in who is seizing that you get a medication, therapeutic medication level.

MS. THRAEN: And I remembered going back to the epilepsy example, I think advocacies group wanted that measure incorporated for purposes of counseling on falls and risks associated with taking the medications and not the seizure condition.

And the same conversation took place that if you weren't having seizures, you were therapeutic. So I just remember what that was about.

CO-CHAIR CONWAY: Okay, any other questions or comments? Shall we move on to voting?

MS. BOSSLEY: Can I ask one clarifying question, please?

CO-CHAIR CONWAY: Yes, sur.

MS. BOSSLEY: Bob, I just wanted to clarify because I looked back, you put this forward for clinician individual group as well as for health plans. But if I understood your response, you are just saying it is for health plan level of analysis?

MR. REHM: Our testing, the testing and the measure specifications are for health plans. The question I asked was does this measure in fact trickle down to other levels of accountability. And the answer would be yes.

MS. BOSSLEY: So in the form, though --

DR. LAWLESS: In the reporting of it, it goes trickles down but unfortunately it wasn't going to the reporting. So the reports on physicians or physician groups, that is a different --

MR. REHM: Yes, but you know this is where we get into kind of measure parentage issues. We have a HEDIS measures parentage is health plans. The measures incorporated into PQRS is accountability is physician level. So I am just telling you that the parenting, the parentage storyline here. the measure that we have put forward in terms of testing and in terms of performance rates are at the health plan level.

CO-CHAIR CONWAY: Lisa.

MS. McGIFFERT: I just have a clarifying question. This is a new measure, not one that has been endorsed before. Right?

CO-CHAIR CONWAY: No, this is a

renewal.

MS. McGIFFERT: It is a renewal.

MR. REHM: Yes, it was endorsed in 2009.

CO-CHAIR CONWAY: Okay, if there are no other questions or comments, Jessica.

MS. WEBER: Importance to measure and report high impact, performance gap, and evidence. It's a yes/no question.

Janet are you still on the phone?

DR. NAGAMINE: I'm here.

MS. WEBER: Okay. What's your vote on the importance?

DR. NAGAMINE: No.

MS. WEBER: Okay. Five yes, 17 no.

MS. BOSSLEY: So because this didn't pass, importances must pass. So unless there is anything that you would like to go back to NCQA and ask questions or anything else I think we are now done discussing this measure.

DR. WEINGART: You know in principle, I think we support this. I think the question is just what is the selection of the drugs. And I think the group would be very receptive to a revised and updated list.

MR. REHM: Yes, can I ask a quick question? I mean, if there is a recommendations on that, as I said, the measure is going to our formal reevaluation process where we develop a measurement advisory panel to re-look at the measure. Basically, it is we do start all over again. And so if there are recommendations that you have and would like to make, we would certainly appreciate hearing those.

I think keeping on context that currently the measure is kind of a population level approach, shotgun possibly. But that would be quite helpful.

DR. MICHALEK: I think if you looked at the --

DR. NAGAMINE: Do you want it now?

DR. MICHALEK: If you wanted to look at just the subsection of that greater population and just pull out the elderly, I think that would be even more supported by the evidence that is out there as well.

MR. REHM: I think that if you were -- I'm not trying to take the role of anything here but if your recommendation was to us -- I mean, we present NQF multiple measures it seems like every week of the year and quite often the panel says, you know, we don't like this measure aspect. We know we are not measure developers but we have a really strong opinion and we think that you know, if you were to make this a 65 and over measure, we would have a different, there is a different evidentiary basis that has been established. The risk is higher. I think we would get it in that case.

And if that was the sentiment of the panel, then we would take that back and respond quite quickly on whether was something

we would then move forward with. And then in which case, in terms of our measure workup, and we have done this before at NQF, asterisk to the measure, willing to change to 65 and over. Sometimes it is the blood pressure level, sometimes it is something where the science has moved and the timing is bad. So again, we are very open to that.

There are some advantages to, if you will, keeping the measure, in terms of timing and keeping the measure, let's call it the measure template, keeping it active in NQF so that then if we were able to do that, then the measure is there and it is simply an act of updating the measure specs.

So on the age group, that is simpler because really it is just we can do that. On the drugs specifically that need to be monitored for persistence use, then I think that that might take a bit more time but that is something we would certainly appreciate hearing from.

CO-CHAIR CONWAY: Okay, Bob. Why don't we just collect some rapid fire suggestions for you. You don't have to respond to each one. We'll go around and collect them.

Steve.

DR. LAWLESS: Yes, one thing for NQF also. This is the second or third time I have heard they are doing a measure in revision but it is up for our revision now. So maybe publishing a timetable so they know to revise before they go here versus do all this work and then find out oh we are revising it anyway, you know, --

MS. BOSSLEY: Right. This is a constant struggle that I think we have and developers have as well as trying to keep up with each other's schedules. We have tried to create a regular schedule of every three years but I think it is going to take a while.

CO-CHAIR CONWAY: I told Heidi earlier they should try to harmonize their

schedules a little bit better.

MS. PROBST: It just feels too lumpy for me. So if you could kind of break it out and be more specific about types of medications together, classes of drugs and what you are actually looking for, just with greater specificity, then the results would be more actionable.

CO-CHAIR CONWAY: Lisa. Lisa, is your card up? Oh, okay. Sorry. Vallire.

DR. HOOPER: I would just say coming from the perspective where long-term medication management is not my area of specialty, I struggle with the fact that there was just really not enough supported evidence not being familiar with the material to really know why these meds, why this timing, some of the references were outdated. So I really felt like it needed a lot more work and needed to be updated. So have more strength than the evidence.

CO-CHAIR CONWAY: Okay, and Saul.

DR. WEINGART: So a couple potential sources you might look at. You know Jerry Gurwitz has done a lot of work on the elderly, community dwelling elderly and drugs at high risk. There have been a couple articles that have been about adverse drug events that result in emergency admissions. The ISMP and MEDMARX collect all kinds of stuff. So I think there are a bunch of organizations that collect information about drugs that commonly result in events that might potentially have been prevented by monitoring.

So I think there is a lot of data sources and we would be very receptive to see them.

CO-CHAIR CONWAY: I could just provide you some experience from a prior panel some of us were on. I think that there were three or four drug testing new measures that the panel rejected. It is a very complicated area to work in because the decision tree gets

very complicated. It is like the example of the seizure patient. If they are not having seizures and not having side effects why do a lot of the blood tests and it may end up over-utilizing tests. But good luck perfecting the measure.

We have a couple more comments down here. Patricia.

DR. QUIGLEY: I don't have a comment. I believe Janet had some comments. Janet?

CO-CHAIR CONWAY: Janet, did I cut you off?

DR. NAGAMINE: No. Thank you. Just kind of reiterating what has already been said. My biggest problem with this one was lumping a bunch of different drugs together. So more tightly coupling the evidence and the type of monitoring with the drug would be helpful.

CO-CHAIR CONWAY: Great. Okay. And Vallire, you are done? Okay.

All right, you've got plenty of food for thought, Bob. Shall we move on to Measure 0022? This is the high-risk medications in the elderly.

DR. QUIGLEY: Thank you, Dr. Conway. This was Group A and this is 0022. This indicator was from the National Committee on Quality Assurance as well. And this is a process measure and this one as well is up for renewal. And the descriptor is a percent of Medicare members age 65 and older who are at least on one of the high-risk medications as well as a second indicator where the other percent of Medicare members 65 and older who are on at least two of the high-risk medications. And these medications that were included in here are medications that we know to cause harm or have adverse events for the elderly.

The denominator was very specific, all patients who are over the age of 65. In contrast to 0021, our members on our workgroup

had high consensus and high agreement for all of the elements of this indicator. We had very little discussion because we did have such agreement. When this indicator was submitted to us, we also had the Beers criteria that was submitted, the 2003 Beers criteria and we had a PDF version of medications and falls risk of optimization. That was provided as well.

As we looked at the evidence supporting this and the review of the literature, even though some of the literature might be dated because of the review based on the 2003 Beers criteria, we did think it was all important because we know these medications that are listed on this indicator are indeed those that should not be given to older people and if they, we should find a way to remove the medication from their regime.

As part of our discussion, part of what we learned from Chris, our member from IMSP is that the American Geriatrics Society

right now has a group of geriatricians who are actually working through the Beers criteria specific to separate out these medications that should not be given to older people by diagnostic cohort, as well as age populations, even separating out the age group. So there is further work being done.

But we thought this was very relevant. We thought it was important. We did think it was a major patient safety initiative. In terms of measure, we thought it would inform patient safety, it would inform healthcare, and it would inform the consumer.

So we had a high level of consensus among all of our members on our workgroup related to this indicator that this was an important indicator to endorse.

Would any of my other team members like to present? Okay.

CO-CHAIR CONWAY: Okay. Is there anything you could possibly add to that, Bob?

MR. REHM: Thank you.

CO-CHAIR CONWAY: Any questions or comments from the panel members? Saul.

DR. WEINGART: Yes, I wasn't sure if this was a subset of the Beers or some overlap between Beers and Zaun. It seemed to be a little bit of a mismatch and I wondered if you would comment about that. And also it looked like there were at least a couple of things that aren't available like meperidine, oral meperidine.

MR. REHM: Thank you for that. I appreciate the comments on the revisions to the Beers list. I was an ex officio member of the AVS panel during their review which was just completed a couple of weeks ago. We are tweaking it right now. We are actually taking that to our geriatric measurement advisory panel on Monday. So we are doing lots of things all at the same time.

So in terms of drugs first that are, essentially no longer available, those do

drop off our list. In terms of the measure, again we have a timing issue between the measure specs here and what we call our 2012 HEDAS specifications. So quite often -- And then we also have what is called an October update which are reviewed by our pharmacy panel and our GMAP to pull medications that are off. If they are not in use, the fact that they are on is kind of housekeeping. But it is important and we do it quite frequently.

So the question about how Beer and Zaun and THICK, the different versions of the original Beers list which was done in the 1990s for nursing facilities, you know, I think the reason if I can work backwards, the reason that the AGS took on this project which is a very resource-intensive activity was A) because it had been a long time, B) because when you get into this kind of competitive criteria stuff and how you define the horizon and the vertical are slightly different. And it created, if you will, noise in the clinical

marketplace. What should I do? What is the right thing to do? Where is clinical guidance here for me as I go one-on-one with this particular patient?

So I think that again the focus on the criteria, the new criteria about to be released was to get this all in a new frame, adopt an approach where these would be routinely updated as opposed to every five, six, three years, whatever the case may be, and have it be consistently done over the common framework.

And just to add a note to the AGS's work, we strongly recommended and they followed the recommendation of using the IOM's new guideline recommendations which really outline steps, guideline developers should use in developing recommendations. And while not technically guideline and they are very careful to not use that term, there was a transparent process. There was public comment, which we very much wanted. All of

our measures go through public comment.

So I think that what you will find is that kind of if you will the variation between those competing reviews will kind of become not to use the word harmonize, but will be much easier to use in clinical practice, once the new list is out. But I do think that the current list shows you the input of clinicians and different panels over time trying to adjudicate between competing perspectives maybe on a particular disease, drug interaction, or on a drug itself for people over 65.

CO-CHAIR CONWAY: Christina.

DR. MICHALEK: I just have a question. A lot of the medications that are in the measure are over-the-counter. Do you have a mechanism that you thought you would be able to capture that?

MR. REHM: So the intention here is that the over-the-counter medications, there is two things going on. From a clinical

practice perspective, if I am a physician I may want to say gee now you may want to be careful with that upper respiratory combination or this antihistamine. And that is one thing. So from a quality standpoint, you want to have a broad list of medications.

At health plans, health plans generally the theory is that if it is over-the-counter it is not paid for. And there are exceptions to that. And so I think the way NCQA approaches measure development is to cast the broadest net possible so that I will just not speak for -- I will speak for health plan X that has an inspired program that understands that over-the-counter medications when properly prescribed actually are efficacious, they are low cost. They help the system out. And it is not like the patient is using these willy-nilly and adding a moderating influence to the recommended therapy. So you want to make sure that those drugs are in, even though you probably know

that maybe ten percent of the plans actually are capturing this data or whatever. We do that quite frequently.

So broad net to make sure that people who have programs because programs vary across the country and I think that is the rationale.

DR. MICHALEK: Thanks.

CO-CHAIR CONWAY: Lisa.

DR. MOORES: Bob, just a clarification. I was just curious if you know when this measure was being looked at whether there was any discussion of including some type of exclusion in the denominator if you had a good reason for using these. I hear you keep saying a broad but there certainly are going to be instances where it would be warranted and why that wouldn't be an exclusion.

MR. REHM: Yes, thanks a lot. This is where we get into the realm that measure developers face around feasibility.

First -- Well, a couple things. In general, NCQA's approach to measures, especially at the population health plan level is to have as few exclusions as possible because there is lots of different reasons. But one is that the exclusions normally -- You know we are trying to measure plan performance, not necessarily get inside the clinician's office and say, it's okay to do this. It's okay to do that. Clinicians have enough guidance to support their clinical judgment and their practice.

So if the exclusions are a significant part of the population, then we do entertain those. Where we believe the exclusions are a small part of that population risk, then we try to, we just kind of let it go and understand that there will be examples where it is totally appropriate to use that.

The problem -- not the problem. The challenge of the Beers criteria or this whole arena is potentially inappropriate

medications. Lots of caveats there. And so this is a measure where we would never, and we would probably not, we would probably hope that there is 100 performance because that would suggest that people are not thinking clinically about what is the right thing to do.

So again, I think that getting the right balance here is what we tried to achieve and hopefully it passes the test.

CO-CHAIR CONWAY: Okay, any other questions or comments?

Should we move on to voting? Jessica.

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

Janet?

DR. NAGAMINE: Yes.

MS. WEBER: Okay, 19 yes, three no.

Scientific acceptability of

measure properties. It is a yes/no question. Janet?

DR. NAGAMINE: Yes.

MS. WEBER: Twenty-two yes.

Usability: high, moderate, low, insufficient. We need one more vote. Janet?

DR. NAGAMINE: Moderate.

MS. WEBER: Nine high, 12 moderate, one low.

Feasibility: high, moderate, low, insufficient. We need one more vote. Janet?

DR. NAGAMINE: High.

MS. WEBER: Eight high, 13 moderate, one low.

Overall suitability for endorsement. Does the measure meet all the NQF criteria for endorsement? We need one more vote. Janet?

DR. NAGAMINE: Yes.

MS. WEBER: Twenty yes, two no.

CO-CHAIR CONWAY: Okay, thank you. We are on a roll here. Two more. Next would

be 0362. This is foreign body left after a procedure in patients less than 18 years of age. And our reviewer was Vallire.

DR. HOOPER: Yes, thank you. And I think 0362 and 0363 we found as a group were basically very similar except one was for pediatrics and one was for adults. So with the group's agreement I think we decided that perhaps we would just team up and discuss both of those together as the issues were very similar. Is that okay?

CO-CHAIR CONWAY: Yes. Thank you NCQA.

DR. HOOPER: This measure is up for renewal and it was 0362 was originally endorsed in 2008, foreign body left after procedure from AHRQ. And basically it is the counts of discharges with foreign body left in during procedure in medical and surgical patients in patients less than 18 years of age. And 0363, Charlotte, was patients greater than 18 years of age.

The numerator is discharges under the age of 18 with ICD-9-CM codes for foreign body left during procedure. And this is a count as opposed to a rate so that there was not a denominator provided. And I think that the major areas of discussion which we have already hit with some of the other AHRQ measures were the issue of count versus rate.

We also had some discussion and John help me with this because I believe you were the person that had the greatest knowledge based on the definition in that we needed some definition harmonization on end of surgery. John we talked about --

DR. CLARKE: Correct. There is a little inconsistency -- There is a little ambiguity in the description on page nine and it says if relevant resolving discrepancies and the patient has been taken from the operating room.

And there is also a discrepancy clinically among people in the field. So if

you would ask a surgeon when does it count as wrong site surgery, you will get different -- or excuse me -- as retained foreign object, you will get different opinions. So a little ambiguity here.

The National Quality Forum definition, however, is very straight forward. The last stitch is put in, the operation is over. Or if it is natural orifice surgery, the instrument has been removed from the natural orifice, the surgery is over. It is not, you are in the room, you get the x-ray back, you open the patient back up. So that just has to be clarified. There is a little bit of ambiguity in there but I think the committee functioned as if we were following the NQF definition.

CO-CHAIR CONWAY: Yes.

DR. ALEXANDER: I thought you were saying, and correct me if I am wrong, is that the verbiage that is here reflects a 2011 update on the National Quality Forum

definition. The disparity is between the current National quality forum definition and the CNS definition.

DR. ROMANO: Okay, that might be true, yes.

DR. ALEXANDER: And whether that needs to be harmonized or not --

DR. ROMANO: Right. So we are fortunate here in that the coding clinics for ICD-9-CM, which is kind of the Supreme Court of coding, it adjudicates questions and discrepancies related to coding, has actually deferred to NQF to define when surgery ends from the standpoint of coding this event. They have explicitly referenced the NQF definition. But the NQF definition has changed. And so the 2011 definition which actually says and I quote, surgery ends after all incisions or procedural access routes have been closed in their entirety, devices such as probes or instruments have been removed, and if relevant, final surgical counts confirming

accuracy of counts and resolving any discrepancies have concluded and the patient has been taken from the operating procedure room.

So the previous definition actually had or logic in it. Now it is and logic. And that was really at the impetus of the surgical community. So the definition of when surgery ends has been pushed forward basically to when the patient leaves the operating room and coders will be following that definition as well.

CO-CHAIR CONWAY: So then your current definition is consistent with the 11 definition out of NQF.

DR. ROMANO: Yes because coders are instructed to follow the NQF definition. It may take them a little while to realize that the NQF definition has changed, to be honest. So that is part of the broader educational process.

CO-CHAIR CONWAY: Okay.

DR. ROMANO: But one thing I do need to point out since this question came up earlier is that the code does not distinguish device fragments that have broken off from sponges and so forth that have been retained. So that is a distinction with the NQF definition. So the NQF definition specifically excludes those device fragments that are left in after the surgeon makes some effort to remove them and decides that he or she can't do that. From the coding perspective, it is still a mishap. It is still an event that happened to the patient. There were still resources involved in trying to extract the fragment. So it still counts from the coding perspective.

And in the VA validation study, I believe that 52 percent of the true positive events were sponge or gauze that was retained; 30 percent were instrument or device fragments; nine percent were drain fragments.

CO-CHAIR CONWAY: Iona and then

John.

MS. THRAEN: So I have both measures pulled up side-by-side. And in the 0362, the description says count of discharges of foreign bodies left in, this is the pediatric version, among patients less than 18 years and not MDC-14, which is pregnancy childbirth, etcetera. And in 0363, if 18 and older but with MDC-14 pregnancy, childbirth, etcetera.

So my question is it looks like the females under the age of 18 and pregnancy related conditions where sponges or devices might be left behind C sections etcetera is not counted in either of these measures. Is that the intent? Being from Utah --

DR. ROMANO: No. So the adult version, which is PSI-5, does not exclude MDC-14. So basically if it is someone who is under 18 who has the foreign body left in in the course of the delivery, it gets counted in the adult indicator. And that is --

MS. THRAEN: Just by virtue of pregnancy?

DR. ROMANO: By virtue of the pregnancy and child birth.

MS. THRAEN: Okay, thank you.

CO-CHAIR CONWAY: John?

DR. CLARKE: You have mentioned a couple of things such as the coders are now driving off the NQF definition and your ability you mentioned before about the ability to affect codes and create new codes. I would strongly encourage there to be a recognition of the fact that when you leave something behind that it be classified, intentionally that it be classified differently than if you leave it behind unintentionally. I think even when it comes to a needle that has been lost or a drill bit or a fragment of a drilling, if it is left behind for medically valid reasons because the cost of retrieval is greater than the cost of leaving it behind, the medical cost, that that should not be counted as a

ding against the institution. You might count is as a ding against the drill manufacturer.

And I think there needs to be some recognition of the difference between a considered medical opinion and neglect

CO-CHAIR CONWAY: Okay. Steve and then Jason.

DR. LAWLESS: Yes, along the same lines is that unretrievable foreign body. We are finding out that the biggest area is laparoscopic surgery clips. Whoops, it slipped. It slipped, it slipped, and you can't get it. And then it will end up being ten clips in there. Under the definition that you are talking about, where would they be?

DR. ROMANO: Well so coders are instructed to apply this code if it has some effect on the management of the patient. So what the effectively means is that if the surgeon dropped a clip and said oh, that's a bad location. I should go in there and try to get that. And it ends up extending the

operation while he or she digs around to try to find it. And then after half an hour, it is like whoops, well, I couldn't get it, then it would count.

But if the surgeon basically says oh, this is just a routine part of the operation. Sometimes we lose these but that's okay because we leave them in anyway, then it wouldn't count. So that is the distinction.

But I would say that I think the FDA has certainly expressed some interest in sort of tracking this problem. From the patient's perspective of course, it doesn't really matter whether the device was left in because the surgeon was careless or because the device was perhaps not optimally designed. But it certainly there would be some interest there.

DR. CLARKE: Yes, I think you need to distinguish the two of them so you can track them.

DR. LAWLESS: Well I would argue

that by not distinguishing them we drive it better. By not distinguishing them we drive it better. You go from rare events to events that have occurred. Whoops, it fell in. It's my judgment. Ten years from now I don't know what is happening. But to better have the FDA and others look at the manufacturers and say design a better clip machine would be this kind of a problem.

So I would argue to include them.

DR. ROMANO: That's basically what our expert panel argued as well.

DR. ADELMAN: So I don't agree with that. First Patrick you said from the patient's perspective it doesn't really matter if it was intentionally or unintentionally left in. But I don't think that is completely true because unfortunately the root cause analysis that I have gone to whether unintentionally left, there are often large sponges that become a real source of infection and the intentional ones are tiny needles that

most surgeons thinks are not really a concern. That is the risk-benefit. If they knew there was a huge sponge, they wouldn't stop until they got it.

Then what this exactly means, I am just looking at the comparative data for PSI and they list all of the PSIs and data, this is from 2008, from foreign body left in during procedure, it is listed as 184. So I know in my institution when somebody reads that, they are going to think okay 184 sponges were left because that is what we have root cause analysis.

I'm just going to point out one of the references that was listed is from 2008 pediatrics. In this study they looked at it was 76 children's hospitals, 1.8 million discharges, and they reviewed 1700 charts. And here they found 153 of these retained foreign body indicators. And when they narrowed it down for the present on admission was wrongly coded, the coders made a mistake.

And then was not considered intentionally left behind, there is a sentence here that I just wanted to read. It says, "Over a three-year period, reviewers indicated that only three cases occurred in which a physician truly forgot a foreign body in the patient." So it went from 153 down to three.

Now I know everyone at my institution that the 153 is the three but really it is not. That is a huge swing. And that is my concern.

CO-CHAIR CONWAY: Lisa.

DR. MOORES: I think I would kind of say that both parties have a very good argument and I think it depends on the perspective that you are looking at it from. And certainly from a patient perspective, I think you want to follow everything and from a quality, you know, I agree with Jason driving it, but I agree with John as well. It would be very nice to track them both but

under different codes because you could actually get a measuring whether the decisions we are making as clinicians are appropriate. If the outcome is the same, then maybe we shouldn't be saying oh that is okay to leave behind. So I think you want to track both outcomes.

CO-CHAIR CONWAY: Okay, Charlotte.

DR. ALEXANDER: Lisa, I think you are right on. One of the discussions we had was how does this lead us toward improving quality. We don't have any data. This has been out for a while. No one is saying that since we have been tracking this we have decreased the number of foreign bodies. My perception is maybe we have but I don't have that information and I would like to make it be a quality indicator.

And when you look at the adult information, 45 percent of them were false positives. And it is a high percentage as well for similar things. They were present on

admission, maybe that wasn't documented but it was recognized and they went and changed that.

So I would like some help to make it a quality issue.

CO-CHAIR CONWAY: Any other questions or comments?

DR. ROMANO: could I just ask Jason which paper are you referring to? I'm sure I have it here but, the pediatric paper.

DR. ADELMAN: Pediatric --

DR. ROMANO: Scanlon, okay. Right. So in Scanlon's paper they reviewed, I'm not sure I see quite the numbers you are referring to but anyway they reviewed 45 charts of foreign body left in during procedure. Is that what you are referring to? And they deemed that 51 percent were preventable.

DR. ADELMAN: I'm sorry. Hold on one second.

DR. ROMANO: Oh, okay, that's a different paper. Sorry.

DR. ADELMAN: Yes, I think that is the other paper.

DR. ROMANO: Okay.

DR. ADELMAN: They are both by Scanlon.

DR. ROMANO: Okay. The only thing I would say in general is that the question of intentionality was discussed with our expert panel. And basically there was some debate about the intentionality of at the beginning of the procedure versus the intentionality at the end of the procedure.

So from the perspective of some stakeholders, what matters is the intention at the beginning of the procedure. So if the surgeon didn't intend to leave a foreign body in in the course of the procedure, then if he or she later chose to leave the foreign body in because of the circumstances, that is sort of secondary. And so they would still view that as unintentional because from the patient's perspective, it is not part of the

intent of the operation.

So there is some room for debate about intentionality at what time exactly. But in the meantime, let me look up the Scanlon paper.

DR. CLARKE: I have a lot of trouble with that as a trauma surgeon. So I have a patient with a gunshot to the abdomen and I intend to fix them. I get into the operating room and I discover it is a through and through laceration of the liver and then I decide that the most prudent medical treatment is pack that and come back at another time. By your definition, then that I didn't start out intending to leave sponges behind but if I wanted to avoid a retained foreign object, I would have a dead patient.

DR. ROMANO: No, no. That is explicitly excluded. I'm sorry. You are quite right. That definitely would not be codable because that would be explicitly part of the surgeon's conduct in the procedure.

CO-CHAIR CONWAY: How do you have a coder who is going to figure all those out when intentionality is not one of their measures.

DR. CLARKE: Well how does that differ from dropping a needle tip and knowing that you will never be able to find it on x-ray or looking for it and just saying oh the heck with it?

DR. LAWLESS: I would argue that is totally different, actually. I think one is a judgment call in terms of medical treatment and the other is a whoops or a reason for change. So I think it is apples and oranges.

CO-CHAIR CONWAY: Well, let's see. We had Lisa and Charlotte up before. Lisa.

MS. McGIFFERT: Well I just agree with all this discussion about intentionality. But I also and maybe I am naive but I hear from patients who have had a surgery years before and something was left in and then they

start having problems later. And so when I hear this talk about well you know it's not really going to be a problem, you know, it makes me wonder from the consumer perspective do we really know if it is going to be a problem. Do we know it is never going to be a problem? And really what this is getting at is did you intentionally mean to leave it in there or not? And to me that is a measure somewhat of quality on the part of the surgeon or the surgical team as to whether they actually are able to follow through with their intent, knowing that in some cases the actually intentional treatment is going to be a certain way. But I just think that we don't really know what happens to all those things that are left in because I would guess that most surgeons never get that kind of feedback years later. And the patients that come to us say they spent years trying to figure out what it was and then finally somebody diagnosed it.

CO-CHAIR CONWAY: Rich.

DR. WHITE: So what I am hearing is we need two codes. Right? We need to put both in the numerator but like you said, pull them apart. So who would go to the CDC and ask for a new code? I mean, is that -- We will just put that as a rider on this vote. I mean, it seems to solve the problem.

DR. ROMANO: Well, we've done that sort of thing before and we could certainly do that again. Obviously we would go with the argument that has been discussed here. How that affects the timing, I'm not sure. I mean, obviously we could withdraw this indicator and then re-propose it after such codes are established. Or you could have provisional. I don't know. I will defer to NQF staff what this means to the vote.

As far as the paper, yes, I mean I think that I agree with Jason's reading basically they reviewed 72 cases. To be precise, 56 of them were confirmed as correctly coded but of those five were

retained sponges and the rest were catheters, screws, drains, etcetera, that broke off during procedures. So at least on the pediatric side, that is the bulk of it. On the adult side, it appears to be more evenly split based on the VA data.

CO-CHAIR CONWAY: Iona.

MS. THRAEN: So earlier, this is another PSI measure. Have you disclosed the predictive value for these two measures and then if there is any activity going on to improve them? Because I think historically these measures have had the same problems the other PSI measures have had.

DR. WEINGART: I think it is --

MS. THRAEN: Is it? I missed it then.

DR. WEINGART: Page ten.

MS. THRAEN: What's the -- mine is --

DR. WEINGART: It looks like 45 percent on the -- Sorry about that.

Page ten in both and it says for 0363, which is the adult one, it says PPV at 45 percent was reported. Yes, and then on the pediatric one, PPV 63 percent and then it says better than the PPV estimates for the adults.

MS. THRAEN: So I will ask the group, is this acceptable since the other one was bumped up to 80?

CO-CHAIR CONWAY: Good question.

MS. THRAEN: And I guess present on admission, is the story the same for this one in terms of if you include present on admission it would improve the predictability?

DR. ROMANO: That's correct. I think because these studies were done before present on admission information was available. So I think that is addressed in the adult submission, if you look at Section 2(b)(2)(3) of the adult submission.

Right, so in the study by Chen at al., the PPV was 45 percent but adjusting for the availability of POA data, the estimated

PPV would be 66 percent.

CO-CHAIR CONWAY: Okay, Patricia.

DR. QUIGLEY: Thank you. I have a question. And my question is related to because this is a count for cases, for all the physicians who have presented, the scenarios that you have presented, would you all list them as a secondary diagnosis on the problem list as a foreign body left behind, whether it was a needle tip or the packing in the liver? Would they all be listed as a diagnosis, a secondary diagnosis? I mean, that is what the numerator is.

Yes? I'm seeing yes and no.

DR. ADELMAN: I thought it wasn't our coding. It is the coders generating the bill for the hospital. That is what they work off, not what the physicians code. is that right?

DR. ROMANO: They work off all-physician documentation. So not necessarily just the problem list but also the operative

note and so forth.

DR. CLARKE: It would definitely be documented, say in the operative note. Wouldn't you say, Susan?

DR. MOFFATT-BRUCE: Absolutely but because it would be a result of your primary diagnosis and that is where the coders would get the information for the most part is from the operative note or the brief operative note.

CO-CHAIR CONWAY: Okay. Is your card up?

DR. ADELMAN: If this does get approved, I would urge that for me it is what I am mostly concerned about is that the name is confusing, that people read foreign body left in during procedure and they automatically presume it is 100 percent the unintended. And if there is a way to change the name to make it clearer or put an asterisk and explain that it is actually a mixture and the majority are knowingly left in or

intended.

It is confusing because it is not like you put an artificial hip because that would be really intended. So it is like unintentional but knowingly left behind.

So I will let you figure out the new name but I don't like this name.

DR. ROMANO: May I suggest we could defer. Should we defer?

DR. MOFFATT-BRUCE: This is an important indicator.

MS. BOSSLEY: Well I think if you are willing I think we can rename it and it be done. But I think the question is on the code, which was something that was discussed, and Patrick you know this better than I do, I'm not sure how quickly that code can be approved and then implemented. And I think this could be something if you are willing, I would probably say if you passed this measure, we can strongly recommend that ARQH go back, ask for two codes and then at the next time,

at the time of maintenance, we would see that come forward or sooner. They can bring it sooner but at that point for sure.

Because I don't know who ICD-10 is going to impact all of this, too.

DR. ROMANO: Yes, it would likely be they are trying to make minimal changes before ICD-10-CM implementation. So it would likely be October 2013. And so then it is the committee's recommendation about whether to withdraw endorsement of the indicator until that time or whether to continue endorsement urging ARQH to proceed along those lines.

CO-CHAIR CONWAY: Susan.

DR. MOFFATT-BRUCE: I think that our individual institutions and the coders are probably more advanced in this than we actually are in their definitions. But I just looked through my PSIs for this year and I know that we had intended retained foreign bodies and yet they are not coding them.

So I think that they are ahead of

us. We just need to formalize that. So I would be in favor of endorsing this with the caveat that it should be changed going forward to reflect intended and unintended retained foreign bodies.

CO-CHAIR CONWAY: Okay, Patricia and then Vallire.

DR. QUIGLEY: Oh, I'm sorry.

CO-CHAIR CONWAY: Okay, Vallire.

DR. HOOPER: I wonder if we are going to change the code to add intended if we need to explore adding a denominator. It just seems like that number is going to be large and I think that we are going to need some public education and that, you know, and I don't know how do you explain that from a risk-benefit analysis it was safer to leave that little needle in as opposed to dig around and spend another hour or two hours under anesthesia to retrieve it. And so I don't know how to deal with that.

DR. MOFFATT-BRUCE: And that is

part of the algorithm that would have to be developed based on this particular new code that that be appropriate risk-benefit ratio was explored that perhaps additional consultation and disclosure to the patient has been made. Those are the things that would absolutely have to be part of that process.

DR. HOOPER: Thank you.

MS. McGIFFERT: I think this is a really slippery slope and it could be used as a loophole to document everything in this way. And to me the issue is not -- It sounds like you are talking about using a new kind of code for the situation you just described. Something is there; it is going to be too difficult to get out.

DR. MOFFATT-BRUCE: Right. The risk is higher.

MS. McGIFFERT: But that is still an unintended foreign object left in the body that shouldn't have happened.

DR. MOFFATT-BRUCE: It wasn't

planned.

MS. McGIFFERT: It did happen. It shouldn't have happened but it did happen and it is more danger to try to dig it out but it did happen. And to me, you know, what this discussion is about is trying to figure out how to carve something up because it didn't cause significant harm at the time that it happened or there was a risk benefit to it. And that is not what this -- This is not -- My understanding is that this measure isn't a foreign body left during the procedure that caused significant harm. This is foreign body left during the procedure. Right? I mean, there isn't a -- That is what this is measuring. Did something unintentional happen? And if not, there is nothing in here about whether or not it caused harm.

I mean, it is just like when you document infections. We don't say well we aren't going to count that infection because it didn't really cause serious disability or

harm. We count all the infections. And so I think in some cases, the measures are looking at serious harm. In this case, my understanding is that is not what this measure looks like. And the unintentional act, the unintentional thing did happen during that procedure and that we are really going down a dangerous path if we start trying to carve it and say well it's okay if it is this and not that and if it is that but not that. You know, it just seems like we are going to neutralize working on this issue.

And frankly, it seems like there is way too many of these happening.

CO-CHAIR CONWAY: Okay, the left side of the room is weighing in. Can we just start at the end of the table and move on, starting with John?

DR. CLARKE: Yes. So I don't think anyone wants to disregard these events. I think the reason for two codings is that there is two solutions to these events. If I

am not counting properly and I leave a sponge behind, there is a solution to that problem. If I have a drill bit break off, it is an entirely different kind of solution.

So I think that the fact that we want to code these differently is not the same as to say we want to exonerate people from the fact that this happened. And in fact the FDA is all over these events because the FDA actually has the ability to go to the manufacturers and say we are seeing too much of this. But if it is retaining sponges, they are not going to go to the manufacturer and say there is too much of this. They are going to come to us as clinicians and say there is too much of this.

DR. MOFFATT-BRUCE: Well I guess I would just say as a clinician you know, when you do a root cause analysis on this you can figure out if it is this camp or that camp when you are figuring out how to improve it. And what I heard being discussed was I heard

someone talk about it, we are going to have to really explain it to consumers like this is okay but this isn't. And if you are not using it to change the information to go to the public, it seems to me that intelligent people within the healthcare community who do root cause analysis can figure out which camp it falls into in order to take the corrective action. If it is a faulty device that is falling apart, then that is something different, I agree, than leaving too many sponges in. But that is -- I don't think you have to change the measure to figure out what the response is.

DR. CLARKE: Well I do see it as different because if I am going to -- any diagnosis you make only has to be specific enough to determine a treatment. So when you go to the doctor with a sore throat, the doctor doesn't care whether it is Coxsackievirus or echovirus because the doctor is going to treat it the same way. But if it

is cytomegalovirus versus HIV, then the doctor is going to be very concerned about which it is because he is going to treat it differently.

And I think that the same is true here. We want a diagnostic parameter which is appropriate for the action that we are going to take in terms of responding to that. So for me, it becomes very useful to say even for instance where we had the incident with the wrong side surgery before, there is a big difference between a wrong implant intraocular lens and other wrong side surgery events doing an arthroscopy on the wrong knee because the solutions for correcting the intraocular implant are different than the solutions for operating on the wrong knee.

So I want that diagnostics to be specific enough to distinguish those. And that is why I want, why I am advocating for two separate codes because I am going to be looking at those buckets differently in terms

of how to solve those problems.

CO-CHAIR CONWAY: Vallire.

DR. HOOPER: Well and I think really am just echoing what John says in that one is a process issue. When the count is incorrect and you leave something in, that is a process issue. When -- it is getting late -- - a drill bit breaks off or the clip falls out, and I am not a surgeon but just coming from a PACU and occasionally in the OR perspective, that is more of a device issue. And I think it is very important that we separate because the solutions are how you are going to remedy that are different. And so I think that is --

MS. McGIFFERT: So I think what you are arguing is even a third code that goes to the medical device falling apart code. And I think that is, I mean that is what you are arguing for. What you just said is real different from what John was saying that the needle that was dropped and is too much

trouble, is too difficult to find and might cause more harm to find, and so let's add another code about the medical device falling apart. I think that would be a great code to put on the table.

DR. CLARKE: I think you are correct. The unretrieved device fragment, for the most part, we are looking at device failures. It is true that some of them are very small needles. But in fact what we are really looking at and what the FDA is looking at is these things that represent a failure of the device to function properly with undue consequences to the patient.

CO-CHAIR CONWAY: Carol.

DR. KEMPER: Kind of along the same lines. I agree with Lisa that I think both are very concerning and we want to capture those because there are different solutions but we want to be able to address both of them.

I think by differentiating it and

having it a little bit clearer measure, though, I think it will be easier to drive change but it also might make it more likely that people will report. Because if it is clear which camp it falls in, I think people would be more likely to feel comfortable reporting that information.

CO-CHAIR CONWAY: And Charlotte.

DR. ALEXANDER: I like your comment because I am sitting there thinking that if I have a drill bit that breaks off in the bone, I can get it out but I make a great big hole in the bone to do it. And the patient is at greater risk of a fracture from that great big stresserizer. And if I know I am going to get dinged for leaving that drill bit in, am I going to think twice about trying to get it out and maybe cause injury?

So some of the choices we say are safer that we have made a calculated decision for the patient's benefit, if we break them up, we actually get to look at those and find

out if we are wrong and we can reassess. So that is another argument for splitting them out. I think we can get good patient quality and safety information from splitting them out and that is not to make an excuse but I think it may be the better way to report it.

MS. McGIFFERT: So you would support another code that is connected to the faulty device?

DR. ALEXANDER: Well connected with the decision to not correct the problem, whether that is taking out the needle that is a microscopic needle, or whether it is taking out the broken drill bit, or it is searching for if the clip has fallen down into the abdomen is going to take two hours --

MS. McGIFFERT: So you don't see -- I guess what I am trying wrap my head around is you guys are just seeing two buckets and I am seeing multiple buckets. Because if really what you are trying to get to is what is the cause and what is the solution, there

would be multiple buckets. But basically you are seeing it as if it is a faulty device and because it is a faulty device, digging around to get it is going to put the patient in danger and you are not going to do it, then you want that to be all in one bucket, as well as a needle that gets dropped that isn't responsible for any -- no device fault would go in that same bucket.

DR. CLARKE: Well except that we could say that the needle, if for instance as Steve mentioned clips falling out of the clip holder, if every tenth clip is falling out of the clip holder, I would call that a device failure. And if I have a needle that is so small that I can't find it and I know that, I am either going to have some mechanism for holding the hemostat on the other end of it so I can fish it out, or I am going to get a needle holder that isn't going to spring on me so that I accidently lose the clip.

So I think to a certain extent, we

are perhaps making this a little too esoteric maybe. I envisioned myself in another NSF conference discussing this very issue.

But I think the issue is you want diagnostics which are going to be related to actions. And we need, I think at least more than one category because there is at least more than one action.

DR. ALEXANDER: And Lisa --

CO-CHAIR CONWAY: Let me --

DR. ALEXANDER: I'm sorry.

CO-CHAIR CONWAY: Go ahead.

DR. ALEXANDER: The one last thing is that not everything that fails do we decide to leave in. If I am doing a scope and I have got something that breaks off in the joint, I have to get that out. There is no choice on that. That is going to be a problem. So even if I have to open the joint when I am doing it.

CO-CHAIR CONWAY: Let me try and pull all this together and Patrick you let me

know if you would disagree with anything.

I am hearing one easy and one complicated thing. One is there is a suggestion that we embrace a name change that clarifies what this is. And you said you agreed to that. And I think we can leave that with the staff and we will see that name change surface in the report that will get a chance to edit.

The other is a lot more complicated in maybe clarifying what is happening when something is left in. And there is at least four different issues at play here; intended left in, device malfunction, unintended left in, important and not important. There is at least four cells of issues her and I am getting advice maybe from Heidi that, with Patrick's agreement, that if you are interested in pursuing this line of clarifying that you bring it back in the course of maintenance of this measure or sooner, whenever the work can be done because

it involves more than just AHRQ in clarifying that. Is that -- let me just check with Patrick on whether you are accepting all that.

DR. ROMANO: I looked up the ICD-10-CM codes in the course of this discussion and there is good news and bad news.

(Laughter.)

DR. ROMANO: So, the good news is ICD-10-CM does have a specific set of codes for retained foreign body fragments. And it specifically distinguishes, for example, metal fragments from plastic fragments and other types of fragments.

The bad news is that those are separated and excluded from the code for accidently leaving a foreign body. So in other words, if somebody says that they are accidentally leaving in a foreign body, then they are not supposed to describe the type of fragment that was left in, in the case of a foreign body fragment.

So this is something -- So at last

the code structure exists but what is needed is some perhaps better instructions about how for coders how to use the combinations of codes rather than currently the instructions are excludes. So if you use this one and don't use that one, and if you use that one don't use the other one. So we might encourage coders to actually use them together in the case of a retained fragment of a drill bit or a drain or something of that type.

So but as far as the timing of all this, I have to defer to the committee and to the staff because there is a certain timing that we will have to go that probably won't happen until 2013.

CO-CHAIR CONWAY: I don't want to over-interpret people's comments but I don't think there is a sense in the room that we want to lose this measure. I think all of that was suggestions on perfecting the measure as rapidly as you could do that. Is that -- correct me if I misinterpret it.

So there is a lot of pressure on you, Patrick, for future work.

DR. ROMANO: As long as AHRQ continues to support this work, no matter how the committee votes, we will certainly come back with a re-specified version of this indicator at the appropriate time.

CO-CHAIR CONWAY: Is that all right? And you captured all that?

MS. BOSSLEY: I got it.

CO-CHAIR CONWAY: Okay, are we ready to vote on this measure? I'm sorry, Charlotte, did you have your thing up? No.

MS. McGIFFERT: Okay, could you clarify again what it is -- Could you clarify are we supposed to vote with the changes that you are asking him to do? And he doesn't know if he can do them yet.

CO-CHAIR CONWAY: Well, yes, I mean the intention is AHRQ would try to follow up and perfect this measure in the way that was described here. They agree with that.

If you don't have trust in that, we could reject it now.

MS. BOSSLEY: Right. I mean I think you have to vote on what you have before you because you don't know what the final codes will be and how that will be, the algorithm will work, etcetera. So I think it is what you have. So you need to vote on that. So you vote assuming there is a total change that you find acceptable because I think, again I don't see that being a huge issue.

What we would then do is also in everything we write up and then in the future when this measure comes up for maintenance put forward the recommendations of this committee, to be sure that it is before that committee that reviews it, that they are aware of the issues, and see how AHRQ has been able to address that or not.

MS. McGIFFERT: Can I ask one more clarifying question? You said the four categories that you were saying. What were

the other two? You weren't suggesting to add the level of harm that was done or not. Right?

CO-CHAIR CONWAY: No.

DR. LAWLESS: Okay, thanks.

CO-CHAIR CONWAY: Just it was associated with devices, it had to do with the intentionality or the need of the surgeon to leave some things in like sponges and livers. It had to do with whether it was an insignificant micro needle that was left in or a significant. They seem to be the four cells. There might be more.

MS. PROBST: If we just accepted it, renewed it from 2008, when would it come up again for review? Is it every two years?

MS. BOSSLEY: Every three years.

MS. PROBST: Every three years.

MS. BOSSLEY: But keep in mind, if they are able to do this earlier than that, they can bring it back during an annual update or at any point and we would just do an ad hoc

review. So you are guaranteed three years but you may get it sooner.

CO-CHAIR CONWAY: And now that I look at this, if the lack of clarity is so serious, maybe we should vote it down, if it is misleading, or are all these comments needed in the future to perfect an important measure.

Okay, so are we ready?

DR. ROMANO: I mean, what I would say is that if you vote this down on importance, then AHRQ probably won't come back because then the message isn't an important area for them to get involved in.

If you vote it down on scientific acceptability, then we would try to come back with a more scientifically acceptable.

CO-CHAIR CONWAY: And if we vote it up, you are going to work to continue to perfect it.

DR. ROMANO: Right. And if you voted it up, then we would continue to use it

and work to perfect it, absolutely.

CO-CHAIR CONWAY: Jessica.

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

We need one more vote. Janet?

DR. NAGAMINE: Yes.

MS. WEBER: All right, 22 yes.

Scientific acceptability of measure properties, reliability and validity. It is a yes/no question.

Janet?

DR. NAGAMINE: No.

MS. WEBER: Fifteen yes, seven no.

Usability: high, moderate, low, insufficient. We need one more vote. Janet?

DR. NAGAMINE: Moderate.

MS. WEBER: Two high; 12 moderate; eight low.

Feasibility: high, moderate, low, insufficient. We need two more votes. Janet?

DR. NAGAMINE: We're on usability?

MS. WEBER: Feasibility.

DR. NAGAMINE: Feasibility. Moderate.

MS. WEBER: Six high, 11 moderate, five low.

Overall suitability for endorsement. Does the measure meet all of the NQF criteria for endorsement? We need one more vote. Janet?

DR. NAGAMINE: Just to clarify, we are voting as is. Correct?

MS. WEBER: As is.

DR. NAGAMINE: No.

MS. WEBER: With the name change.

DR. NAGAMINE: I'm sorry. What?

MS. WEBER: The name change to make it more clear.

DR. NAGAMINE: I would still say no.

MS. WEBER: Okay, 17 yes, four no.

CO-CHAIR CONWAY: Okay, thank you.

PARTICIPANT: Okay, wait. Stop.

CO-CHAIR CONWAY: Yes.

PARTICIPANT: Did we do the pediatric one already?

MS. WEBER: No.

PARTICIPANT: Were we voting on both of these or just one?

MS. BOSSLEY: So I guess one of the questions I would have to everyone is would your votes change for the other one?

(Chorus of noes.)

MS. BOSSLEY: Then if everyone agrees, we will just move those over and apply them.

CO-CHAIR CONWAY: All right. So, next do we want to open to the public? Jason are you still with us?

OPERATOR: Yes, sir.

CO-CHAIR CONWAY: Could you open the lines?

OPERATOR: Thank you. Once again, if you would like to ask a question, please press *1. Again that is *1 to ask a question.

(No response.)

OPERATOR: Again, that is *1.

CO-CHAIR CONWAY: All right. Next why don't we get a quick recap of what just happened today?

CO-CHAIR CIPRIANO: Well just first of all, a big thank you to everyone for your excellent participation. We have completed 16 of the 25 measures that are on our agenda for this meeting. So I think we can feel very good about that. We approved 11, rejected three, deferred one, and had one withdrawn.

We also have taken specific notes about a number of follow-up items, some specific to measures but some general areas, such as harmonization of timelines; harmonization of reporting; longitudinal measures that cross settings and have multiple measurement periods; the issue of reliability and validity with measures that only collect accounts; the move to more outcome measures

and asking the question of how measures improve quality; and then again any specific additions that we have directed the measure developers.

So I think we have accomplished a great deal and we thank you for that.

CO-CHAIR CONWAY: Okay, start at nine tomorrow. If there is anybody interested in huddling for dinner together or something we can get together in the back of the room.

For people who are new to this panel, I think this is my third one, panel where I have had a similar experience, the work is never 100 percent satisfying because this isn't easy. So don't go home feeling bad. It is very complicated stuff.

MS. WEBER: And please give back, your voting devices. I will hand them out again tomorrow.

(Whereupon, at 5:25 p.m., the foregoing meeting was adjourned to reconvene at 9:00 a.m. on Friday, December 16, 2011.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Patient Safety Complications

Before: NQF

Date: 12-15-11

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter