NATIONAL QUALITY FORUM

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PATIENT SAFETY
STANDING COMMITTEE MEETING

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WEDNESDAY
June 17, 2015

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

PRESENT:

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

CHRISTOPHER COOK, PharmD, PhD, Director, Quality
      and Performance Measurement Strategy,
      GlaxoSmithKline
MELISSA DANFORTH, BA, Senior Director of Hospital
      Ratings, The Leapfrog Group
THERESA EDELSTEIN, MPH, LNHA, Vice President of
      Post-Acute Care Policy, New Jersey Hospital
      Association
LILLEE GELINAS, MSN, RN, FAAN, System Vice
      President & Chief Nursing Officer, CHRISTUS
      Health
STEPHEN LAWLESS, MD, MBA, FAAP, FCCM, Vice
      President, Quality and Safety, Nemours
LISA MCGIFFERT, Project Director, Safe Patient
      Office, Consumers Union
SUSAN MOFFATT-BRUCE, MD, BSc, PhD, MBOE, FACS,
      FRCP(C), Chief Quality and Patient Safety
      Officer, The Ohio State University
ANN O'BRIEN, RN, MSN, CPHIMS, National Director
      of Clinical Informatics, Kaiser Permanente
PATRICIA QUIGLEY, PhD, MPH, ARNP, CRRN, FAAN,
      FAANP, Associate Director, VISN 8 Patient
      Safety Center, Department of Veterans
      Affairs
VICTORIA L. RICH, PhD, RN, FAAN, Hospital of the
      University of Pennsylvania
JOSHUA RISING, MD, MPH, Director of Medical
      Devices, The Pew Charitable Trusts
MICHELLE SCHREIBER, MD, MS, SVP Clinical
      Transformation and Associate Chief Quality
      Officer, Henry Ford Health System
LESLIE SCHULTZ, PhD, RN, NEA-BC, CPHQ, Clinical
      Consultant, Premier, Inc.
LYNDA SMIRZ, MD, MBA, Chief Medical Officer and
      Vice President of Quality, Universal Health
      Systems of Delaware
TRACY WANG, MPH, Public Health Program Director,
      WellPoint, Inc.
KENDALL WEBB, MD, FACEP, Associate Chief Medical
      Information Officer, University of Florida
      Health Systems

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

NQF STAFF:

HELEN BURSTIN, MD, MPH, Chief Scientific Officer
ANDREW ANDERSON, Project Manager
LAURA IBRAGIMOVA, Project Analyst
JESSE PINES, MD, Senior Director
SUZANNE THEBERGE, MPH, Senior Project Manager

ALSO PRESENT:

AKEEM ADEBOGUN, MD, American Hospital Association
SHERYL DAVIES, MA, Stanford University *
TERRY ENG, PhD, RN, MS, RTI International
ORIT EVEN-SHOSHAN, MS, Children's Hospital of
        Philadelphia *
CORINNA HABERLAND, MD, Stanford University *
TARA MCMULLEN, MPH, PhD, Centers for Medicare &
        Medicaid Services
JACK NEEDLEMAN, PhD, FAAN, UCLA School of Public
        Health and Management
EUGENE NUCCIO, PhD, University of Colorado *
SEAN O'BRIEN, PhD, Duke University Medical Center
DANIELLE OLDS, PhD, RN, University of Kansas
        School of Nursing
MAMATHA PANCHOLI, MS, Agency for Healthcare
        Research and Quality
PATRICK ROMANO, MD, MPH, UC Davis Health System
LEE SANDERS, MD, MPH, Stanford University *
HARDEEP SINGH, MD, MPH, Center for Innovations in
        Quality, Effectiveness and Safety *
HARVEY SKINNER, PhD, CPsych, FCAHS, York
        University *
LAURA SMITH, PhD, RTI International
GARTH UTTER, MD, MSc, UC Davis Health System *

* present by teleconference

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1	P-R-O-C-E-E-D-I-N-G-S
2	(8:30 a.m.)
3	CO-CHAIR SEPTIMUS: Good morning. I
4	really appreciate everybody's time in coming this
5	morning. Some of us had some travel issues
6	yesterday but I'm glad that everybody got here.
7	We have got, as you know, not only a
8	robust agenda but an agenda that I think is
9	critically important to patient safety.
10	Just a couple of quick announcements.
11	For those of you who want internet access, do you
12	know how to get that? It is scrolling up on the
13	screen but the login is Guest and then the
14	password is NQF Guest, in case you want to get
15	that.
16	So, with that, I am going to turn it
17	over to Iona, who might want to make some
18	introduction comments as co-chair.
19	CO-CHAIR THRAEN: So, we wanted to
20	reinforce everybody because Suzanne was just
21	telling me that this may be one of the first
22	times everybody has been here on time to start

1 with a quorum. So, I think we ought to give

2 ourselves a round of applause. Good job.

3 And just welcome to everybody. I'm

4 done. How about that? Short and sweet.

5 CO-CHAIR SEPTIMUS: Okay. So, as you

6 look at your agenda, just to briefly tell you, we

7 obviously are going to take our first official

8 break at noon. The reason I mention that, for

9 those of you who need to take bio breaks, just

10 get up, take your bio breaks and come back. We

11 figured if we build in a 15-minute break, it

12 would become a 30-minute break. And so that is

13 the reason why. But please feel free to get up

14 and use the restrooms. I think you all know

15 where the restrooms are, out the hallway, turn

16 right.

17 Okay, with that, Jesse, do you have

18 any comments you want to make?

19 DR. PINES: No, just echo what Ed

20 said. I'm just glad everyone made it today and

21 we are very excited for what I think is going to

22 be a very packed agenda. We are going to be

1   talking about some of the sort of new elements

2   that you haven't seen before.

3   Specifically new this cycle are

4   eMeasures, which are going to be in Day 2 and

5   also what we are going to be looking at PSI90

6   again along with three ad hoc reviews. So, we

7   are very excited. And what we are going to,

8   again, going to do a little differently, try to

9   keep things moving. We have a very tight agenda

10 with a specific time frame for each measure. So,

11 we will be flagging everyone at ten minutes, five

12 minutes, and two minutes, which doesn't

13 necessarily mean the discussion needs to end at

14 that point but just to let everyone know sort of

15 where we are in terms of the timing.

16   DR. BURSTIN: Good morning, everybody.

17 Welcome back. I see everybody is on time and

18 knows what to do because you have all been doing

19 this for a while. That's the beauty of a

20 standing committee. We knew we were right.

21   So, welcome again. It has been a

22 while so we are just going to quickly, as we go

1 around, ask you to introduce yourself, say your

2 affiliation, and indicate if you have any

3 conflicts of interest.

4 Again, we have seen your CVs. They

5 are incredible. We are not asking you to give us

6 a recitation of your CV. Really, just indicate

7 if there any conflicts you may have with any of

8 the measures before the table -- on the table

9 today, both financial but also whether you are

10 engaged in any of the measurement development

11 work around that. We recognize there is both

12 conflicts and bias. Bias means you bring an

13 expertise to the table. We expect that. That is

14 why you are seated here. But particularly, we

15 are interested in whether there is any conflicts

16 that you would want to know about each other or

17 anything you would want to share.

18 Before we begin, I just want to check

19 and see if there is any committee members on the

20 telephone.

21 DR. APPLEGATE: Yes, this is Kimberly

22 Applegate.

1   DR. BURSTIN: Oh, hi, Kimberly.

2   Anybody else?

3   Okay, so why don't we begin with the

4   chairs? Ed.

5   CO-CHAIR SEPTIMUS: I'm trying to mute

6   myself, which is probably a good idea.

7   Ed Septimus. My background is

8   infectious disease and hospital epidemiology.

9   I'm at HCA Health Care System in Nashville and I

10 have a faculty appointment at Texas A&M Health

11 Science Center College of Medicine in Houston.

12 And my one conflict is the measure on ED rescue.

13   CO-CHAIR THRAEN: Good morning. Iona

14 Thraen. I have a background on social work and a

15 Ph.D. in medical informatics from the University

16 of Utah. I am also an Associate Instructor with

17 the University of Utah College of Social Work and

18 Simmons College in Boston.

19   I am the Patient Safety Director for

20 the Utah Department of Health from its origins in

21 2001. Thank you.

22   DR. BURSTIN: Kimberly, can you just

1 introduce yourself and do disclosure, so I don't

2 forget you?

3 DR. APPLEGATE: Sure. My name is

4 Kimberly Applegate and I am a pediatric

5 radiologist at Emory University in Atlanta. I

6 don't have any conflict of interest on any of

7 these measures. I do a lot of work in radiation

8 protection nationally and internationally to look

9 at the evidence for low dose radiation.

10 DR. BURSTIN: Great. Thank you.

11 MS. GELINAS: Good morning, everyone.

12 I am Lillee Gelinas. I am the System Vice

13 President and Chief Nursing Officer for CHRISTUS

14 Health, which is headquartered in Irving.

15 I don't have any disclosures in terms

16 of connections to the measure developer having

17 developed measures but I do disclose that I co-

18 chaired the National Quality Forum Nursing

19 Sensitive Measures original committee that

20 established the Nursing Sensitive Measure set in

21 2004. So, four of the measures coming before us

22 today, nursing hours per patient day, skill mix,

1   falls, and falls with injury, to be specific,

2   were all measures that were included in that

3   initial measure set and voted into practice. So,

4   I have been a part of the team for a long time,

5   having tracked those measures.

6   And Helen, I don't know if you want me

7   to say any more on that. Is that sufficient?

8   Okay.

9   Oh, I brought a copy of that original

10   document that I think was some of NQF's best work

11   that drove a lot of -- there's my bias --

12   foundational work. And it has been built on ever

13   since. So, if anyone needs to refer to the

14   original work, I did bring it and I am sure in

15   the archives of NQF we could find any other

16   resources that you needed to answer a question

17   about any of the Nursing Sensitive Measures we

18   are going to be talking about today.

19   Thank you, Ed.

20   DR. RICH: Good morning. I'm Victoria

21   Rich and I just recently resigned from the

22   University of Pennsylvania as the Chief Nurse and

1 on faculty and have accepted and moved to Florida

2 and now I am the Associate Dean for Clinical

3 Practice at the University of South Florida.

4 DR. BURSTIN: Anything to disclose?

5 DR. RICH: No, I have nothing to

6 disclose. I am a tabula rasa today.

7 DR. QUIGLEY: Thank you. I'm Dr. Pat

8 Quigley and I am with the Department of Veterans

9 Affairs. I am Associate Director of Our Patient

10 Safety Center in Tampa, Florida, with the James

11 A. Haley VA Medical Center and I have nothing to

12 disclose, except to tell you I am a nurse.

13 MS. ARDIZZONE: I guess we all sat

14 together. I am also a nurse. My name is Laura

15 Ardizzone. I am the Director of Nurse Anesthesia

16 Services at Memorial Sloan Kettering Cancer

17 Center. I also have faculty appointments at

18 Fairfield University and Columbia University

19 School of Nursing. And I have nothing to

20 disclose.

21 DR. SCHULTZ: Good morning. Leslie

22 Schultz. I, too, am a nurse. I am going to draw

1   into the positive energy over here. I am a

2   director of the Safety Center with Premier Inc.

3   I am an employee of Premier Inc. I have no

4   disclosures relevant to this topic.

5   And I am not contagious, if you fear

6   me. I am allergic. So, I promise not to give

7   you any germs.

8   DR. YU: Good morning. I am Yanling

9   Yu. I am new on this committee. Good to see

10   everyone. And I am a researcher at the

11   University of Washington. I have a background

12   and Ph.D. in climate and oceanography. That is

13   quite different from patient safety but I'm glad

14   to be here.

15   And I am president of Washington

16   Advocate for Patient Safety and also I am a

17   member of the Consumer Union Safe Patient Project

18   Network. I'm glad to be here.

19   MS. MCGIFFERT: Good morning. I'm

20   Lisa McGiffert I'm with Consumer Reports Safe

21   Patient Project. And we work on a variety of

22   patient safety issues, mainly focusing on

1 infections and errors, physician care, and the

2 safety of medical devices. And we work with a

3 whole network of people all around the country

4 handling as one of many. And I have nothing to

5 disclose except that I am an unabashed advocate

6 for patients and consumers.

7 CO-CHAIR SEPTIMUS: And she's very

8 shy.

9 DR. RISING: Hi. Good morning,

10 everyone. I am Josh Rising. I am the Director

11 of Healthcare Programs at The Pew Charitable

12 Trusts, which includes Pew's work on end of life

13 care and medical devices. I trained originally

14 as a pediatrician. I am not actively seeing

15 patients right now but I have got three kids

16 between the ages of two and eight. Don't worry.

17 I'm putting the training to good use.

18 DR. BRILLI: Good morning, everybody,

19 My name is Rich Brilli. I am a pediatric

20 intensivist and Chief Medical Officer at

21 Nationwide Children's Hospital in Columbus, Ohio.

22 I have been a member since the

1 beginning of the 90 Children's Hospital Solutions

2 for Patient Safety work on safety. And that is

3 sort of a big project that is going on

4 nationally. And I don't have anything to

5 disclose.

6   CO-CHAIR SEPTIMUS: Go Buckeyes.

7 Right?

8   DR. BRILLI: Go Buckeyes.

9   DR. LAWLESS: I'm Dr. Steve Lawless.

10 I am a pediatrician with Nemours Pediatric

11 Healthcare System and I am also a Professor of

12 Pediatrics at Thomas Jefferson University. I

13 have nothing to declare.

14   MS. WANG: Good morning, everyone. I

15 am Tracy Wang, Public Health Program Director for

16 Anthem, Inc., previously known as WellPoint. And

17 I lead patient safety for our organization. I

18 have nothing to disclosure.

19   DR. SMIRZ: Good morning, I'm Lynda

20 Smirz. I am a recovering OB/GYN. Currently, the

21 Chief Medical Officer and Vice President of

22 Quality at Universal Health Services at Delaware

1   and I have nothing to disclose.

2   DR. COOK: Good morning. I am Chris

3   Cook. I am a Director of Quality and Outcomes

4   Policy at GlaxoSmithKline. My background is as a

5   clinical pharmacist and a health services

6   researcher. And with these measures, I have

7   nothing to disclose. But I will say I have been

8   doing work towards medication optimization.

9   DR. WEBB: My name is Kendall Webb.

10   I am at the University of Florida. I am an

11   emergency physician and pediatric emergency

12   physician and just took on the role of Chief

13   Medical Informatics Officer.

14   DR. MOFFATT-BRUCE: Good morning. I'm

15   Susan Moffatt-Bruce. I am the Chief Quality and

16   Patient Safety Officer at the Ohio State

17   University Wexner Medical Center. I am a

18   cardiothoracic surgeon and I have been sitting on

19   this committee now I think almost four years and

20   have enjoyed it immensely. I have no disclosures.

21   DR. ALEXANDER: If Susan didn't bring

22   it to her attention, her name is not on the list.

1   DR. MOFFATT-BRUCE: It's a long name.

2   DR. ALEXANDER: I'm Charlotte

3   Alexander. I am an orthopedic hand surgeon and I

4   am from the Memorial Hermann Healthcare Health

5   System in Houston. I am currently doing a

6   fellowship with the Disparities Leadership

7   Program also in Boston. I have no disclosures.

8   DR. SCHREIBER: Good morning. I'm

9   Michelle Schreiber. I am the Chief Quality

10 Officer at the Henry Ford Health System in

11 Detroit. I am a practicing general internist. I

12 have nothing to disclose, except as we get to

13 some of the eMeasures. I do want to the

14 committee to know that I serve on Epic's Patient

15 Advisory Council, their Safety Council.

16   MS. EDELSTEIN: Good morning. I am

17 new to this committee. My name is Theresa

18 Edelstein. I am Vice President of Post-Acute

19 Care Policy at the New Jersey Hospital

20 Association.

21   My background is as a nursing home

22 administrator. I am licensed in two states, New

1	York and New Jersey. I have my masters in public

2	health and looking forward to joining you. No

3	disclosures.

4	CO-CHAIR SEPTIMUS: Well, I think we

5	can tell and one of the things I remarked on last

6	time, we are an incredible group of men and women

7	who sit around this table. And by the way, one

8	of the strengths is really the diversity of the

9	backgrounds that you bring. So, you do not need

10	to be worried if you feel like this hasn't been

11	your focus. You will add enormously to our

12	conversations.

13	There are a few people I don't think

14	are here yet.

15	DR. BURSTIN: I will just check to see

16	if anybody else joined us on the phone, besides

17	Kimberly, who is on the committee? We just have

18	a couple folks running late, who I am sure will

19	appear.

20	So, just briefly, last question for

21	you, since you have all had a chance to introduce

22	yourself and disclose, if you have any questions

1   of each other, this would be the opportunity to

2   ask if somebody has raised any mention of

3   anything, like gives you concern or just, at any

4   point during this meeting, if you have any

5   concerns about potential bias or conflict of

6   interest, please come forward and talk to us. It

7   is always better to hear those issues in real-

8   time, rather than trying to fix them later.

9   In general, I think, having standing

10   committees has helped. You guys have developed a

11   rapport that really makes these discussions

12   really so much more productive. And welcome to

13   our new folks.

14   And with that, Ed, I will turn it over

15   to you.

16   CO-CHAIR SEPTIMUS: Now, those of us

17   who had dinner last year, you remember the name

18   of the wine that we had? Anybody remember? What

19   was it? It was Septimo -- it was Septimus.

20   Wasn't that true?

21   DR. BURSTIN: And he bought a case of

22   it.

1   CO-CHAIR SEPTIMUS: I did not buy a

2   case of it.

3   DR. BURSTIN: Now we all know what to

4   buy him for Christmas.

5   CO-CHAIR SEPTIMUS: Okay, Jesse, your

6   turn.

7   MR. ANDERSON: So, we're just going to

8   take this opportunity to quickly introduce the

9   staff. My name is Andrew Anderson that I am the

10   new Project Manager for this phase of patient

11   safety. All the emails you guys have been

12   getting are from me.

13   This is Laura.

14   MS. IBRAGIMOVA: My name is Laura

15   Ibragimova. I was on the team last year. So,

16   many of you probably remember me. And I will be

17   helping you out with the voting.

18   MS. THEBERGE: Good morning, everyone.

19   I'm Suzanne Theberge. I am a Senior Project

20   Manager here at NQF on the Patient Safety Team.

21   DR. PINES: And Jesse Pines. I think

22   I have met everyone in person over the last few

1   years. It is very nice to meet the new people.

2   I am a Professor of Emergency Medicine

3   and Health Policy at GW. I have been with NQF

4   for about four years now.

5   MR. ANDERSON: So, we are going to

6   just get started by going over the ground rules,

7   even though you guys are already familiar with

8   this.

9   You guys have had some time to prepare

10   and review the measures beforehand and we would

11   like you guys to make sure that you are basing

12   your recommendations and evaluations on the

13   measure evaluation criteria that I will be

14   skimming through after this.

15   And try to remain engaged throughout

16   and try to remove any distractions like your

17   phones. I know you have your laptops up. And

18   try to be present as much as you can.

19   Like earlier, Jesse was saying that we

20   have two breaks. So, if you do need to use the

21   restroom, you can excuse yourself but, aside from

22   that, we would like you to remain present. And

1　keep your comments concise and focused.

2　　　　　As I was saying earlier, we have a lot

3　of measures to get through. So, we need to be as

4　concise as possible. And try to indicate your

5　agreement without repeating things that have

6　already been said.

7　　　　　Just a little bit about the measure

8　discussion, how it will work. The developers

9　will start with three minutes of an overview.

10　You guys have all received your lead discussant

11　assignments and you will start off by reviewing

12　the committee's comments.

13　　　　　You will then provide a summary of the

14　pre-evaluation comments and emphasize areas of

15　concerns or differences of opinion. And the

16　group, since there are three to four of you on

17　each measure, you can work together to present

18　the measure.

19　　　　　As Jesse was saying earlier, we are

20　trying a new timekeeping exercise. We are going

21　to have three cards. The green card means that

22　we are at the halfway point. So, for each

1   measure, there will be about 20 minutes, except

2   for PSI90, which will be the first measure that

3   we will review. And I will be putting up this

4   ten minute card. At five minutes, we will be

5   putting up the five minute yellow card. And at

6   two minutes, this is when we would like you to

7   start wrapping it up and I will put up the pink

8   two minute care.

9   This is just a brief overview of the

10 process you are very familiar with. As we are no

11 win the standards review process, following that

12 will be the public comment period, where we will

13 be putting together the draft report and we will

14 be meeting again to discuss those comments.

15 There will be member voting. It will be

16 submitted to the CSAC and the Board of Directors

17 for ratification. And finally towards the end of

18 the year and into next year, there will be a 30-

19 day appeals period.

20   These are the criteria that you are

21 all very familiar with. There is the importance

22 for measure, measure and reporting. The measure

1 has to be evidence-based. There is scientific

2 acceptability, looking at the validity and

3 reliability of the measure. There is

4 feasibility, making sure that the data that is

5 required is readily available. Usability, that

6 it can be used for accountability programs and

7 performance improvements. And finally, there is

8 the harmonization of selected measures. So, if

9 there are related or competing measures that are

10 new, that are endorsed and new or related, you

11 will have to choose between the two for

12 harmonization or best in class.

13   And I will turn it over to Suzanne.

14   MS. THEBERGE: Okay, I just want to

15 talk briefly about achieving consensus. As you

16 all know, NQF's process is focused on achieving

17 consensus. And so we have come up with a set of

18 guidelines about when we achieve consensus.

19   Our quorum is 66 percent of the

20 committee. We have reached that. And for a

21 measure to move forward, as it passed for one of

22 the sub-criteria, or as recommended by the

1 committee as a whole. We have to have achieved

2 greater than 60 percent yes votes. And that

3 would be some of the high, moderate, and

4 insufficient with evidence exception.

5   The consensus not reached, or what we

6 call in the office the gray zone, is for 40 to 60

7 percent.

8   And anything that hits that level, say

9 like 55 percent will move forward either to the

10 next criteria or, as consensus not reached, and

11 the measure will go forward to a comment period.

12 We will specifically seek comments on that

13 measure. And if you folks feel like you need

14 more information from the developers to really

15 make a decision, we will have time for the

16 developers to get that information into you and

17 the committee will be offered the option to

18 revote on that measure after the comment period.

19   And then do not pass criteria or not

20 recommended is less than 40 percent of the yes

21 votes.

22   So, it is pretty straightforward. We

1 will do the math before we do any voting so we

2 know what numbers we are at to achieve consensus.

3   I am just going to really quickly

4 summarize our patient safety activities. Here

5 are some of the projects we have done around

6 patient safety in the last few years. I think

7 many of you have been involved in many of these

8 projects. So, we don't need to go into them in

9 real depth. That is just kind of a high-level

10 list.

11   We also have non-CDP projects related

12 to patient safety. MAP has some work around

13 safety. We have the Patient Safety

14 Collaboration. So, there is lots of work here at

15 NQF. It is one of our important project areas.

16   Our Patient Safety Measures portfolio,

17 we have 64 measures around patient safety,

18 ranging from medication safety, healthcare

19 associated infections, falls, BTE, pressure

20 ulcers, and then some smaller topic areas.

21   We have actually got a great cross-

22 section in this project. We are looking at

1   measures across almost every one of these areas.

2   So, you are getting a good slice of the portfolio

3   right now.

4   We do also have safety-related

5   measures in other projects. Sometimes when we

6   took a look at who the best folks to evaluate a

7   measure might be, that seemed like it might be in

8   the cardiovascular committee or the behavioral

9   health committee, depending on the other measures

10 and what the exact topic of that measure is.

11   So, as you can see, we have got a

12 great portfolio.

13   Now, I just want to speak briefly

14 about composite measure evaluation but I will

15 pause to see if anybody has any questions on our

16 projects, consensus not reached portfolio.

17   CO-CHAIR SEPTIMUS: Before you go into

18 the composite measure, which will take us into

19 PSI90, Jason, do you want to introduce yourself

20 and any conflicts?

21   DR. ADELMAN: Sure. My name is Jason

22 --

1   CO-CHAIR SEPTIMUS: By the way, this

2   time I can see you. The last time he sat over

3   there.

4   DR. ADELMAN: So, good morning,

5   everybody. My name is Jason Adelman. I am the

6   Patient Safety Officer at Montefiore Medical

7   Center in the Bronx and I do have one conflict.

8   Today I am also a developer and so you may have

9   seen a measure from Montefiore Medical Systems.

10 So, I think I am going to switch seats tomorrow

11 when my measure comes up. But otherwise, I have

12 no conflicts.

13   MS. THEBERGE: All right. So, we

14 actually just realized our slides are a bit out

15 of order. So, maybe we will jump ahead and have

16 Jesse go over the portfolio we are looking at

17 today and then we can talk about the criteria.

18   DR. PINES: Sure. So, we have 23

19 separate measures that we are going to go through

20 over the next couple of days. A lot of these

21 measures are measures that this standing

22 committee has seen and endorsed before. So, we

1 expect that some of the discussion should be,

2 hopefully, should sort of run under the 20-minute

3 time frame. We also have several new measures,

4 one of which is Jason's measure, the Wrong

5 Patient Retract and Reorder measure. So, there

6 are several new measures that we are looking at.

7 But the large buckets are in falls,

8 complications, pressure ulcers, some nursing

9 measures, and also some infection measures

10 related to central line infections.

11 So, anyway, I think everyone is

12 familiar with a lot of these measures that have

13 come through this committee before.

14 So, we are also doing three separate

15 ad hoc reviews. One is for PSI15, which we are

16 going to actually have to go through the full

17 discussion and vote on every separate element of

18 PSI15 because it has been changed considerably

19 since the last endorsement and also there is two

20 measures, 0139 and 0138, which are also

21 undergoing an ad hoc review, which hopefully are

22 more of a clarification and a little bit of a re-

1   specification so we won't specifically have to go

2   through every criteria on those matters.

3   MS. THEBERGE: So the composite

4   measure evaluation criteria are pretty similar to

5   the regular evaluation criteria. We have just

6   added a few things to address the composite.

7   For evidence, the evidence criteria

8   must be met for each component of the composite,

9   unless those components are already NQF-endorsed

10   under the current evidence requirements. And

11   that evidence could be for the group of

12   interventions included in a composite performance

13   measure, such as studies in which multiple

14   interventions are delivered to all subjects and

15   the effect on the outcomes is attributed to a

16   group of interventions.

17   The performance gap criterion must be

18   met for the composite performance measure as a

19   whole and the performance gap for each component

20   should also be demonstrated. However, if a

21   component measure has little opportunity for

22   improvement, we would accept a justification for

1   why it should be included for a composite, such

2   as if it increases the reliability.

3   The extra piece of the importance

4   criteria for a composite measure is 1d, the

5   quality construct, which includes the overall

6   area of quality, including component measures and

7   the relationship of the component measures to the

8   overall composite and to each other. In 1d2, the

9   rationale for constructing a composite measure,

10   which is how the composite provides a distinctive

11   value over the component measures individually

12   and then 1d3, how the aggregation and weighting

13   of the component measures are consistent with the

14   stated quality construct and rationale. So, that

15   is one extra criterion for importance.

16   For scientific acceptability, again,

17   it is similar with a little bit of extra added

18   in. Criteria 2a2 reliability testing for

19   composite performance measures, reliability must

20   be demonstrated for the composite measure score.

21   Testing should demonstrate that measurement error

22   is minimal, relative to the quality signal.

1   And examples of testing include

2   signal-to-noise analysis, inter-unit reliability,

3   intraclass correlation coefficients, et cetera.

4   And demonstration of the reliability of

5   individual component measures is not sufficient.

6   In some cases, component measures that are not

7   independently reliable can contribute to the

8   reliability of the composite.

9   For validity testing, validity should

10   be empirically demonstrated for the composite

11   measure score. If empirical testing is not

12   feasible at the time of initial endorsement,

13   acceptable alternatives include systemic

14   assessment of content of base validity and

15   demonstration that each of the component measures

16   meet the NQF's criteria for validity.

17   By the time of endorsement maintenance

18   which would be the case for PSI90, validity of

19   the composite performance measure must also be

20   empirically demonstrated.

21   We do have a sub-criterion 2d, which

22   is a new criterion for composites. It must also

1   be met to pass the must pass criteria of

2   scientific acceptability. If empirical analyses

3   do not provide adequate results or are not

4   conducted, other justification must be provided

5   and accepted for the measure to potentially meet

6   the must pass criterion and specific examples

7   should be provided.

8   Feasibility is pretty much the same,

9   as is usability. And in comparison to related

10   and competing measures, we have to look at both

11   related and competing measures for the components

12   and then for the composite measure as a whole.

13   So, that is just a really quick

14   introduction. We do have a statistical

15   consultant on the line, Sean O'Brien will be

16   joining us to give you a little bit of

17   information about the testing of the composite

18   and he will also be available to answer questions

19   in addition to the staff resources that we have

20   around the table.

21   DR. QUIGLEY: So, I have a quick

22   clarification question. So, in the composite

1   there were two new components included that were

2   not NQF endorsed. Can you sort of describe what

3   that means?

4   DR. BURSTIN: So NQF does not require

5   that the individual elements within a composite

6   be endorsed or that they should at least be

7   discussed as a part of the evaluation to consider

8   whether they are appropriate for the composite.

9   Again, when we redid the composite

10   measure evaluation framework, there was a sense

11   that we should really be focusing on the

12   composite, rather than what is inside it and

13   emphasize more of the qualities than the

14   requirements.

15   CO-CHAIR SEPTIMUS: And I will be

16   getting into that a little bit when we introduce

17   the measure.

18   Lisa.

19   MS. MCGIFFERT: I think I remember

20   reading in all the things we read that there were

21   some categories of measures that were priority

22   for NQF, for example, outcome, and it seems like

1   composite was on there. Can you talk to us about

2   how that fits into our discussion, the fact that

3   a composite is a priority? I may be using the

4   wrong words.

5   DR. BURSTIN: So, for a long time,

6   people had to emphasize the need to have a

7   patient safety composite as recently as some of

8   you may have seen Vital Signs, the most recent

9   Institute of Medicine report on a set of measures

10   for the nation. They emphasized, again, the idea

11   of a safety composite. They didn't specify a

12   specific measure. So, I think there is,

13   generally, a push towards having measures that

14   are more comprehensive composites, more

15   understandable, more usable for consumers and

16   others.

17   So, I agree. But in terms of the

18   measures before you, you have got to look at the

19   measures of the qualities. Other than beyond

20   considering that it is important, it really is

21   about the evaluation of the measure on its

22   merits.

1   Does that make sense?

2   MS. MCGIFFERT: So perhaps I read that

3   somewhere else that NQF priority were to focus on

4   composites. It was?

5   DR. BURSTIN: Absolutely. No, no, I

6   am agreeing completely.

7   MS. MCGIFFERT: Okay.

8   DR. BURSTIN: It is a priority.

9   Everybody said it is a priority. Again, I am

10   just reemphasizing that at least at this table,

11   part of what we depend on you to do is review the

12   merits of the measure in front of you, based on

13   our picture.

14   CO-CHAIR SEPTIMUS: Anyone who is

15   talking about PSI90, let's hold that discussion.

16   But if there are other questions about the

17   composite. So, Lillee and then Charlotte.

18   MS. GELINAS: Just going back to

19   Suzanne's slides that she was swiping through and

20   we were talking about the group of measure that

21   was called staffing. For a long time, those

22   measures were referred to as workforce. And I

1 must have missed when the category changed from

2 workforce to staffing because those two terms

3 mean something very different. So, it was early

4 in your slide deck there.

5   So, how do those categories get

6 represented or change? Because when we look at

7 research and we look at outcomes, frequently, we

8 are looking at impact of the workforce and the

9 work of the workforce as opposed to staffing. Am

10 I being clear there?

11   So, I missed something big time in

12 terms of categorization.

13   DR. BURSTIN: It is actually not

14 something big time.

15   MS. GELINAS: It's not?

16   DR. BURSTIN: It is something that is

17 easy to fix. No, this is just the internal

18 taxonomy NQF uses. And I'm not sure how the term

19 got changed.

20   MS. GELINAS: Okay.

21   DR. BURSTIN: But if there is a

22 preference for the term workforce, we can change

1   it. It's that simple.

2   MS. GELINAS: Okay.

3   CO-CHAIR SEPTIMUS: Charlotte?

4   DR. ALEXANDER: I have sort of a basic

5   question. It is something that came up at one of

6   our other meetings. When we are looking at

7   approving measures, we are looking for both

8   public reporting and accountability. There was

9   some discussion at previous measures that they

10   were important for probably forwarding internal

11   use for quality development but they weren't

12   ready for accountability. We are still expecting

13   all measures to be ready for accountability is a

14   question.

15   DR. BURSTIN: There is currently an

16   expectation that an NQF measure can be used for

17   any potential application. And that would be

18   range from quality proven benchmarking all the

19   way through public reporting, payment, penalties

20   in this day and age as well, certainly.

21   I will say there is an extra panel

22   that has been convened but for now, you are still

1 held to the current approach, which is looking at

2 whether it is time for NQF to move away from a

3 binary yes/no endorsement decision to, in fact,

4 have measures that may have endorsement and

5 criteria specifically related to their intended

6 use. More on that to follow but for today's

7 perspective, yes, they should assumed to be

8 appropriate for NQF purposes.

9   CO-CHAIR SEPTIMUS: Lisa, did you have

10 another comment? Okay. All right, anybody else?

11   Okay, so we are running a few minutes

12 ahead, which is just fine. So, we are going to

13 dive right into -- oh, I'm sorry.

14   DR. BURSTIN: I'm told one more

15 committee member joined us. Ann O'Brien, are you

16 with us?

17   MS. O'BRIEN: Yes. Good morning,

18 everyone.

19   DR. BURSTIN: If you could please

20 introduce yourself and let us know if you have

21 got any disclosures.

22   MS. O'BRIEN: Yes. My name is Ann

1   O'Brien. I met all of you last year. I am the

2   Senior Director at the National Level of Kaiser

3   Permanente in Clinical Informatics.

4   I have a broad background in quality

5   and safety and I have no conflict.

6   DR. BURSTIN: Great, thank you. Back

7   to you, Ed.

8   CO-CHAIR SEPTIMUS: Okay, so we are

9   going to go right into PSI90. We are going to

10   change the format a little bit than you have

11   heard presented. I am actually going to present

12   an overview from last year to this year as my

13   report. We are going to then hear from the

14   measure developer, I think it is Dr. Romano. And

15   then as we mentioned, Sean O'Brien has done some

16   independent work for NQF that will present next.

17   And then we will go into discussion.

18   So, I am sure all of you have read the

19   200 and something pages that were presented to

20   with PSI discussion about that from last year.

21   As you know, this is an outcome measure. It has

22   been expanded from eight to eleven components.

1   Two of those, it was already mentioned by Iona,

2   are not NQF endorsed. And so there is

3   postoperative hemorrhage and hematoma, there used

4   to be acute renal failure, and postoperative

5   respiratory failure. It has been redesigned two

6   measures, one of which we are going to have a

7   thorough discussion we have heard before. PSI15,

8   which is looking at lacerations and punctures

9   that has been refocused on abdominal pelvic

10   surgery that is returned to the operating room.

11   And the other major redesign change, at least

12   from my reading was in PSI12, which is DVT, where

13   they are eliminating calf DVTs from the

14   numerator. So, that is a couple of changes which

15   I think is important.

16   In addition, the weighing format, one

17   of the things we had a lot of discussion on last

18   year has gotten away from volume and looking more

19   at attributable harm. So I think that is a big

20   change in the current measure.

21   And in prior discussions, the evidence

22   behind this measure is being discussed and it has

1 not been a real issue for this committee. So,

2 depending upon what the committee wants to do, we

3 can go right to 1b, which is looking at the

4 composite aspects of this.

5   Let's see if there are any other

6 comments.

7   So, I think overall, I think from my

8 view that this is a much stronger measure than

9 the one we looked at last year and discussed

10 whether or not we should endorse this or not

11 endorse it. As most of you know, this is part of

12 it. And I asked Helen beforehand, HACs, by the

13 way, were part of the 2005 Medicare Deficit

14 Reduction Act and I believe, I think is a

15 statute.

16   And so even though we did not endorse

17 PSI90 last year, it is still part of value-based

18 purchasing. But we think, if you agree, this is

19 a stronger measure and it is worthy of

20 endorsement this year, as opposed to last year,

21 that CMS will probably hopefully endorse the

22 stronger PSI90.

1   So, that is sort of my comments as a

2   start. So, there is a ten-minute presentation.

3   Dr. Romano, welcome back. It is good to see you

4   again. There was discussion last year that we

5   were using the Romano measure and he told me he

6   doesn't use it anymore.

7   DR. BURSTIN: I also want to just

8   check to see if Sean O'Brien has joined us on the

9   phone.

10   CO-CHAIR SEPTIMUS: Jesse told me he

11   is going to be there momentarily.

12   DR. BURSTIN: Okay, great. We will

13   make sure Sean has an opportunity. Sean is a

14   statistician at Duke who we have worked with

15   before who had previously done evaluations of all

16   the outcome measures that have become our

17   Outcomes Committee in the past.

18   Given the complexity of this measure,

19   I thought it would be useful to give you a

20   statistical review. He's worked closely with

21   Karen Johnson. He is a measure methodologist and

22   he will share his perspectives or answer any

1 specific technical questions on what is, as we

2 know, a pretty complex measurement.

3   MS. PANCHOLI: So, good morning. My

4 name is Mamatha Pancholi. I am the Program

5 Officer at the Agency for Healthcare Research and

6 Quality. I direct quality indicators for AHRQ.

7   Since the last time we were here, we

8 have done a lot of work on PSI90 and I am quite

9 excited about giving an update to you all.

10   Of course, all of you know Dr. Patrick

11 Romano, who is our Clinical Lead and he will be

12 giving us a technical presentation and I am happy

13 to answer questions from our perspective as well.

14 Thank you.

15   DR. ROMANO: Good morning, everyone.

16 My name is Patrick Romano. I'm a Professor of

17 General Medicine and Pediatrics at UC Davis

18 School of Medicine in Sacramento, California and

19 I am contractor to AHRQ Technical Development and

20 Enhancement of the Patient Safety Indicators.

21   MS. PANCHOLI: Which is what I said.

22   DR. ROMANO: Okay, so I am just going

1   to give kind of a brief overview of some key

2   elements that changed since the last time I came

3   before you. We will start with a quick review of

4   the conceptual foundation of the composite, a

5   review of our interpretation of the Standing

6   Committee's critique of the composite and

7   modifications, which Dr. Septimus alluded to.

8   One is PSIs that were previously excluded. Two

9   is redesigning two of the component PSIs and

10   third is relating the component (sound system

11   interference) on the concept on the source of

12   impact of the events.

13   So, just in general, this was already

14   raised as a point but I think there are some more

15   recognized benefits of composite measures as a

16   way of summarizing quality across multiple

17   indicators, simplify interpretation and

18   decisionmaking.

19   Those of us who are into

20   decisionmaking say that a smartly designed

21   composite will avoid cognitive shortcuts, where

22   people may tend to put too much emphasis on one

1   measure or another, by designing composites

2   properly, we can hopefully avoid these kind of

3   flawed statistics and help people better

4   understand the balance of all the factors that we

5   should consider.

6   Composites also, of course, more

7   reliably detect differences among providers or

8   groups that could include discrimination because

9   they compile information from multiple

10   indicators.

11   In research context, in volume curbing

12   context, they can facilitate identification of

13   important domains and drivers of quality that may

14   influence performance across multiple composites.

15   And of course, they provide a signal to

16   prioritize action with quality improvement and to

17   support better decisionmaking. Given that

18   healthcare consumers don't know exactly what kind

19   of healthcare they are going to need in the

20   future and even we, on the provider side, don't

21   know exactly what the community is going to

22   demand of us. And so these kinds of composites

1   provide a way to signal areas that perhaps should

2   be priorities.

3   And of course, the Institute of

4   Medicine has recently recognized the importance

5   of composite measures in patient safety and ours

6   is just one many potential composites that

7   hopefully this committee will review and endorse

8   other composites.

9   So, a little conceptual foundation.

10   So, we start the concept of patient safety,

11   defined by WHO as the absence of preventable harm

12   to a patient during the process of healthcare.

13   We are focusing here on inpatient healthcare for

14   adults.

15   In addition, AHRQ's congressional

16   mandate includes reducing harm caused to

17   patients. So, this work is very much consistent

18   with AHRQ's congressional mandate.

19   Our underlying purpose is to optimize

20   the outcomes of inpatient hospital care by

21   providing a single, transparent metric --

22   transparent but complex, that can be used to

1   better understand, communicate, and track patient

2   safety in U.S. hospitals.

3   And of course, an earlier version of

4   this was endorsed by NQF in 2009. So, we are

5   back here with some substantial revisions.

6   So, there are basically two forms of

7   composites. Some of you may know that I co-

8   chaired the NQF committee that actually worked on

9   the methodology for evaluating composite

10 measures, along with Liz Long at Duke University.

11   And so we adopted this approach of

12 considering two types of composites, what were

13 originally called psychometric composites but we

14 prefer now to call reflective composites and

15 formula composites.

16   So, the idea here is that in a

17 reflective composite, there are some underlying,

18 unobserved, latent, quality construct. And we

19 say that these things that we measure are

20 reflecting this unobserved construct through some

21 unobserved processes. And so with this type of

22 approach, we generally use analytic methods from

1 item response theory, principal components

2 analysis and so forth to extract this shared

3 variance across multiple indicators to get at

4 this latent construct.

5 The other approach is the approach

6 that AHRQ has adopted here, which is a formula

7 approach. The idea here is that the outcomes

8 that we measure are, in fact, associated with

9 subsequent changes to patient health, what we

10 call utility or disutility. And so we are

11 interested in forming a composite from these

12 things that we measure because we believe that

13 each of these things is important in and of

14 itself. And it is important particularly because

15 it is associated with health states that are

16 meaningful to patients and to society.

17 So, in a formative design, we have a

18 bunch of components that go into the construction

19 of the composite, based on this concept of harm

20 or preventable harm.

21 So, three key concerns that we have

22 addressed through this revision process. First,

1   was a relatively small number of included events,

2   eight events. Over 70 percent of the weight fell

3   on two of those events that admittedly have

4   variable clinical significance, perhaps signaling

5   incorrectly that these events are particularly

6   important or preventable among all patient

7   safety-related events.

8   The second critique was that the

9   number of occurrences of a PSI is really an

10   inadequate proxy for its marginal impact on

11   population health. So, if we really want to

12   better understand population health and how to

13   improve the health of patients coming out of

14   hospitals, then we need to consider the

15   importance of the events as well as their

16   frequency and reliability.

17   And finally, because of the above

18   limitations, there is concern -- there was

19   concern that PSI90 may encourage misallocation of

20   effort. If people spend a lot of time focusing,

21   for example, on how to avoid coding accident

22   punctures and lacerations through pre-billing

1 code review programs, rather than focusing on the

2 quality improvement, which is the essence of the

3 enterprise.

4 So, we have addressed each of these

5 three concerns. So, first we have expanded the

6 scope from eight events to eleven events. We

7 have added three additional events. One of those

8 is currently NQF endorsed. Postoperative

9 respiratory failure was recently reviewed and,

10 again, recommended for maintenance endorsement.

11 Two others have not been endorsed but

12 we believe that they are comparable in importance

13 and scientific acceptability. And I will point

14 out, again, that both PSI9 and PSI10 had been

15 redesigned over the last several years in

16 response to evidence from validation studies that

17 AHRQ has supported, the VA has supported, and

18 other organizations have supported.

19 So, both of these measures now include

20 both diagnoses and procedures. In other words,

21 perioperative hemorrhage or hematoma requires a

22 diagnosis of hemorrhage or hematoma plus a

1 procedure that appears to involve addressing or

2 fixing that event. Similarly, postoperative

3 physiologic derangement involves a diagnosis of

4 acute kidney injury along with a procedure for

5 dialysis to treat that diagnosis.

6 Second, two of the component measures,

7 PSI12 and 15 have been redesigned. For PSI12,

8 the key concern was ascertainment by us, or what

9 really might be better called over-diagnosis

10 bias, due to variation in postoperative

11 surveillance. So, the idea here is that some

12 hospitals are routinely screening asymptomatic or

13 minimally symptomatic patients after surgery to

14 look for blood clots. They often find blood

15 clots in distal veins down in the calf, lower

16 extremities.

17 And when this diagnosis was made, we

18 as clinicians often feel compelled to treat these

19 events. And of course, it leads to a codeable

20 diagnosis.

21 So, we have seen a couple things in

22 the data that support that concern. One is that

1   over time, as we look over the last three years

2   of data available to us, the rate of proximal

3   DVTs and PEs has been decreasing, as hospitals

4   have paid more attention to this problem and

5   implemented protocols with thromboprophylaxis.

6   But the rate of isolated distal DVTs has not

7   decreased. In fact, it has been slightly

8   increasing or stable.

9   In addition, when we look to the

10   isolated calf DVTs, we found three times as much

11   variation across hospitals as for the proximal

12   DVTs and the blood clots in the lungs.

13   So, what we have done is to remove the

14   isolated calf vein DVTs from the numerator of

15   this indicator. So, the revised indicator

16   captures the proximal clots and the clots in the

17   lungs, which everyone agrees are clinically

18   significant, which everyone agrees need to be

19   treated with anticoagulant medication.

20   Now, it turns out this removes only 17

21   percent of the events that are currently captured

22   by PSI12 but that percentage does vary across

1   hospitals. And even in the 95 percent range, it

2   varies from zero percent up to about a third of

3   all the events across hospitals.

4   So, the overall performance of the

5   indicator is unchanged but it may have an impact

6   for certain hospitals that are doing this more

7   aggressive surveillance.

8   For PSI15, the concern here was that

9   accidental punctures or lacerations are

10   relatively frequent events that have uncertain

11   clinical significance. Sometimes we have a

12   difficult operation, a lot of scar tissue,

13   difficult anatomy and the accidental laceration

14   may be inevitable in the procedure. It may be an

15   inherent risk or it may be a minimal event, a

16   serosal injury that can be easily repaired at the

17   same time, with essentially no risk to the

18   patient.

19   So, what we have done here is to focus

20   on a more homogenous set of operations involving

21   the abdomen and pelvis and then to look at the

22   subset of patients who have a coded event and a

1   return to the operating room to reopen the

2   abdomen or pelvis, presumably to repair that

3   event or do some other related operation

4   necessary because of the accidental puncture.

5   So, what impact does this have? A

6   couple of key data points. One is that this

7   really identifies a subset of patients who have

8   bad outcomes. So, with this new specification,

9   either percent of patients -- I'm sorry -- 34

10   percent of patients have sepsis, 6 percent of

11   patients have postoperative respiratory failure,

12   31 of patients are discharged to skilled nursing

13   facilities, 10 percent of patients die after

14   their reoperation. So, these are unquestionably

15   poor outcomes.

16   Because this change does substantially

17   reduce the incidence of PSI15 over 90 percent, we

18   did recommend, and NQF agreed, that a full

19   review, ad hoc review is necessary. And that

20   will be occurring tomorrow and Dr. Utter, who is

21   a surgeon on our team at UC Davis will be leading

22   the presentation there.

1   So, with this change, we have also

2   changed the name of PSI15 to Unrecognized

3   Abdominal Pelvic Accidental Puncture Laceration.

4   So, in terms of the weighting, so as

5   you recall, the way that this composite is

6   designed is that it is a composite of individual

7   measures. So, each measure requires its own risk

8   adjustment or risk standardization. So, this is

9   done with a tailored risk adjustment model for

10   each indicator, incorporating age, gender, age-

11   sex interactions, comorbidities, as well as MS-

12   DRG categories that represent why the patient was

13   admitted to the hospital, as well as information

14   about whether they were transferred to another

15   hospital, if appropriate.

16   So, each of these components is

17   indirectly risk standardized. And then those

18   observed to expected ratios are reliability

19   adjusted. So that, for example, if a measure has

20   a relatively low signal at the hospital level,

21   the O/E ratios come closer to one. If a measure

22   has a higher signal at the hospital level, then

1 the O/E ratios remain closer to their empirically

2 estimated values.

3 So, in general, we can do a couple

4 things with those O/E ratios. We can weight them

5 according to the number of patients who are at

6 risk or the number of opportunities, or we can

7 weight them according to the number of events.

8 And historically, for the patient

9 safety indicators, we have chosen a numerator

10 based weighting, based on the relative frequency

11 of the events. But in our new approach, we are

12 adding a component, incorporating the marginal

13 meta impact or importance of each of the events,

14 reflecting both the incidence and the severity of

15 the events, where severity if operationalized in

16 terms of the harms that we can identify occurring

17 after the PSIs, using linked Medicare data.

18 So, we borrow concepts from the

19 utility assessment literature. Utility values

20 reflect a patient's preferences for different

21 health outcomes. There are two components to

22 that. One of them is defining and describing

1 health states. The second is valuing those

2 health states. There are a variety of different

3 methods in the literature to measure those. Each

4 has advantages and disadvantages.

5 We, fortunately are able to borrow

6 extensively from the literature to find utility

7 valuation estimates for different health states,

8 like being on dialysis, for example, or being in

9 a skilled nursing facility. But for some events,

10 such as having a chest tube in, while you are in

11 the hospital, there is no literature on what the

12 disutility associated with that event is.

13 So, we engaged a group of clinicians

14 to rank all of the different events and we then

15 recalibrated those scores, using a literature-

16 based estimates. So, the clinicians could give

17 us a relative ranking of how getting a chest tube

18 would fall in-between the different other health

19 states for which we do have patient-centered

20 utility values and we use those to, essentially,

21 interpolate the values for the conditions for

22 which we don't have literature-based estimates.

1   So, again, the steps in the

2   specification of each harm, the literature

3   review; the clinical expert panel, including

4   nurses and physicians from a variety of relevant

5   specialties. And then we used a regression to

6   calibrate the expert clinician rankings to

7   literature-based utilities, thereby generating

8   disutility estimates that reflect patients -- we

9   hope reflect patients' perspectives.

10   We used CMS Medicare Fee-for-Service

11   data from two years identifying a cohort of

12   patients who are at-risk for each PSI event. We

13   then compared patients who experienced a PSI

14   event with patients who did not experience the

15   event. But of course, that is strictly

16   comparison because the patients who experience

17   the event are sicker. So, we used a commonly

18   applied approach called propensity score matching

19   and specifically the inverse propensity weighting

20   approach, incorporating, essentially, the risk

21   adjustment model that goes into the estimation of

22   the observed to expected ratios but we added some

1 things as well.

2 So, in this case, in this propensity

3 matching we also added socioeconomic factors,

4 which by tradition with NQF are excluded from

5 risk adjustment. But here, since our goal was to

6 understand what is the marginal harm that

7 results, for example, mortality within 60 days or

8 90 days that results after a PSI. So, now we

9 felt it was important to take into consideration

10 other socioeconomic factors that may confound the

11 relationship between PSI events and subsequent

12 harms, such as mortality, that might be post-

13 discharge against.

14 So, we followed patients up for up to

15 12 months, depending on the specific event. For

16 an event like an iatrogenic pneumothorax, we

17 assumed that if you were out of the woods in a

18 month, that that was good enough. But for other

19 events like postoperative renal failure,

20 obviously, the consequences of that could go on

21 indefinitely.

22 So, this slide just summarizes the

1 harm weights and these are rescaled so that they

2 sum to one. So, you can see in essence here, for

3 example, that the most serious events like

4 postoperative sepsis at 0.232 and PSI8, which is

5 postoperative hip fracture, the more clinically

6 serious events now carry heavier harm weights.

7   There is a volume component and the

8 final weight is basically a rescaled sum product

9 of those harm and volume weights.

10   So, you can see that just in this new

11 weighting, the weighting for PSI12 goes down to

12 0.21 and the weighting for PSI15 goes down to

13 0.011.

14   So, a couple of quick sensitivity or

15 robustness analyses that we have done since on

16 the materials that you have reviewed, one is to

17 look at how sensitive the PSI90 is to any single

18 composite. So, we want to be able to show that

19 it is not unduly influenced. So, this shows,

20 essentially, how many hospitals are switching

21 across quartile rankings. And the key point here

22 is with respect to PSI7, which is central line-

1   associated bloodstream infection.

2   So, we understand that many users had

3   access to the CDC/NHSN measure of central line-

4   associated bloodstream infection. And they might

5   prefer to substitute that measure for PSI7 in the

6   composite, essentially to remove PSI7.

7   And so this will be an option in the

8   new version. And you can see if when PSI7 is

9   removed from the composite that only about five

10 percent of hospitals shift a quartile in the

11 ranking.

12   This shows there is some error in our

13 utility estimates. And we have done some work to

14 understand, as we enroll more and more experts in

15 our expert panels, and as we review more and more

16 literature, we have looked at how much variation

17 we are getting in our disutility estimates from

18 different sources. And, generally, we seem to be

19 staying within a plus or a minus 15 percent

20 range. So, we did a 15 percent plus or minus

21 random perturbation of all the disutility

22 estimates in the thousand simulations to see what

1   the impact of that would be. And you can see,

2   actually, that it has minimal impact. So, these

3   are weighted kappas and you can see that the

4   weighted kappas are all centered around 0.98.

5   So perturbing the disutility estimates

6   actually has, within a reasonable range, has

7   minimal impact on the ranking of hospitals, given

8   the number of indicators that are included.

9   So, in conclusion, we think there are

10   some strengths with this new approach but there

11   are also some limitations. The total weight is

12   more evenly balanced across PSIs. No single

13   indicator carries more than about 30 percent the

14   total weight.

15   The PSI events with worse health

16   consequences are weighted more heavily. Those

17   that are easy to prevent by changing coding

18   practices are no longer weighted more heavily.

19   And to the extent that some PSIs have false

20   positives, events that didn't actually happen

21   actually reduced the corresponding harm weights.

22   Because if the event didn't happen, then it is

1 not associated with subsequent harms. And so it

2 reduces the weight that is assigned to that

3 component PSI.

4   We think that PSI90 is now better

5 aligned with the concept of patient safety or

6 reducing harm that occurs in the process of

7 inpatient medical care. And we find that PSI is

8 reasonably robust to variation in which

9 components are included and how the disutilities

10 are estimated. But we must anticipate that the

11 component weights, just like risk adjustment

12 parameters may vary slightly from year to year,

13 as we update our reference population, as we re-

14 estimate these models, there will be some

15 variation.

16   And of course, this is work that we

17 did very quickly within nine months and we

18 anticipate that additional harms will be

19 considered. Many of you may have thought of

20 harms that you didn't include in the estimation

21 and we are eager to do that. So, there will be

22 an incremental process but we hope that this

1 process addresses the concerns that we discussed

2 last year.

3   CO-CHAIR SEPTIMUS: I always love

4 listening to your analysis and your team has an

5 incredible amount of work in a short period of

6 time. In fact, some of us weren't sure you could

7 get it done by this date and you did. And you

8 should be congratulated, regardless of the final

9 outcome of our conversation. We really

10 appreciate you coming back to the committee and I

11 think certainly making this a much stronger

12 composite than what we saw last year.

13   With that, I think we have -- Sean are

14 you on the line?

15   DR. O'BRIEN: Can you hear me?

16   CO-CHAIR SEPTIMUS: Yes. So, this is

17 Dr. Sean O'Brien. Sean, would you introduce

18 yourself to the group and then give us your

19 analysis, please?

20   DR. O'BRIEN: Sure. I'm Sean O'Brien.

21 I'm from Duke University Medical Center. I work

22 on several professional society registries

1   regarding improvement and have been involved in

2   risk model development and including some work on

3   composite measures in a consultant role with NQF.

4   I was asked to kind of participate in this call

5   to providing kind of a summary of framework for

6   looking at the methodological and statistical

7   issues.

8   So, I just will -- I guess I will jump

9   in. I was going to start this by basically

10   describing my framework or a framework for

11   evaluating evidence provided for composite

12   measures and then we will go through some of the

13   evidence that was provided in the Nissen

14   materials.

15   I think Dr. Romano already mentioned

16   some of the advantages of composite measures, in

17   the sense that they can simplify reporting and be

18   more comprehensive than single measures and they

19   can often gain precision compared to single

20   measures by aggregating data across multiple

21   endpoints. The concerns about composite

22   measures, they can be challenging particularly

1 because of the weighting issues. So, although

2 they can distill a large amount of information

3 into a smaller distilled summary, quality or even

4 a facet of quality is often multidimensional.

5 And so when you combine information from multiple

6 measures that are measuring slightly different

7 things, there is clearly potential for

8 information loss. And it is most challenging

9 that when the items that are being combined into

10 a single summary measure don't always track

11 together.

12 So, when you have multiple items that

13 are being averaged together in a weighted

14 average, if they are all highly correlated and

15 measuring exactly the same things and no matter

16 how you weight them, you are going to pretty much

17 get the same ranking of the units that are you

18 are evaluating. When you are combining items

19 where hospitals may do the units being evaluated

20 do better on one and worse on others, then the

21 results can be quite sensitive to the approach to

22 weightings adopted.

1   And unfortunately, there is no single

2   agreed upon objective method of developing

3   weights. And I think a realistic way of thinking

4   about the weighting is that no matter what you do

5   there is an inherently subjective component that

6   is inherently normative and how you weight the

7   different items really determines what is being

8   measured and how you should think of that

9   measure.

10   And really, and I think this is

11   consistent with the kind of philosophical

12   approach that was adopted by the developers, is

13   that in the end, the validity of the weighting

14   really depends quite a bit on its acceptance to

15   the users and the various stakeholders that are

16   going to be using information from the composite.

17   So, really, in a way, the ultimate criteria is

18   that the weights make sense to the users and the

19   stakeholders.

20   Also, it can be heard to understand

21   the weights and they may seem less transparent

22   when items are combined by really exploring the

1   consequences of the weights from different angles

2   and doing sensitivity analyses like some that

3   just were presented is really, I think, the best

4   that you can do in terms of understanding how the

5   composite measure is going to be behaving in

6   practice and ensuring that there were no

7   unintended consequences, that the weights make

8   sense to the users.

9   So, with that in mind, one thing that

10   people frequently look at with respect to

11   composite measures is the correlation between the

12   items that are being combined in the measure.

13   So, that was one of the, using HCUP data from

14   2012, the measure developers reported that the

15   items in the composite were positively

16   correlated. The correlation was not extremely

17   high. There are correlations ranging in the low

18   0.08 up to the 30s. And I think some

19   methodologists approaching measure development

20   from kind of a psychometric framework would often

21   say well, it is important for this correlation to

22   be very high, as articulated by the measure

1   developers. It basically measures different

2   things. If you can argue that they are all

3   important to measure, then regardless of their

4   correlation, the justification for combining them

5   is that they are all important. The fact that

6   they are not correlated means that there is more

7   risk or impact if the weights are not chosen

8   appropriately. But I would just say that high or

9   low correlations is probably not the main thing

10   to look at in the assessment of the composite

11   measure.

12   But in the end, after assigning

13   weights, you can kind of look to see empirically

14   which measures seem to be most explaining the

15   variation in the composite. And so in one of the

16   tables they provided, the items the total

17   correlations, where they look at any single item

18   in the composite and look at its correlation of

19   the overall composite, and those correlations

20   range from very low, for example PSI08, which is

21   postoperative hip fracture, which is essentially

22   zero correlation to around 30. And the message

1	there is that basically the items that are

2	regarded by the developers as being relatively

3	important were contributing variations of the

4	composite, which is expected and desirable and

5	with the exception of maybe one of the measures,

6	they are all appearing to contribute. And so, I

7	think their assessment of the underlying behavior

8	that you see empirically is consistent with the

9	intention.

10	 And finally, another aspect of testing

11	that was presented had to do with reliability and

12	reliability can refer to a lot of different

13	things. Here, they are looking at basically

14	whether the sample sizes, the number of eligible

15	cases of the units being evaluated are enough to

16	provide precise estimates to really differentiate

17	performance across the units. So, reliability,

18	in that sense, is the proportion of variation in

19	what you measure that is really explained by true

20	difference, rather than random chance and noise.

21	And it is also basically a measure of how well

22	correlated is what you measure with the

1   underlying thing that you are trying to measure.

2   So, it is related to a correlation coefficient.

3   And their results for reliability were

4   in the 70s, which compared to a lot of NQF

5   endorsed measures and things that are submitted

6   for measurements, that seems to be relatively

7   acceptable.

8   And regardless of the subjective

9   judgment about whether reliability is high or

10   low, when you combine items across multiple items

11   in a single measure, you tend to increase

12   reliability. So, several of the components in

13   the composite were NQF endorsed and presumably,

14   some of these may have had lower reliability.

15   So, if there is any concern about

16   reliability, in the sense of the statistical

17   reliability, certainly aggregating across

18   multiple items into a composite is an approach to

19   address and improve the reliability. So, even as

20   low, it is probably higher than what you would

21   see when analyzing the endpoints individually.

22   And another way to get at reliability

1   in a little bit more simple and direct way is to

2   look at the results of a test run of the data to

3   see how many units could be classified, basically

4   being different from one another or different

5   compared to various benchmarks. And frequently,

6   you look to see whether you can distinguish

7   whether units are better or worse compared to the

8   average. And often, I see reported what

9   proportion can be classified compared to the

10   average here. In their empirical testing, the

11   developers reported what percentage of hospitals

12   could be distinguished by being below the best --

13   below the 80th percentile, meaning they could be

14   ruled out as having top-notch performance or

15   whether they could be classified as being above

16   the 20th percentile, meaning they could be ruled

17   out as not being in the really bottom

18   classification of performance.

19   And the results were that it depends

20   on sample size but that certainly of the half or

21   more than half, three-quarters were able to be

22   classified in that respect. I think if you were

1   trying to classify units as being above or below

2   average, it is actually harder to make that

3   classification. It is relatively easier to say

4   based on the observed data for your hospital, we

5   can tell you are not the top but there may be

6   some uncertainty about how they compare relative

7   to the average.

8   But in any case, based on the results

9   presented, the results are not dominated by

10   random sampling variation. There is clearly

11   ability to make useful conclusions that are based

12   on true signal differences and not just noise.

13   So, I think I will pause there and

14   just say that in my assessment, in terms of the

15   analyses presented in the conceptual approach,

16   although it is extremely technical in nature,

17   their methods were really responsive to the

18   underlying clinical intent. So, it wasn't just

19   methods that were complicated because of a desire

20   to be complicated. All the choices really

21   responded to the criticisms from last round and,

22   basically, the intent of the measure. And it was

1   a relatively complete analysis and quite

2   comprehensive.

3   So, I will participate in the rest of

4   the discussion, if desired, but I will stop

5   there.

6   CO-CHAIR SEPTIMUS: Thank you very

7   much, Sean.

8   So, at this time I think we are going

9   to open it up for questions. Go for it.

10   DR. SCHULTZ: This is Leslie Schultz.

11   I just have a clarification question. So, on the

12   weights that we see for the fully specified model

13   with the 11 components, now you are using the old

14   label for PSI15 but did you use the new

15   specifications for 15? Okay, thank you.

16   CO-CHAIR SEPTIMUS: For those on the

17   phone, the answer was yes. If you could speak

18   into the mike or speak on the phone so we can

19   hear you.

20   Charlotte first and then we will go to

21   Michelle.

22   DR. ALEXANDER: So, I have a concern

1   about DVT. Many of us have been working under

2   the premise that it was a preventable thing, if

3   you took certain actions. And our experience

4   both here and abroad has been that

5   pharmacological prophylaxis does not seem to

6   change the rates. There is new article out in

7   JAMA this year. There was a mice study that

8   looked at that that showed that the rates stayed

9   exactly the same.

10   Most of these measures are harm

11   measures where a lack of activity or something

12   that is done by us created harm. What I am

13   seeing is that large facilities are doing more

14   trauma are the ones that are greater risk and I

15   don't see that as a harm issue.

16   So, I just would like to bring that to

17   the forefront and have a discussion.

18   CO-CHAIR SEPTIMUS: Okay, we will go

19   to Michelle, Steve, Jesse, and then over here.

20   DR. SCHREIBER: Thank you. First of

21   all, thank you for all the incredible work that

22   has been done --

1   CO-CHAIR SEPTIMUS: Is your mike on?

2   Speak closer to it.

3   DR. SCHREIBER: It's on. Thank you.

4   I was just saying thank you for the incredible

5   work. I think this has made this a much stronger

6   measure.

7   DR. QUIGLEY: Excuse me. May I

8   interrupt? Point of information. I think for

9   the purposes of reporting, we did this last time,

10   we all had to identify our name as we get

11   started. So, that might be helpful. And then if

12   people wouldn't mind just speaking closer to the

13   microphone that would be helpful because some

14   people are very soft. But I think we are

15   supposed to identify our name as we get started.

16   Thank you.

17   DR. SCHREIBER: Sure, happy to.

18   Michelle Schreiber from Henry Ford. And I was

19   saying, again, thank you for strengthening this

20   measure. But I do have a question.

21   In looking at the hospital-acquired

22   condition rankings that came out from CMS, there

1 seem to be a large number of academic medical

2 centers, for example that were ranked in the

3 lowest quartile. And I am wondering if you feel

4 that there was an underlying bias because of the

5 academic medical center and whether or not this

6 will adjust for that if there is any bias that we

7 should be thinking of.

8 CO-CHAIR SEPTIMUS: Do you want to

9 answer her? Go ahead.

10 DR. ROMANO: Yes, we have just begun

11 to explore the question. And what I can tell

12 you, in fact, I just reviewed some output, along

13 with my boss here yesterday. And so I can say

14 that PSI15, in particular for accidental puncture

15 laceration, this change actually reverses

16 direction of the weighted mean observed to

17 expected ratio.

18 So, with the previous classification

19 of PSI15, teaching hospitals were overwhelming

20 non-teaching hospitals four to one or the

21 specification of actually teaching hospitals are

22 slightly below one and non-teaching hospitals are

1 slightly above. A very small difference, like

2 two percent but it did reverse the direction.

3   For PSI12, the change did not reverse

4 the effect but it did markedly narrow it. So,

5 now there is roughly a 20 percent higher rate of

6 the observed to expected ratio related to

7 teaching hospitals versus non-teaching hospitals,

8 which is close to 35 percent.

9   So, I think how this comes out in

10 terms of the overall composite, I can't say. But

11 at least for those two components, it is either

12 reverse the effect or it has reduced its

13 distinction.

14   CO-CHAIR SEPTIMUS: Just a follow-up

15 before we go to Steve.

16   So, this is not one of the confounders

17 that you used in terms of your observed versus

18 expected as to teaching status, size of beds,

19 those kinds of beds.

20   DR. ROMANO: Well, we never used

21 hospital characteristics in the analysis.

22   CO-CHAIR SEPTIMUS: Steve.

1   DR. LAWLESS: Yes, I'm Steve Lawless

2   from Nemours. Three questions or three sub-

3   parts. You can answer just if they have a

4   substantial impact or not. I may have missed it

5   in all the conversation.

6   But the PSI7 on the Nissen is my

7   understanding a little bit is that Nissen has

8   changed its definition a little bit of central

9   line infection in terms of oncology patients,

10   that there are central line infections and there

11   is one bowl ischemia associated or whatever.

12   CO-CHAIR SEPTIMUS: Mucosal barrier.

13   DR. LAWLESS: Mucosal barrier. Some

14   of your data -- thank you IV specialist. Does

15   that impact at all? Because that loosens the

16   definition in ob verses where your model came in.

17   Second is, it looks to me that if you

18   had one hip fracture, most likely from the

19   management you are going to get a metabolic

20   disorder or you could have something else happen

21   or thrombosis. Is there something almost like a

22   tolerance or a cross-tolerance or measures?   Or

1   is that already impacted in the weighting, that

2   if you have had one, the likelihood of having a

3   second or a third of these measures escalates

4   versus isolated events themselves.

5   And the third you mentioned a little

6   bit, which was the test, re-test, different from

7   your simulation of what is already -- you rerun

8   the numbers. And by rerunning the numbers, you

9   are seeing differences.

10   At what point would you suggest there

11   is enough stability in the model so that people

12   one year aren't real low and the next year they

13   are real high, they have that celebration massive

14   firing of teams effect?

15   DR. ROMANO: So, I'm not sure I quite

16   caught the first issue. So, is this an issue

17   with respect -- because this is based on IC-9

18   coded data. So, does this affect the --

19   DR. LAWLESS: Well, you had mentioned

20   a little bit that people can substitute Nissen

21   for another definition of some sort. And I just

22   want to make sure that if people do, the Nissen

1   definition of mucosal barrier has changed a

2   little bit and so they are not necessarily apples

3   to apples. It is apples to oranges. And so

4   where would you weigh in on that or is that

5   impacted?

6   DR. ROMANO: Right. Well, that,

7   honestly, would be up to the user. If the user

8   wished to remove PSI7 for a particular

9   application, it would be possible to do that.

10   But of course, the CLABSI measure from CDC is a

11   completely different structure. I mean so it is

12   based on catheter days, as opposed to patient

13   discharges. It is based on specific units as

14   opposed to all adult hospitalized patients. So,

15   there are a lot of things that would make that

16   sort of an apples to oranges difference.

17   So, that is sort of caveat emptor to

18   some extent.

19   CO-CHAIR SEPTIMUS: So, your measure

20   as it is now for line infections, that is based

21   on administrative data. Correct? I just want to

22   maybe clarify your question.

1   So, that is based on physician

2   documentation as taken by coders and may or may

3   not correlate with what facilities report into

4   NHSN in terms of definition of CLABSI. So, there

5   are two different measures.

6   Now, the MBI, mucosal barrier injury

7   definition, even though it is separated by a

8   reporting mechanism, it is still included

9   together, at this point.

10   DR. ROMANO: Right. So, and obviously

11   there is a lot of older literature showing that

12   the ICD-9-CM codes for central line infection are

13   really poor. But in response to petitions from

14   CDC and AHRQ, they actually changed, as many of

15   you know, they actually changed the ICD-9-CM code

16   so that it is very specific to central line-

17   associated bloodstream infection, at this point.

18   The other question, so, in terms of

19   hip fracture, yes. So, we have been empirically

20   exploring this question and there are some

21   particular patterns where PSIs co-occur. And in

22   fact one of the more common patterns, for

1   example, is postoperative sepsis with

2   postoperative pneumothorax.

3   So, we are in the process of doing

4   some empirical analyses to assess how to allocate

5   harms for these patients. And that was alluded

6   to a little bit in the last bullet, where we do

7   find that, of course, the patient died and you

8   don't want to be carrying that death twice in the

9   harms estimation. So, we have to assign that

10   death in one place.

11   Now, it turns out that empirically

12   there is relatively little. So, it won't have

13   that much of an effect on the weighting and it is

14   kind of built into that 15 sort of percent error.

15   But nonetheless, we are actively working now on

16   sort of cleaning it up and making sure that when

17   patients have two PSIs, that they are allocated,

18   essentially for the purposes of the harms

19   estimation, to one and only one PSI or to a

20   specific combination of PSIs when we do empirical

21   estimating.

22   And the final point was about

1 stability and I would refer you to I think the

2 ICC estimates, which are reported here at 0.76,

3 which is a reasonable level of liability.

4 Now, of course, we only had two years

5 of data to use for this because we are using a 36

6 state reference population that has good coding

7 of present on admission data. So, as we get more

8 data and we will have the 2013 data hopefully

9 soon, we will be able to get a better sense of

10 the stability across time, which I think is more

11 direct.

12 CO-CHAIR SEPTIMUS: Okay, Jason, I can

13 see you.

14 DR. ADELMAN: Jason Adelman.

15 CO-CHAIR SEPTIMUS: We can't hear you,

16 Jason.

17 DR. ADELMAN: Okay. All right. Can

18 you hear me now? All right.

19 I have two points and questions. The

20 first was well, I wanted to echo some of the

21 things that were said. I appreciate the

22 responsiveness from the last time we were given

1   the measure until now and, specifically, I think

2   we commented that the weighting occurred by

3   volume did not really make sense to us and that

4   was addressed. Also, there was a lot of weight

5   given to accidental punctures and that was

6   partially addressed.

7   But I think it was Charlotte who

8   talked about preventability. That was another

9   point that was discussed a lot. And I don't

10   think that was addressed as well.

11   When Dr. Romano gave his presentation

12   at the beginning, he gave the definition from the

13   WHO, the World Health Organization, their

14   definition of patient safety and, in fact,

15   underlined the word preventability.

16   And these measures are a real mix of

17   measures that have incredible evidence for us

18   patient safety officers to work on to reduce the

19   outcomes. So, most notably, CLABSIs, we can

20   refer to the Michigan Keystone initiative, Peter

21   Pronovost's work.

22   And then there are other things I

1   recall. At the last meeting, I had asked Dr.

2   Romano about the accidental puncture and he gave

3   sort of a more obscure reference that I couldn't

4   find after I asked NQF and I never identified it.

5   But the point is, I'm sure there is an

6   article about every adverse event that exists.

7   There is an article about something that might

8   prevent it and some of it is large Keystone State

9   of Michigan studies and some are obscure

10   articles. But at some point, the World Health

11   Organization defines patient safety but they also

12   define adverse events.

13   And there is a cutoff point where at

14   that one point ventilator-associated pneumonias

15   were considered an adverse event and then

16   research the bed at 20 degrees, use suction, and

17   Pepcid, for some reason that I don't understand,

18   it can really reduce ventilator-associated

19   pneumonias. And it sort of switched from just

20   asking a patient to sign consent to something

21   that we really have to do and if we don't do it,

22   we should be held accountable.

1   This measure, to me, is a mix of

2   adverse events and patient safety. It is just a

3   mix.

4   I remember I made this point last time

5   and Lisa sort of countered with they are all

6   valuable and I thought that was a good point and

7   I agreed. However, I also think one of the

8   criteria is usability and use. And mixing it all

9   together and then calling it a patient safety

10   composite is confusing to me.

11   The one other thing I wish they would

12   have done is split the composite in two; taken

13   the things where there is real solid evidence,

14   called it a patient safety measure and held us

15   all accountable to those things. And then taken

16   things that were adverse events where there is no

17   real strong research but we should still measure

18   it because there is still harm to patients, to

19   Lisa's point, but put it in a separate bucket and

20   measure those also.

21   And you know I am encouraged that our

22   process works. So, if anything, let's send them

1 back to go do that. But short of that, in case

2 that is a little too much, because it is really

3 an incredible measure and a lot of great work,

4 just at a minimal, I think the title should be

5 changed to like a patient safety and adverse

6 event composite because it is, in my view, is not

7 patient safety.

8   And the last point I will make about

9 this is there is this HAC Pay-for-Performance

10 program that is out there. And back in my

11 hospital, while we didn't have to work on CLABSIs

12 because we are doing great because we are

13 following the Peter Pronovost Keystone thing, we

14 all do our checklist, we didn't do well in CAUTIs

15 but there is a tremendous amount of evidence to

16 prevent CAUTIs, so we are working hard at it.

17   And then we also didn't do that well

18 on the AHRQ PSI90. So, we have our chart

19 abstractors trying to fix how they chart. And

20 that's it because there is really not some great

21 program. If Dr. Romano and AHRQ can point to

22 some great initiative that I can use that is

1   really evidence-based that I could sell to the

2   surgeons to prevent accidental punctures, I will

3   go back home and do it. But right now, it is

4   just working with the coders and that is like the

5   reality. If you take a typical patient safety

6   officer from a big hospital, that is what is

7   going on.

8   So, that was one comment. And the

9   second comment I'm following up with what Steve

10   said. The substitution of the AHRQ PSI for

11   CLABSIs to NHSN is a bit confusing to me. Like I

12   have never heard of that before. When it is up

13   to the user, I don't understand if that means the

14   hospital or CMS. So, like in the next HAC

15   program, are they just going to say include it or

16   not? And I think, generally speaking, most

17   people, except that the NHSN measure is the

18   better measure than chart. So, why not just dump

19   it and use it?

20   DR. BURSTIN: Anybody on the phone,

21   please put your phone on mute. We are catching

22   some background noise you probably don't want to

1   share. Thank you.

2   DR. ADELMAN: Right now in the HAC

3   program, AHRQ PSI90 is there with CLABSIs as part

4   of this composite. And then also the NHSN full

5   cut. So why have both? Why not just drop it and

6   have one measure with one very clear instruction?

7   I just don't understand the substitution. Those

8   are my two points.

9   CO-CHAIR SEPTIMUS: Any comments that

10   you want to make?

11   DR. ROMANO: Sure. So, a couple

12   things. So, one is that we have tried to address

13   the evidence question by putting an evidence

14   table into the materials that were submitted.

15   So, there is a fairly high-level summary of

16   evidence for each of the PSIs related to

17   processes of care that had been shown to prevent

18   or believed to prevent those events. So, I

19   encourage you to look through that table and the

20   reference is cited there.

21   For the measures that are currently

22   endorsed by NQF, we left that evidence review to

1   the committee that considered the measure for

2   endorsement. So, those particular measures are

3   not in this table.

4   So, I don't think there is an easy

5   split between components that are more

6   preventable, components that are less

7   preventable. What we have tried to do is

8   incorporate -- well, so there are two ways in

9   which preventability is implicitly incorporated.

10   One is that each of the PSIs was rated on face

11   validity by a clinical panel. And if it didn't

12   meet the threshold for at least an acceptable

13   level of preventability, according to the

14   clinical panel, then it wasn't initially proposed

15   by AHRQ as a PSI.

16   And then second, we do this

17   reliability adjustment of each of the component

18   indicators. So, one of the implications of that

19   is if an indicator has -- if hospitals can't do

20   anything to prevent an indicator, then there is

21   not going to be any hospital level signal that is

22   going to be randomly sorted across hospitals

1   after risk adjustment. And so everything will

2   shrunk back towards one. All those observed to

3   expected ratios will get shrunk to one.

4   So, if in fact there is no

5   preventability, then the absence of

6   preventability results in a relatively small

7   impact of the indicator because all the O to E

8   ratios being close to one.

9   So, trying to build a preventability

10 factor on top of that was empirically beyond our

11 capability during this period and I'm not sure

12 what evidence we would use.

13   I do want to specifically address the

14 DVT issue because I will strenuously protest

15 about deep vein thrombosis. So, there is, of

16 course, a body of literature of randomized

17 control trials supporting pharmacologic

18 prophylaxis as well as mechanical prophylaxis to

19 prevent DVTs. That evidence has been reviewed by

20 countless expert panels, has been endorsed by the

21 American College of Test Physicians and other

22 organizations. So, I don't think that there is

1 any doubt that with the appropriate prophylactic

2 interventions that we can prevent about half of

3 these major proximal clots and lung clots.

4   In addition, I think if you look at

5 the work that we have published in the Journal of

6 Hospital Medicine, as well as two other papers,

7 we did a case control study of patients

8 undergoing total knee arthroplasty in 15 teaching

9 hospitals, 130 cases, 463 controls. And all of

10 these patients met the SCIP criteria for

11 appropriate thromboprophylaxis. But even within

12 this cohort of patients, we found that the

13 patients who received pharmacologic prophylaxis,

14 as opposed to mechanical prophylaxis had an odds

15 ratio of 0.5. The patients who were out of bed

16 the day after surgery had an odds ratio of 0.3.

17   So, we believe that early mobility, in

18 particular, provides additional opportunities for

19 prevention that may be under-recognized by

20 healthcare organizations.

21   So, the continuing focus on PSI12 we

22 believe is important to prevent events that

1   really have serious consequences.

2   CO-CHAIR SEPTIMUS: And we had

3   somebody on the phone. Then, we are going to go

4   this way. Kim?

5   DR. APPLEGATE: Yes, can you hear me?

6   CO-CHAIR SEPTIMUS: Yes.

7   DR. APPLEGATE: Okay, good. This is

8   a very interesting discussion and I don't want to

9   lengthen it too much. I just had a question for

10   the author about actually the measure as a sub-

11   measure of PE and DVT. And just to help us

12   clarify how the rates that were mentioned in the

13   original presentation are done. I may have

14   missed it but are they based on the trend over

15   time on using imaging, for example, to decide

16   that I think it was said originally in the

17   discussion that they have gone down?

18   So, for example, I know that our

19   hospital looks at the rates and looks at the

20   imaging rates of the ultrasound for DVT and the

21   CTA for PE for meaningful use and we do look at

22   the positives rates. And I think that that can

1   be tricky because of a lot of factors, such as

2   overuse of imaging and how each healthcare

3   institution uses the imaging. And there is also

4   a lot of debate out what is a positive study and

5   what is a meaningfully positive study, in terms

6   of the patient's outcomes? And I don't want to

7   get into that debate here. I just want to ask

8   about the measure.

9   DR. ROMANO: Well, we are certainly

10   aware of that debate and so we tried to factor

11   that in. The big debate is about how far down in

12   the calf we look and how significant. If you are

13   down in the soleal vein, for example, the

14   peroneal vein, just what is the clinical

15   significance of these distal events.

16   And I know that some radiologists,

17   some ultrasonographers believe that they are

18   obligated to look at the distal veins and to

19   report findings in distal veins. Others argue

20   that these events are of uncertain clinical

21   significance and lead to over-treatment.

22   So, to get around this debate, we

1 basically required in the definition that the

2 clot be in the popliteal vein or above.

3   Now, this may still be somewhat

4 sensitive. Obviously, if a hospital, at the

5 extreme, never does ultrasounds, then it won't

6 find these clots. But presumably, we are all

7 trying to provide good care. We are all trying

8 to image patients who may have symptoms after a

9 surgery that places them at risk.

10   So, I don't think that this bias can

11 be entirely eliminated but we don't necessarily -

12 - we believe it is still important to look at the

13 clinically important outcomes of proximal clots

14 in lungs.

15   DR. APPLEGATE: Okay, I just wanted to

16 bring it up.

17   CO-CHAIR SEPTIMUS: I want to come

18 back to Charlotte's comment because I don't want

19 to lose that. Do you want to follow-up with your

20 comment about the recent article? I also want to

21 have Dr. Romano comment on that.

22   DR. ALEXANDER: So, the article I am

1   talking about came out of JAMA and it was done --

2   I'm sorry. I thought I could pull this up

3   quickly for you.

4   DR. ROMANO: Are you referring to

5   Chmeil Deloria's paper?

6   DR. ALEXANDER: Yes. No, that one I

7   saw. That you had referred to as part of your

8   evidence and that was very weak evidence. But

9   the one I decided was coming from the Colorectral

10   Writing Group for the Surgical Care and Outcomes

11   and Assessment Program, this was out of

12   Washington, I believe, and they had 16,120

13   patients and they had aggressively at

14   chemoprophylaxis because that is what we have all

15   been scurrying around accommodation of

16   chemoprophylaxis and mechanical prophylaxis and

17   early ambulation. And the thought was if you

18   push the chemoprophylaxis, you are going to get

19   better rates. And what they found is that they

20   moved their chemoprophylaxis rates up to 91

21   percent, which is what we have done as well. And

22   their DVT rates did not change. And that has

1   been our experience as well.

2   So, I have a concern that the evidence

3   is not giving us good guidelines. If someone can

4   tell me how to prevent a DVT, I want to hear it.

5   We have been running around trying to follow

6   these guidelines that we have been told work and

7   they are not all working.

8   So, as with many other quality

9   indicators, I am finding that so much is

10 multifactorial, I don't think we understand this

11 completely yet.

12   CO-CHAIR SEPTIMUS: Do you care to

13 comment, Dr. Romano, on that?

14   MS. PANCHOLI: So, one of the things

15 I would like to bring to the folks' attention

16 here is that not only does AHRQ support the

17 Quality Indicators Measure Program but we also do

18 a good amount of working looking at issues around

19 quality improvement, specifically, and being able

20 to instruct hospitals of specific action they can

21 take to make sure that these adverse events don't

22 occur.

1   So, one of the tools that we actually

2   support is the AHRQ Quality Indicator Toolkit.

3   It is an evidence-based toolkit that looks at

4   various individual PSIs. It offers hospitals an

5   opportunity to convene their teams, gives them a

6   process to follow to actually look at specific

7   interventions that could actually affect those

8   outcomes.

9   So, we try to make sure, whenever

10 possible, that we provide hospitals with sort of

11 a more comprehensive package. We have got a

12 measurement tool. We have got a quality

13 improvement I will say tool or following a

14 quality improvement initiative within their own

15 hospitals. We hope that, again, that when they

16 measure again, that they do see some type of

17 improved outcome.

18   I know that is a little bit more

19 general but when you are talking about quality

20 measures, until you are in that specific hospital

21 looking at their specific cases, it is a very

22 difficult thing to do from a government

1   perspective. So, where we can, we are offering

2   toolkits and information that are evidence-based

3   to help those outcomes actually improve.

4   CO-CHAIR SEPTIMUS: Okay, Yanling.

5   DR. YU: Thank you. Yanling Yu. I

6   have a question, three questions mostly focused

7   on the composite.

8   One is, because I am new, I don't know

9   the background of this being endorsed before.

10   So, my first question is how the PSI selected.

11   One of the serious harm events is wrong site

12   surgery and the foreign object after the

13   operation. And it is very common from the Joint

14   Commission. And I was just wondering if you have

15   any explanation why this is not included.

16   And also the second one is the

17   medication error and that had been really a big

18   issue for Medicare patients, especially, and for

19   general population.

20   And then my third question is when you

21   do the weighted access harm, I just try to better

22   understand how this weighting you are doing to

1   evaluate the harm. For example, the patient's

2   death to adverse events versus a readmission

3   multiple times, would that be separated in a

4   certain way when you do the weighting?

5   And I have one more question is I

6   don't know how this composite with the estimated

7   is at a hospital facility level. There are some

8   hospitals do not have the pay-per-surgery. They

9   don't do those things. When you do a weighting,

10   sometimes you have that data when you calculate

11   the composite either zero or non-zero or not

12   apply. And so I am just wondering how you

13   separate those out. You are not just outputting

14   zero in there which were counted as composites.

15   But not apply would be totally different.

16   So, I am just wondering how you handle

17   those. Thank you.

18   CO-CHAIR SEPTIMUS: Thank you. Just

19   before you answer, we are going to kind of finish

20   round of questions and I think the next thing we

21   will do is we are still having comments around

22   the evidence, that when we get done with this

1   round of questions, we may want to get to voting

2   on that and see whether or not we want to go

3   forward with the other components of the

4   measures.

5   But we are talking a lot about

6   evidence. So, let's get a round of questions and

7   you may want to go right with the voting on the

8   evidence and see whether or not there is enough

9   evidence in this group to then go along to

10   validity and reliability, et cetera, if that is

11   okay with everybody else.

12   DR. ROMANO: I'm going to try talking

13   into a different microphone because I hear there

14   is a lot of static coming.

15   So, a couple of things. So, as far as

16   retained surgical items, wrong site surgery, and

17   so forth, yes, these are -- of course, they are

18   serious reportable events. They are part of a

19   separate NQF process, unquestionably very

20   important patient safety-related events.

21   It turns out that they don't

22   empirically work in a composite of this type

1   because these events are so rare that they are,

2   essentially, randomly distributed across

3   hospitals. So, without a hospital-level signal

4   that we can estimate and then aggregate, it

5   doesn't work empirically. So, these events are

6   undeniably important but they just can't be

7   estimated as risk-adjusted rates and then folded

8   up into a composite of this type because of their

9   rarity and basically because of their random

10   distribution across hospitals.

11   With reference to the separation of

12   adverse events, yes, so, we can consider death,

13   for example, to be the ultimate event. So, death

14   trumps any other event that may occur. It leads

15   to a utility state of zero or a harm of one. For

16   other states, we do allow for other harms to

17   occur together in the same patient.

18   Now, in our clinical panel process,

19   where we ask clinicians to rank the different

20   harms, we ask them, based on their clinical

21   expertise, to attempt to isolate those harms.

22   For example, to isolate the occurrence of a

1   pneumothorax requiring a chest tube during the

2   hospital stay from a patient who might require

3   readmission because of respiratory failure or

4   respiratory problems occurring after discharge.

5   That separation was achieved based on the

6   experience and knowledge of clinicians. But we

7   acknowledge that it may be difficult for them to

8   do that. It was just that was how we had to do

9   it, given the constraints of time and data. But

10   death is considered to be a separate event.

11   Finally, this is estimated at the

12   facility level. So, the way this works is that

13   because we start with these observed to expected

14   ratios, these indirectly standardized morbidity

15   ratios, and then we shrink those ratios down

16   towards the overall mean of one, based on the

17   signal, based on the reliability of data coming

18   from each hospital.

19   So, if a hospital is contributing no

20   data for a particular indicator, then its O/E

21   ratio for that indicator gets brought down to

22   one. So, then it contributes nothing,

1   essentially when the weighted average is done

2   across all of the component measures so this

3   makes sense.

4   So, in the case of a hospital that may

5   have patients who are eligible for some PSIs but

6   not others, the PSIs that are included in a

7   composite for which they don't have patients

8   would have observed to expected ratios of one.

9   It would go into the weighted average, along with

10 whatever other PSI components they have that are

11 relevant to them.

12   And frankly, these are smaller

13 hospitals, typically, where the estimation is

14 going to be less reliable anyway. So, it is kind

15 of inherent in the process. It is always more

16 difficult to estimate these kinds of parameters

17 for smaller hospitals. They have limited product

18 lines.

19   CO-CHAIR SEPTIMUS: Okay, Pat and then

20 we will go to Lisa, and then we will go to

21 evidence.

22   DR. QUIGLEY: Thank you. Patricia

1   Quigley. My comments -- and I, too, thank you

2   for all the great work you have done, as always.

3   But while I am not a supporter of a composite

4   measure of indicator of patient safety of a

5   hospital, my criticism has been of this measure

6   specifically related to the post-op hip fracture

7   indicator and I made that same criticism in my

8   last discussion. And Dr. Romano, I would like to

9   respectfully say that your to our last colleague

10   in that these are rare events indicates why they

11   should not be part of this measure. And that is

12   my criticism.

13   And my question to you is if there was

14   any consideration of including the endorsed

15   measures already for fall rate and fall injury

16   rates, as if there was to be a composite measure

17   that are two endorsed measures of the National

18   Quality Forum.

19   And to the Agency for Healthcare

20   Research and Quality, in 2013, there was an

21   incredible article by Bolden and others in the

22   Journal of Patient Safety. Colleagues, they

1   included in that research an analysis of NDNQI

2   data over a 27-month period of over I think it

3   was 1200 hospitals that were included in this

4   study with 6100 units. What were those clinical

5   units? They were medicine, medical surgical

6   units, and surgery.

7   So, where do we have adverse events

8   that are picked up? They are going to be on your

9   unit level. Colleagues, on those units, there

10   were 316,000 falls. Of those falls, 26.1 percent

11   had injury. Only two percent had a hip fracture.

12   So, when you think about a fall in a

13   neurosurgical unit, to have post-op hip fractures

14   as an indicator of this measure does not work.

15   And I just think that there are more important

16   measures. And I also think that this continues

17   to speak to the importance of select measures as

18   an indicator of safety, rather than a composite

19   measure.

20   But I still say to this body of

21   patient safety for the National Quality Forum

22   that there are two already really important

1 measures that are much more relevant to a post-op

2 patient population than a hip fracture after a

3 fall.

4 So, I just still hope to provide that

5 compelling discussion to you as you go forward in

6 making decisions because falls remain the top

7 adverse reported event that gets an incident

8 report. And even when you look at this data, to

9 my colleagues from the Agency for Healthcare

10 Research and Quality I had suggested that this be

11 a discussion point with the American Nurses

12 Association and NDNQI, but I would suggest to you

13 that if falls and fall injury had been part of

14 this composite measure, your weighting

15 distribution would have been very different.

16 And those are my comments. So, my

17 question to you is did you go back and look at

18 including fall rates overall and fall injury

19 rates, overall, not just a hip fracture? Thank

20 you.

21 DR. ROMANO: So, the inherent

22 construction of this composite is that it is

1   intended for use by organizations that have

2   access to ICD-9-CM coded, soon ICD-10-CM coded

3   administrative data. The original impetus for

4   the entire Quality Indicators Program actually

5   came from state health data organizations and

6   state hospital associations and others that were

7   interested in these kinds of new and expanded

8   applications of ICD coded administrative data.

9   So, yes, it would be hypothetically

10   possible to take out the PSI8 from the composite

11   and to substitute an alternative measure. But

12   with the CLABSI measure, we have a measure that

13   is now publicly available for almost all

14   hospitals in the United States that take care of

15   Medicare patients. We are not yet at that point

16   for the NDNQI measures, as you know.

17   So, until we get closer to that point,

18   we have to substitute other measures that are

19   available from all hospitals, from the universe

20   of hospitals. So, that is why rely on measures

21   that are based on administrative data.

22   Now, your point that we could expand

1   the definition of PSI8 to include other types of

2   fractures, other types of injuries that are

3   occurring to patients who fall in hospitals, I

4   think we would agree completely with that. So,

5   there is an ongoing process. We focused our

6   effort in response to previous discussion on

7   PSI12 and 15 but I think PSI8 could certainly be

8   revisited as well, with potentially an expanded

9   definition to include additional types of

10   injuries, particularly, we see, as you know, a

11   lot of risk fractures that occur when patients

12   fall in the hospital.

13   So, there are some potential

14   expansions. So, given the alternative, we could,

15   of course, taken PSI8 out but I think that would

16   send the wrong message. That would send a

17   message that falls don't matter, that hip

18   fractures occurring in hospitals after surgery

19   aren't important and that we would take it out of

20   the composite.

21   So, I agree with expanding it in the

22   future but I wouldn't support taking it out as an

1 interim measure because I think that would send a

2 message in the wrong direction.

3 DR. QUIGLEY: And again, in saying

4 that falls with hip fractures are very rare. But

5 when you look at the CDC data, in today's

6 hospitals patients over the age of 65 are over 40

7 percent inpatient population, patients over the

8 age of 85 are 9 percent inpatient population.

9 So, when you say that it is age

10 adjusted and gender adjusted, there are other

11 measures that are much more relevant.

12 So, thank you again, for the ability

13 to comment.

14 CO-CHAIR SEPTIMUS: Thanks, Pat. And

15 Lisa, and then we have one other, Susan, and then

16 we will -- who is that?

17 MS. MCGIFFERT: Okay. I just also

18 want to thank you, AHRQ and Patrick, for

19 addressing the issues that were raised. And it

20 really looks like a much improved measure.

21 We think that composite measures are

22 essential for consumers. And I know that most of

1   the people in this room are looking for it for

2   internal purposes and I also know that many

3   hospitals use these for internal purposes. But

4   this is really the only broad measure of medical

5   harm that is publicly reported. And we believe

6   that it is very important to get that out there.

7   With regard to the preventability, I

8   would just argue that if you went out on the

9   street and made statements that accidental

10   punctures and lacerations are not preventable, if

11   you said that to every single patient with great

12   meaning, and saying we have no idea how to keep

13   from puncturing something accidently in your

14   body, that they would not believe you. And I

15   don't believe you. And I think preventability

16   changes over time.

17   When we first started working ten

18   years ago, more than ten years ago on infections,

19   all of the experts said about 30 percent of

20   infections are preventable. Now they are saying

21   at least 70, many are saying all. It changes

22   over time and public reporting of this

1		information and tracking it is so essential to

2		change the culture and the mindset and to find

3		those solutions that we, obviously, think this is

4		an important measure.

5				CO-CHAIR SEPTIMUS: Thank you, Lisa.

6		I just also just want to make a comment here that

7		measures can be altered and updated over time.

8		We have two measures later for tomorrow afternoon

9		on CAUTIs and CLABSIs coming from the CDC. So, I

10		think there are some really good constructive

11		comments that you have heard, some of which I

12		think you would like to follow up on.

13				So, I guess you all will have to

14		decide whether or not it has come far enough for

15		you to give this an endorsement but I don't think

16		we are looking at this measure as being static.

17		I think it is going to evolve in a way that Lisa

18		just mentioned also.

19				So, I just think we need to think

20		about that in terms of you do plan to update this

21		over time and then represent that to NQF. Would

22		that be fair?

1   MS. PANCHOLI: I actually think that

2   is a cornerstone of the actual whole program.

3   All of the quality metrics, not just PSI90, are

4   dynamic. I mean we are updating them constantly

5   with the latest evidence base that is out there

6   with new codes. We are going into a new world of

7   ICD-10. There is a whole new opportunity there

8   as well.

9   But I can say with certainty that the

10   comments that come out of this committee will

11   certainly be followed up and, where possible, we

12   will invest in the new methods and the new

13   research that we need to to make sure that we get

14   to an even better version of PSI90 that addresses

15   as many of the issues as we can.

16   Now, I will caveat that by saying

17   there is no perfect measure. And so, while are

18   always going to try to the best we can, it is

19   going to be subjected to the data, the codes,

20   ICD-10. There is just a lot of variability in

21   that. But to the extent that we can overcome

22   those obstacles, we certainly will do our best to

1   do so.

2   And one last comment, if I may, about

3   I think there was a comment about preventability

4   and trying to maybe rename the measure. We

5   certainly did that with PS15. As a group, if one

6   of the considerations that comes out today is

7   that you would like us to consider renaming

8   PSI90, we certainly can do that. I'm not quite

9   sure at the moment what that would look like but

10   it something that we can certainly take back to

11   the QI team and come back with a name that maybe

12   seems more relevant or more accurate for the

13   purpose of the contentment.

14   CO-CHAIR SEPTIMUS: And I think this

15   committee now has a track record of when new

16   evidence becomes available of doing ad hoc

17   reviews and then changing it.

18   And by the way, I think Helen can

19   probably testify to this, our discussion about

20   sepsis and the discussion about PSI90 have

21   received, I think, overall, a claim to the

22   rigorous that you all did in the last couple of

1   years. So, the kudos go to all of you but I

2   think NQF certainly appreciates the tremendous

3   effort that all of you make in making this a

4   stronger process and a better process.

5   So, Susan. We can't hear you.

6   DR. MOFFATT-BRUCE: Okay, thank you.

7   CO-CHAIR SEPTIMUS: You're like me,

8   you put yourself on mute.

9   DR. MOFFATT-BRUCE: Yes, thank you.

10   Patrick, you have said it twice now. I just want

11   a point of clarification for PSI6 as inherent to

12   PSI90. You have said twice now when an

13   iatrogenic pneumothorax is created and a chest

14   tube is required. That is not how the definition

15   reads. And it is a very contentious point that

16   we have with our electrophysiologist and thoracic

17   surgeon.

18   So, can you grant us some

19   clarification on that because that is the second

20   time you have said that in this forum?

21   DR. ROMANO: Okay, I'm not sure that

22   I said a chest tube was required.

1   DR. MOFFATT-BRUCE: You did.

2   DR. ROMANO: What I said or what I

3   mean to say was that that was one of the common

4   harms that result.

5   DR. MOFFATT-BRUCE: Correct.

6   DR. ROMANO: And so in our estimation,

7   I'm not going to remember the numbers off the top

8   of my head but, as I recall, it is about 70 to 75

9   percent of the patients who experience this event

10   who have a coded chest tube, thoracostomy.

11   DR. MOFFATT-BRUCE: Maybe that is --

12   I guess it depends on the institution.

13   DR. ROMANO: Yes, so that goes into

14   the harms estimation. So, basically, we asked a

15   bunch of clinicians to rank what it is like to

16   have a chest tube in compared with other things.

17   We rescaled that with the patient-reported

18   utilities and that harms data was applied to

19   roughly 70 percent of the patients who experience

20   the PSI6 event.

21   And then you have about 10 percent of

22   the patients who actually go back on the

1   ventilator and who require respiratory support

2   after the iatrogenic pneumothorax and of course,

3   that is a worse harm with a lower utility. And

4   so that gets factored in proportionately.

5   DR. MOFFATT-BRUCE: Into your risk.

6   Okay, very good. Thank you very much.

7   DR. ROMANO: So, it is a weighted sum

8   of the product of these harms.

9   CO-CHAIR SEPTIMUS: Okay, we have a

10   couple of hopefully relatively quick comments. I

11   want to try to keep ourselves on schedule but I

12   also do not want to cut off important discussion

13   on this measure. So, Iona.

14   CO-CHAIR THRAEN: First, a point of

15   clarification. So, the two non-endorsed NQF

16   measures that were included, why are they not

17   endorsed? Is that a timing problem or is there

18   an issue on that?

19   DR. ROMANO: Well, they just I mean

20   there is a tremendous burden associated with

21   bringing measures to NQF for endorsement. And so

22   these two measures just haven't sort of risen to

1   the top in terms of part of it was the timing

2   issue, as you suggest, because we knew from

3   earlier validation studies that there were some

4   limitations with these measures as they were

5   originally developed. And so we didn't pursue

6   NQF endorsement until we re-specified the

7   measure.

8   So, for example, for PSI10, those of

9   you who are geeks in this literature, you may

10   know that PSI10 used to have a component that was

11   about postoperative hypoglycemia or hyperglycemia

12   and it turned out that there was too much random

13   noise in that component. So, we took out that

14   component.

15   For PSI9, it turned out that our list

16   of operations that might be done to repair or

17   follow-up on a hemorrhage or hematoma was too

18   short and so we were missing a lot of we had

19   inadequate sensitivity. We were missing a lot of

20   real events that were happening that were

21   bringing patients back to the operating room.

22   So, we had to expand the list of procedures.

1   So, those three specifications have

2   been under previous contract about two years ago

3   and so we just haven't had the opportunity to

4   bring them back for NQF endorsement.

5   In principle, I think that the

6   components that go into a composite, if the

7   components are short on reliability but still

8   reasonably strong on importance and validity, it

9   may be appropriate for them to be in the

10   composite but not to be separately endorsed. And

11   so we would have to evaluate that specifically

12   with respect to these two, at least one of these

13   two might be on the borderline in terms of

14   individual reliability.

15   CO-CHAIR THRAEN: So, and the other

16   thing is I just wanted to comment, and actually

17   Lisa said it for me about the preventability

18   question, absolutely underscore the position

19   which it is on a range of continuum. And I know

20   those of you that are trying to improve your

21   processes internal to your hospitals are pulling

22   your hair out trying to figure out how to solve

1   some of these problems but, in reality, by

2   measuring and reporting, it brings attention to

3   those areas and the opportunity for creativity

4   and change. There may not be a solution today

5   but there will be a solution somewhere down the

6   road. So, I just wanted to underscore her point.

7   Thank you. Iona Thraen.

8   CO-CHAIR SEPTIMUS: Jason and then

9   Charlotte and then we are going to go to vote.

10   DR. ADELMAN: Jason Adelman. Just a

11   couple of very quick points. I wasn't going to

12   say this but just Lisa, to your counterpoint, I

13   am going to say we are not talking about walking

14   down the hallway and accidently tripping and

15   puncturing somebody. We are talking about six-

16   hour surgeries with complicated cancers that you

17   have to cut out. Imagine having to paint the

18   Mona Lisa but not allowed to slip for a second

19   and erase your error. You know people will die

20   of these.

21   But I wanted to respond to many of the

22   measures in this composite are related to

1   surgery. And Lisa commented that this is like

2   the only measure that we have as a composite for

3   harm. And I had made a note that we work on

4   CAUTIs, we weight from CLABS and from this, we

5   try to fix our coding. But what I didn't way is

6   that we also have this other measure, the NSQIP

7   measure that many of you may know of. We pay for

8   it. It is very expensive and we really believe

9   in it. We look at charts very carefully. We

10   call patients after to see if there is harm. It

11   is an incredible measure.

12   So, Dr. Romano made the good point

13   that until -- he made it to Pat about falls. And

14   the NQI is a very good fall measure but that is

15   also not required. For some reason, the CDC

16   requires this manual process for NHSN but there

17   is no agency that is requiring a manual process

18   for NDNQI to make that national because it costs

19   money and this NSQIP, because it costs money.

20   So, short of that, we have to rely on taking

21   codes that we used for billing and trying to

22   repurpose them in this incredible way that they

1 have figured out. But it less than some of the

2 things that those that can afford.

3   And so but the fact of the matter is

4 is that as we endorse these measures and it is

5 out there, then it may just delay the reality

6 that the really good measures that some of us use

7 won't become national measures. Somebody won't

8 say let's do what we did with NHSN with NDNQI and

9 with NSQIP because we have these composite

10 measures.

11   So, it is more a philosophical point

12 because I think that if the measure meets the

13 criteria that NQF has proposed, then we should

14 vote on it accordingly. If it passes the test,

15 it passes the test, but it may have the

16 consequence of delaying some of the better

17 measure.

18   Because I am on this NQF Health IT

19 Safety Committee and there, we just don't have

20 measures right now to measure harm. They just

21 don't exist. For some of these, they exist, we

22 just can't afford them. Healthcare in general

1   can't afford them and that is unfortunate and we

2   should get the better measures and use them.

3   But the real question and point is, I

4   had asked previously, I still don't know what to

5   do about the fact that there is this one part,

6   the CLABSI that we may or may not include and are

7   we talking about CMS or hospitals and why not

8   just drop it, if there is -- the NHSN one is the

9   one that is currently required by every hospital.

10   It doesn't fall into that category that Dr.

11   Romano said. So, why not just drop it from the

12   composite? Like when we vote on it right after

13   this comment, are we voting it with or without or

14   with the variable in place?

15   DR. ROMANO: Yes, so currently the

16   composite, as it is constructed, includes PSI7.

17   And there are some reasons why some users may

18   prefer that approach.

19   So for example, as you know, the NHSN

20   measure uses catheter days as the exposure factor

21   in the denominator. So, all the things that we

22   do in hospitals to try to minimize unnecessary

1   use of catheters to try to get catheters out

2   earlier and so forth, it doesn't affect the

3   CLABSI rate, as it is measured by NHSN.

4   In addition, as you know, the NHSN

5   measure is not individually risk-adjusted. It is

6   standardized based on hospital and unit

7   characteristics. And this has been an ongoing

8   point of discussion, obviously, here at NQF and

9   elsewhere. But there are some users that feel

10   strongly that that is not appropriate and that

11   they would prefer to have a measure that is risk-

12   adjusted based on individual characteristics,

13   rather than unit characteristics.

14   So, at this point, we prefer to offer

15   the option. So, we certainly expect that in

16   CMS's implementation of the measure, since they

17   are constructing their own composite, which

18   includes PSI90 at 25 percent, along with 75

19   percent other stuff, that they will probably

20   request or remove PSI7 but other users may prefer

21   to include PSI7 for the reasons I have mentioned.

22   CO-CHAIR SEPTIMUS: All right, last

1   comment, Charlotte, and then I want Missy to

2   introduce yourself.

3   DR. ALEXANDER: Thank you. Charlotte

4   Alexander. Again, I want to echo the compliments

5   to you about this measure being much, much, much

6   improved and very responsive. And thank you.

7   I have a point of clarification or

8   perhaps a understanding on PSI9, hemorrhage and

9   hematoma. As I read your supporting data, what I

10   read was that this was intended to catch things

11   that could have been controlled better in the

12   operating room and worked. So, that if there had

13   been clips applied more appropriately or little

14   vessels tied off more appropriately, that would

15   prevent the hemorrhage and the harm.

16   But the codes that are there as I see

17   them, and when we see things going on in our

18   system, if someone mentions that a little side

19   branch was bleeding and it was tied, it is

20   falling out.

21   So, just to help clarify, what are you

22   trying capture here? Is there a degree of

1   severity?

2   DR. ROMANO: I'm going to ask if Dr.

3   Utter is on the phone with us. He is my surgical

4   colleague.

5   DR. UTTER: Yes, I am on the phone.

6   DR. ROMANO: Okay, could you address

7   Dr. Alexander's question?

8   DR. UTTER: Well, I'm not sure I

9   understood it exactly but I can comment a little

10 bit about the degree of severity that PSI9

11 attempts to detect, just by emphasizing that it

12 is focused on hospitalizations in which a

13 hemorrhage or hematoma occurs and is diagnosed

14 and a procedure plausibly associated with

15 addressing it is also used.

16   So, there is no absolute threshold for

17 the amount of bleeding or the size of the

18 hematoma but there is a requirement for it to

19 require an operation to treat it.

20   DR. ALEXANDER: So, this is one that

21 requires another operation to treat?

22   DR. UTTER: Yes.

1   DR. ALEXANDER: I did not get that.

2   I saw a surgery associated but I didn't see a

3   return to surgery. So, this is a return to

4   surgery?

5   CO-CHAIR SEPTIMUS: It is a return to

6   surgery.

7   DR. ALEXANDER: Thank you.

8   DR. ROMANO: When it is done

9   incidentally in the course of the index

10 operation, then it is not coded separately

11 because it is considered to be wrapped into the

12 bundle of the initial operation. Everybody, you

13 have to tie of bleeders in the course of any

14 operation.

15   DR. ALEXANDER: Thank you.

16   CO-CHAIR SEPTIMUS: And I missed

17 someone. I apologize.

18   DR. BRILLI: Just a very quick point

19 of clarification. It says on the list it is

20 catheter-related bloodstream infections. So, I

21 just wanted to make sure that that is indeed what

22 the measure is not catheter-associated

1   bloodstream infections because they are

2   different.

3   DR. ROMANO: Give me a minute to look

4   it up.

5   DR. BRILLI: Yes, catheter-related is

6   much more specific. It requires a couple blood

7   cultures, and Ed probably knows this way better

8   than I do, catheter-associated is a surveillance

9   definition used in pediatrics because we don't

10 usually get two or three blood cultures to

11 confirm that it is just from the catheter.

12   Catheter-related is often used in

13 hospitals as a research method but many hospitals

14 use catheter-associated as a screening tool.

15 Because they are different and the numbers would

16 be different and I just want to make sure which

17 one this is. It says catheter-related.

18   DR. ROMANO: Yes, so just to be clear,

19 the code, the ICD-9-CM code that we are using is

20 999.32, which is bloodstream infection due to

21 central venous catheter. And then the indexing

22 provides specific examples, including PICCs,

1   portacaths, triplelumens, HICKMANs, BROVIACs and

2   so forth.

3   And the term catheter-related

4   bloodstream infection, NOS, is also indexed here.

5   So, this is the ICD-9-CM code that coders would

6   typically apply when a clinician documents a

7   catheter-related bloodstream infection.

8   DR. BRILLI: Okay, well the codes may

9   or may not relate to the difference between

10   catheter-related and catheter associated. I'm

11   not an expert on coding but that adds --

12   CO-CHAIR SEPTIMUS: It is partly

13   driven by physician documentation and it may not

14   match the surveillance definition but infection

15   prevention is used to report into NHSN.

16   I mean you are correct that there is

17   some variation there but the intent of the PSI7

18   -- have I got that right 7 -- I'm beginning to

19   learn the numbers -- is that presumably that the

20   bacteremia is related to the catheter.

21   Presumably.

22   Pat, did you have one more comment

1 before we vote?

2   DR. QUIGLEY: I'm sorry to interrupt

3 but I'm reading the section that is in the NQF

4 document and it appears to me to say the opposite

5 of what you just said in definition.

6   It says NHSN is based primarily on

7 microbiologic testing and is called catheter-

8 associated or central line-associated bloodstream

9 infections. Is that different than what you were

10 saying?

11   CO-CHAIR SEPTIMUS: I think that is

12 what he was saying.

13   DR. BRILLI: There are very clear

14 definitions in NHSN. Catheter-associated and

15 catheter-related are very different. Catheter-

16 related is much more precise and it really gets

17 at the fact is it really related to the catheter?

18   Catheter-associated is you have a

19 catheter, you have a bacteremia and you can't

20 find another cause. So, it may not be as

21 precise.

22   And what is in your definition, it

1   says catheter-related. That word is in there.

2   And whether that links to the coding is where the

3   imprecision is. Because I think what happens in

4   coding is people see bacteremia, they see

5   catheter, they see that they are linked and they

6   may or may not be linked is all I am trying to

7   say.

8   CO-CHAIR SEPTIMUS: Pat, did you have

9   another comment before we vote? Because we

10   really have to vote.

11   DR. QUIGLEY: Thank you, Dr. Septimus,

12   yes, I do. I had a point of clarification. I

13   wanted to respond to Dr. Adelman, if I may, in

14   case I was unclear, and it was related to the

15   post-op fall indicator as part of the patient

16   safety indicator 90 and that was to say that my

17   criticism was that AHRQ could have used existing

18   NQF indicators fall rate and fall injury rate,

19   rather than just a post-op hip fracture, because

20   these are already endorsed by NQF and that that

21   would have made a very different composite and a

22   different weighting. And that was my criticism

1 last year.

2 So, it was not NDNQI. It was related

3 to already existing NQF measures for patient

4 safety that should have been part of this

5 composite measure if it was to go forward.

6 Thank you.

7 CO-CHAIR SEPTIMUS: This has been an

8 incredible discussion. I think we were very wise

9 to allow a little extra time for PSI90.

10 But I think what I hear is, regardless

11 of what we decide to do in terms of voting on the

12 evidence and if we go further, is that this

13 certainly is a better measure and we commend AHRQ

14 for coming back with a better measure. I think

15 even if it is approved, I think you had some

16 suggestions on even how to make it better, which

17 I think is the real purpose of this discussion.

18 So, Suzanne, are you going to lead us

19 through the voting?

20 MS. THEBERGE: Actually, Laura is

21 going to lead us with the voting.

22 CO-CHAIR SEPTIMUS: Oh, I'm sorry,

1   Laura. Everybody know how to use these things, I

2   hope?

3   MS. IBRAGIMOVA: Yes, so it is very

4   simple. All you have to do is select the number

5   of the option that you want. So, in this case,

6   we only have two options. One on your clicker

7   corresponds to yes and two corresponds to no.

8   And you just point in my direction. That's it.

9   MS. THEBERGE: And I will just clarify

10   that we will be receiving votes from our members

11   on the phone via chat and Drew and I will be

12   controlling the clicker so those will show up.

13   MS. IBRAGIMOVA: Yes.

14   CO-CHAIR SEPTIMUS: Okay, so if you

15   will read the first element on the evidence.

16   MS. IBRAGIMOVA: So, importance to

17   measure and report, 1A, evidence, health outcome

18   or PRO, rationale supports the relationship of

19   health outcome or PRO to at least one healthcare

20   structure, process, intervention, or service.

21   One, yes; two, no.

22   CO-CHAIR SEPTIMUS: And as I

1 understand it, before you vote, that if this is

2 no, then that is going to be the end of the rest

3 of the conversation. If it is yes, we go on to

4 the other elements. Okay?

5   MS. IBRAGIMOVA: Correct.

6   CO-CHAIR SEPTIMUS: Less than 40

7 percent, excuse me.

8   MS. THEBERGE: Kim, we need your vote

9 via the chat.

10   DR. APPLEGATE: Sorry about that. How

11 do I do that?

12   MS. THEBERGE: You should be able to

13 just type into the chat box and send it to a

14 leader.

15   MS. O'BRIEN: So, slide all the way

16 down. This is Ann. It is just a little bit hard

17 to find. You need to use the scroll bar, scroll

18 to the bottom and then you will see an empty

19 white space.

20   DR. APPLEGATE: Do you see it?

21   MS. THEBERGE: Yes.

22   CO-CHAIR SEPTIMUS: We really should

1 have some background music for this.

2 Do we have a vote, Laura? Should we

3 vote again? Do we need to vote again?

4 (Laughter.)

5 MS. IBRAGIMOVA: So, if you can try

6 again voting.

7 DR. ROMANO: Can I make one slight

8 correction? My team has corrected me. It is 63

9 percent additional pneumothoraxes, not 70

10 percent.

11 MS. IBRAGIMOVA: So, the results are

12 67 percent yes, 33 percent no.

13 CO-CHAIR SEPTIMUS: So, we will move

14 on. And before we move on, I forgot, Missy, who

15 was listening the whole time, actually physically

16 made it in the room later. So, Missy, if you

17 will quickly introduce yourself -- I apologize --

18 and any conflicts you have.

19 MS. DANFORTH: I apologize for not

20 having my phone on mute in the cab.

21 So, Missy Danforth, Vice President for

22 Hospital Ratings of the Leapfrog Group. Thank

1   you. Sorry I was late.

2   CO-CHAIR SEPTIMUS: Conflicts?

3   MS. DANFORTH: I have no conflicts.

4   CO-CHAIR SEPTIMUS: Okay, why don't we

5   go to the next vote, Laura?

6   MS. IBRAGIMOVA: So, importance to

7   measure and report, 1b, performance gap. Data

8   demonstrated considerable variation or overall

9   less than optimal performance across providers

10   and/or population groups disparities in care.

11   One, high; two, moderate; three, low; four,

12   insufficient.

13   MS. THEBERGE: Ann and Kimberly, we

14   still need your votes. We need one, high; two,

15   moderate; three, low; four, insufficient.

16   DR. APPLEGATE: Sorry.

17   MS. IBRAGIMOVA: So, the results are

18   38 percent high; 38 percent moderate; 25 percent

19   low; zero insufficient.

20   CO-CHAIR SEPTIMUS: Keep going.

21   MS. IBRAGIMOVA: So, importance to

22   measure and report, 1d, composite explicitly

1   articulated and logical. 1d1 quality construct,

2   including components; 1d2, rationale for

3   distinctive/additive value; 1d3, aggregation and

4   weighting. One, high; two, moderate; three, low;

5   four insufficient.

6   DR. APPLEGATE: Could you repeat that

7   one more time?

8   MS. IBRAGIMOVA: You want the options?

9   DR. APPLEGATE: The whole thing.

10   MS. IBRAGIMOVA: So, 1d, composite

11   explicitly articulated and logical. 1d1 quality

12   construct, including components; 1d2, rationale

13   for distinctive/additive value; 1d3, aggregation

14   and weighting. One, high; two, moderate; three,

15   low; four insufficient.

16   The results are 25 percent high; 29

17   percent moderate; 46 percent low; zero percent

18   insufficient.

19   MS. THEBERGE: That was 1d, the

20   composite. So, it looks like it is in the gray

21   zone, consensus not reached. So, we will

22   continue to go forward.

1   Is there a question?

2   DR. YU: Yes, we didn't get the last

3   whatever described, the last voting result.

4   CO-CHAIR SEPTIMUS: You didn't get it?

5   DR. YU: Oh, we didn't hear the

6   explanation. What is the --

7   CO-CHAIR SEPTIMUS: It is in the gray

8   zone. It didn't reach over 60 percent for the

9   high and moderate so, it is in the gray zone but

10   we still go on with the next vote.

11   DR. YU: Okay.

12   CO-CHAIR SEPTIMUS: Okay?

13   DR. YU: Yes, thanks.

14   MS. IBRAGIMOVA: So, scientific

15   acceptability of measure properties, 2a,

16   reliability. Reliability including 2a1, precise

17   specifications, and 2a2, testing appropriate

18   method and scope with adequate results. One,

19   high; two, moderate; three, low; four,

20   insufficient.

21   And the results are 17 percent high;

22   42 percent moderate; 38 percent low; four percent

1   insufficient.

2   CO-CHAIR SEPTIMUS: That is gray,

3   also.

4   MS. IBRAGIMOVA: Scientific

5   acceptability of measure properties, 2a,

6   reliability. 2b validity, including 2b1,

7   specifications consistent with evidence; 2b2,

8   testing appropriate method and scope with

9   adequate results and threats addressed; 2b3,

10   exclusions; 2b4, risk adjustment/stratification;

11   2b5, meaningful differences; 2b6, comparability-

12   multiple specifications; 2b7, missing data,

13   eMeasures, composite, PRO-PMs. One, high; two,

14   moderate; three, low; four, insufficient.

15   The results are 17 percent high; 46

16   percent moderate; 29 percent low; 8 percent

17   insufficient.

18   CO-CHAIR SEPTIMUS: Okay, that was 63

19   percent, so that was a consensus. Next.

20   MS. IBRAGIMOVA: Scientific

21   acceptability of measure properties, 2d,

22   composite. Empirical analyses support composite

1 construction and demonstrate 2d1, component

2 measures fit quality construct, add value

3 parsimony to extent possible; 2d2, aggregation

4 and weighting fit quality construct simplicity to

5 extent possible. One, high; two, moderate;

6 three, low; four, insufficient.

7   The results are 17 percent high; 50

8 percent moderate; 29 percent low; four percent

9 insufficient.

10   CO-CHAIR SEPTIMUS: That was a

11 consensus. Okay.

12   MS. IBRAGIMOVA: Feasibility, 3a, data

13 generated during care; 3b, electronic sources;

14 and 3c, data collection can be implemented,

15 eMeasure feasibility assessment of data elements

16 and logic. One, high; two, moderate; three low;

17 four insufficient.

18   The results are 50 percent high; 33

19 percent moderate, 13 percent low, 4 percent

20 insufficient.

21   CO-CHAIR SEPTIMUS: That's clear.

22   MS. IBRAGIMOVA: Feasibility in use,

1   4a accountability/transparency use in

2   accountability within three-year public

3   reporting, within six-year or if new credible

4   plan; and 4b, improvement, progress demonstrated

5   if new credible rationale and; 4c, benefits

6   outweigh evidence of unintended negative

7   consequences to patients/populations. One, high;

8   two, moderate; three, low; four, insufficient

9   information.

10   The results are 50 percent high, 25

11   percent moderate, 25 percent low, zero percent

12   insufficient information.

13   CO-CHAIR SEPTIMUS: That was a

14   consensus. And now the last one.

15   MS. IBRAGIMOVA: Overall suitability

16   for endorsement. Does the measure meet NQF

17   criteria for endorsement? Note: This may not

18   yet be a recommendation for endorsement. Final

19   recommendation for endorsement may depend on

20   assessment of any related and competing measures.

21   One, yes; two, no.

22   The results are 58 percent yes, 42

1 percent no.

2   CO-CHAIR SEPTIMUS: Didn't reach 60

3 percent. Okay.

4   MS. THEBERGE: It moves forward as

5 consensus was reached.

6   CO-CHAIR SEPTIMUS: Yes, it will move

7 forward but it is not at 60 percent. Correct.

8 Okay.

9   DR. QUIGLEY: Could you please clarify

10 that?

11   CO-CHAIR SEPTIMUS: It is in the gray

12 area.

13   MS. THEBERGE: So, it will move

14 forward to public comment. We will specifically

15 seek comments on this measure regarding consensus

16 not reached. And you will have the opportunity

17 to revote after the comment period.

18   CO-CHAIR SEPTIMUS: Isn't that fun?

19 This reminds me of sepsis.

20   MS. IBRAGIMOVA: So, the way it is

21 hooked up is that this cord is hooked up to those

22 screens and that cord is hooked up to these four

1   screens.

2   CO-CHAIR SEPTIMUS: I want to thank

3   the developers, who, as I said before, have done

4   incredible effort to improve on the measure.

5   Thanks, Sean, who I know is on the phone who did

6   a rough evaluation and, of course, all of you for

7   your superb comments and thorough discussion. I

8   think we all learned a lot. I think, regardless

9   of the final outcome of this measure, I think

10   that there is some initial stuff that you can now

11   go back on, regardless of whether it gets

12   endorsed or not, to improve on the measure and I

13   think that is the whole purpose of this process.

14   So, I think it worked well and we

15   thank you so much for your time.

16   So, we are going to move on. We are

17   only four minutes late. That is pretty good. Of

18   course, we started early. And do we have a

19   developer for 0347 to come up?

20   MS. MCGIFFERT: Can we get a very

21   clear explanation about what happens with a

22   measure in the gray area?

1   DR. BURSTIN: So, the measure will go

2   out in the report from this committee that just

3   fully indicates exactly what the votes were on

4   each criteria, with a summary of all the issues

5   raised at this meeting. We will seek public

6   comment on that measure. And because it is in

7   the gray zone, you will have an opportunity to

8   post public comment to consider the comments

9   brought forward and see if you would like to

10   revote on that measure and see if you can, in

11   fact, meet consensus.

12   We just try to identify it as such

13   because, in general, there has been a lot of

14   discomfort about measures that go out where votes

15   are split. So, we just try to be more

16   transparent when there is apparently not yet

17   consensus. This one is obviously one of those.

18   MS. MCGIFFERT: So, if the committee

19   decides not to revote, then it is not endorsed?

20   DR. BURSTIN: No, it is still pretty

21   early in the process.

22   MS. MCGIFFERT: Okay.

1   DR. BURSTIN: So, again, what happens

2   at that point is even measures that don't reach

3   consensus we got the vote and continue down the

4   path. But usually, committees do usually, and I

5   suspect we will get many comments on this one and

6   will probably, I suspect, choose to revote, based

7   on the volume of comments.

8   CO-CHAIR SEPTIMUS: I can't wait.

9   We need to move on, Pat, really. If

10   you have got something really to question go

11   ahead, but we need to move on.

12   DR. QUIGLEY: It's related to the

13   comment process. And I know that we had leads

14   and teams but I would just like to say that a lot

15   of our discussion was from our perspective but

16   there were public comments that were submitted in

17   the Excel spreadsheets and I don't know that

18   everyone had a chance. But as we go forward,

19   just make sure everybody gets those comments

20   because it is a lot of material to get through

21   that other people make in terms of the public

22   comment process. Thank you.

1   CO-CHAIR SEPTIMUS: And by the way, at

2   the end, before we go to lunch, we are also going

3   to ask for public comment as well, so you may

4   hear some additional.

5   Before we go to lunch, we actually ask

6   for public comment also. So, you may get some on

7   the phone as well. Okay?

8   So, who are the developers for the

9   next one? You want to come forward?

10   You still want to do this? So, we

11   have the developers, who, of course, we don't

12   have to change seats. And then I believe that

13   Suzanne is going to -- who is running the

14   discussion? Yes, you are the discussant. Good.

15   Okay, so you have a few minutes to

16   present your measure as a developer.

17   DR. ROMANO: Yes, just very quickly.

18   So, this is another one of the family of Patient

19   Safety Indicators that is not part of the PSI90

20   composite. This is a measure of deaths among

21   patients who are admitted to the hospital in

22   certain MS-DRG categories that have been

1   identified as having a very low risk of

2   mortality. So, these are -- this measure is,

3   basically, a tool to identify deaths that have a

4   higher likelihood of reflecting of some issues

5   related to the process of care in the hospital.

6   Of course, as with any death measure,

7   it is many of these events are not preventable.

8   That is recognized. It is simply a risk-adjusted

9   mortality indicator, which is intended to focus

10   on a subset of deaths for which there appears to

11   be a higher likelihood of process failures or a

12   subsequent issue. So these are, in common

13   parlance, these would be patients who were

14   admitted to the hospital and weren't expected to

15   die but something happened and they died.

16   So, I think that is sort of the

17   conceptual summary of the indicator.

18   CO-CHAIR SEPTIMUS: And this is an

19   endorsed measure, so this is coming back for re-

20   endorsement. Correct? Okay.

21   Suzanne, you want to lead us through

22   your review of this?

1   DR. MOFFATT-BRUCE: So, as Patrick

2   said, this is an outcome measure. It is

3   inclusive of patients that are admitted that are

4   in DRGs that are felt to be less than 25 percent

5   of having a risk of mortality. It nicely

6   excludes trauma, cancer, immunocompromised and

7   transfer patients, which I think is reasonable.

8   It is at the facility level.

9   As I said, it is an outcome measure.

10   And it does seem to follow on that there are

11   processes that do impact this and I think the

12   validation of this have been shown over two

13   decades, one back in 1989 and then again

14   revalidated in 2010 that is a significant

15   increase of having some sort of patient safety

16   event or less than standard of care if these

17   patients die whilst in hospital.

18   The rate of these events have stayed

19   constant through the years and I think that

20   stands to demonstrate that this is a measure that

21   should be continued to be measured and acted

22   upon. I know in our own institution, these are

1   triggers for us to review. Cases, if we have a

2   case, they are rare but each of those cases

3   brings something of clarity and process

4   improvement to the institution. So, I think it

5   is still very valid.

6   So, as a priority, I think it

7   continues to be one.

8   One of the challenges or one of the

9   questions I had was around looking at the

10   numerator. Inclusive in that is kind of a vague

11   DRG around chest pain, which I find is the one

12   that flags most for us when we have these rare

13   events. And so I would ask maybe the developers

14   to comment on that DRG 311 and 313.

15   Otherwise, I think the validity is

16   reasonable, although I think that larger

17   hospitals, over 400 beds, are advantaged by this

18   measure, as compared to the smaller hospitals.

19   And I would have to ask Patrick as well to

20   comment on that.

21   Lastly, I think that the exclusion

22   criteria are appropriate and actually, I think,

1 more reflective of really what this is, which is

2 a trigger tool to be used.

3   There are some competing measures

4 here. There are some similarities with the death

5 after treatable surgical conditions, the PSI04.

6 But I think on its own merit, I still think it is

7 a measure that should be continued and I found no

8 other questions, other than those two that I have

9 identified for Patrick.

10   CO-CHAIR SEPTIMUS: Did you want

11 Patrick to comment on your questions first and

12 then we will open it up for discussion?

13   DR. MOFFATT-BRUCE: Yes, please. If

14 you don't mind.

15   CO-CHAIR SEPTIMUS: Okay, Patrick.

16   DR. ROMANO: So, I am just curious

17 what you are finding in your review. So, all of

18 these MS-DRGs, they go into the denominator in

19 constructing this indicator, have an underlying

20 mortality rate of less than 0.5 percent. So, can

21 you tell me a little bit more about what is going

22 on with chest pain? There is nothing unique

1   about chest pain that shows up in the empirical

2   analysis.

3   DR. MOFFATT-BRUCE: I think it is just

4   a little bit vague. And I think sometimes it is

5   what comes in as a category of vague

6   characteristic of say a young person who has some

7   unrecognized cardiac disease that is having some

8   sort of cardiac event, either myocarditis or a

9   non-STEMI that has been difficult to diagnose

10   because of other comorbidities. And so it just

11   sits there. These patients sit there and it is

12   this undifferentiated chest pain category.

13   And I would just ask for maybe some

14   clarification as to if that might be improved

15   upon.

16   DR. ROMANO: Yes, well those are the

17   patients that go into that MS-DRG because,

18   obviously, if the diagnosis of AMI is established

19   or the diagnosis of heart failure is established,

20   those MS-DRGs are going to get higher payment and

21   they are going to preferred.

22   So, these are patients who generally

1 have ruled out for myocardial infarction. But

2 for some reason there isn't an alternative

3 diagnosis that has been established.

4 But I think it certainly -- I mean we

5 have seen over time that the prevalence of this

6 MS-DRG has dropped.

7 DR. MOFFATT-BRUCE: I would agree.

8 DR. ROMANO: Which is, of course, not

9 surprising because typically patients are now

10 ruled out in emergency rooms so we only admit the

11 ones who actually have MI.

12 DR. MOFFATT-BRUCE: Right.

13 DR. ROMANO: But in terms of what is

14 left in here, we could explore that a little bit

15 more empirically.

16 DR. MOFFATT-BRUCE: I think it is the

17 younger population that really have an

18 undifferentiated, especially in the myocarditis

19 seems to be the one that we are seeing the most

20 often. And they usually sit on non-cardiac

21 services in the hospitalist type of environment.

22 Patrick, the other question I had for

1   you is kind of the risk adjustment for the larger

2   versus the smaller hospitals because there seems

3   to be some statistical challenge there maybe that

4   maybe I am just not reading it correctly.

5   DR. ROMANO: I am going to ask Dr.

6   Skinner or Dr. Houchens, are you on the phone?

7   DR. SKINNER: I am on the phone. Can

8   you repeat the question for me?

9   DR. ROMANO: Could you clarify exactly

10   what section you are referring to in the

11   materials?

12   DR. MOFFATT-BRUCE: I will. There is

13   actually -- it speaks to the adjusted c-statistic

14   is 0.8833, which is reasonable for large

15   hospitals but perhaps the validity is not as -- I

16   wrote that down from somewhere in the materials

17   here. So, maybe it is around understanding the

18   c-statistic.

19   DR. ROMANO: Hal, did you get that?

20   DR. SKINNER: I did. So, the c-

21   statistic we use in this context to describe the

22   strengths of the risk-adjustment model so you can

1 view it as how much difference there would be if

2 we weren't risk adjusting the 0.88 is relatively

3 high for a c-statistic, in our experience with

4 the PSIs.

5   Is there something else I can clarify

6 about it, though? I am happy to.

7   DR. MOFFATT-BRUCE: I'm just wondering

8 if within the model there is something that

9 adjusts for the larger versus the smaller

10 hospitals.

11   DR. SKINNER: Right, so we don't do an

12 adjustment based on hospital characteristics.

13 These are individually risk-adjusted.

14   DR. ROMANO: Are you referring to the

15 discrimination being lower?

16   DR. MOFFATT-BRUCE: Yes, it may be,

17 Patrick, that is what I am referring to.

18   DR. ROMANO: Okay, right. So, I think

19 you may be referring to the discrimination being

20 lower for smaller hospitals. So, how could you

21 pull up that discrimination table and interpret

22 it for the group across the deciles of hospital

1   volume?

2   DR. SKINNER: Yes, I'm working on

3   pulling it up now.

4   CO-CHAIR SEPTIMUS: And as they are

5   pulling it up, we are going to truncate this. We

6   are going to ask for comments on the evidence and

7   then we are going to vote on that and then we

8   will talk about the reliability, feasibility, and

9   usability. We want to get right to the vote on

10   the evidence.

11   So, comments around the evidence after

12   Susan finishes.

13   DR. LAWLESS: Yes, this is Steve

14   Lawless. I have a question for you and it may

15   sound a little bit off but it is not. Do you

16   know what the death rate, the normal death rate

17   is in the population per day and how this

18   compares to -- or are we just tracking a

19   variation that normally exists except for in the

20   hospital?

21   DR. ROMANO: Death rate per day.

22   DR. LAWLESS: In the populations, per

1 thousand per day, how many people in the United

2 States die in this population? And are we just

3 seeing a variation of it is low mortality DRGs?

4 Are we capturing what is a normal phenomenon out

5 there?

6   DR. ROMANO: Well, I mean you could do

7 a little simple math. If the average hospital

8 stay is four or five days, 0.5 percent would put

9 one in a thousand patients dropping dead every

10 day. So, clearly, we are in a different order of

11 magnitude here. But I understand. I accept your

12 point that some of these events, whether it is

13 one percent or two percent, we could do a little

14 back of the envelope math but it is clearly a

15 very small percent. But some portion of these

16 events could be randomly occurring in hospitals.

17   DR. LAWLESS: Yes, just curious

18 whether that is -- it ends up being a non-issue

19 or not. But just if you are thinking about it,

20 means it is going to --

21   CO-CHAIR SEPTIMUS: Now, again, what

22 we are looking at and tell me if I am wrong, what

1   we are looking at here is are these low mortality

2   deaths more likely to be due to error? That is

3   what this measure is, which would indicate that

4   perhaps this should be studied more. And I think

5   that is what they are proposing the evidence

6   suggests that these low risk mortality are more

7   likely to be due to error versus just random

8   events.

9   So, that is what the measure is about.

10   DR. MOFFATT-BRUCE: Almost five times

11   more.

12   CO-CHAIR SEPTIMUS: Right, almost five

13   times. So, that is the evidence at least that

14   they are proposing.

15   Charlotte?

16   DR. ALEXANDER: I would like to speak

17   to adding disparities to this measure. I think

18   adding race ethnicity and language would give us

19   a great deal of information. We know that the

20   risk of complications increases in that

21   population and it may well be that that is a

22   significant driver.

1   Thank you, Charlotte, again. Let's,

2   again, we are going to go around for evidence and

3   then we are going to vote on evidence.

4   Jason?

5   DR. ADELMAN: I have to apologize

6   because I am not 100 percent sure if this is

7   evidence or validity or reliability but I will

8   just ask it.

9   CO-CHAIR SEPTIMUS: We will let you

10   know, Jason.

11   DR. ADELMAN: Thank you. So, Jason

12   Adelman. I have one major question about this

13   measure, which is I have worked as a hospitalist

14   in several hospitals and I have seen real

15   variability in social work services and the use

16   of hospices. So, I just don't understand -- for

17   example, if somebody has a terrible error,

18   hypoxic brain damage but a very good social

19   services, they may leave the hospital several

20   days after and go to a home hospice. And they

21   will die because of that error three days after

22   they leave the hospital and I'm not sure if that

1   would count.

2   So, there seems to be like competing

3   forces, patient safety and the ability to take

4   advantage of hospice and home hospice. So,

5   people are dying and we are just not capturing

6   it.

7   In my hospital, we certainly collect

8   measures on mortality and we also use the Social

9   Security Death Registry, I think it is called.

10   And so we captured that even if they leave the

11   hospital, like four days after they left, they

12   died, we will take ownership of that.

13   So, I am just wondering, I went

14   through it and I couldn't find if this issue was

15   addressed or if the developers considered it or

16   if they used the Social Security Death Index in

17   any way because I am concerned that this will

18   really confound the measure.

19   Was that evidence, by the way?

20   CO-CHAIR SEPTIMUS: Yes.

21   DR. ADELMAN: I don't know whether

22   either of you would like to comment on that.

1   DR. ROMANO: Well, yes, it is a

2   potential source of bias in any inpatient risk-

3   adjusted mortality measure, for that matter, any

4   measure that is based on inpatient data. It is

5   an inherent limitation.

6   So, to the extent that some hospitals

7   may be more resourceful than others in

8   transferring patients who are about to die, it is

9   a potential bias.

10   CO-CHAIR SEPTIMUS: Any other comments

11   on evidence? Charlotte, do you have another

12   comment? Okay.

13   Okay, well, let's go ahead and vote on

14   the evidence and then we will talk about the

15   other elements.

16   DR. ROMANO: I'm sorry. Did we address

17   -- Susan, did we address your question --

18   DR. MOFFATT-BRUCE: Disparities.

19   DR. ROMANO: -- with respect to the

20   discrimination?

21   DR. MOFFATT-BRUCE: Not to the fullest

22   but maybe that comes on later in the

1 conversation.

2 CO-CHAIR SEPTIMUS: That will come on

3 later. Okay, we are ready to vote on evidence.

4 MS. IBRAGIMOVA: So, importance to

5 measure and report, 1a evidence health outcome or

6 PRO. Rationale supports the relationship of the

7 health outcome or PRO to at least one healthcare

8 structure, process, intervention, or service.

9 One, yes; two, no.

10 CO-CHAIR SEPTIMUS: Wasn't there a

11 movie on the 50 Shades of Grey?

12 (Laughter.)

13 MS. IBRAGIMOVA: The results are 88

14 percent yes; 13 percent no.

15 CO-CHAIR SEPTIMUS: Okay, so let's

16 have discussion then about reliability, usability

17 and feasibility.

18 Okay, reliability. Do we have any

19 discussion on this because we really didn't

20 finish discussion on the reliability and the

21 other elements for the measure? You don't vote

22 again. Does anybody have any other question?

1	DR. MOFFATT-BRUCE: Is this where the

2	discrimination clarification came in?

3	DR. ROMANO: I'm sorry. So, Table 2,

4	the signal-to-noise ratio is an indicator of the

5	reliability of the indicator overall and the

6	reliability for specific subsets of hospitals

7	stratified by hospital size. And the overall

8	reliability, in terms of the average signal-to-

9	noise ratio, its weighted average across all

10	hospitals is 0.72. And that certainly is in the

11	ballpark for other NQF-endorsed measures.

12	What we show here is that for the

13	smallest hospitals, the reliability does drop

14	below 0.4 or 0.5. So, for example, for the

15	hospitals that have an average of 16 eligible

16	discharges in a year, the reliability is only

17	0.16. So, it basically indicates that this kind

18	of a measure, just like any other risk-adjusted

19	mortality measure should be interpreted very

20	cautiously for the bottom 20 percent of hospitals

21	in terms of size.

22	This is, of course, this is

1   incorporated into our analytic approach because

2   the risk-adjusted rates are smoothed or shrunk

3   towards the overall weighted mean for the

4   population. This is a standard approach that has

5   been adopted by other measurement groups as well.

6   DR. MOFFATT-BRUCE: Thank you very

7   much.

8   CO-CHAIR SEPTIMUS: The NQF staff has

9   correctly reminded me that performance gap is

10   part of evidence. And I apologize. We need to

11   vote on the performance gap.

12   So, Laura.

13   MS. IBRAGIMOVA: So, importance to

14   measure and report, 1b, performance gap. Data

15   demonstrated considerable variation or overall

16   less than optimal performance across providers

17   and/or population groups, disparities in care.

18   One, high; two, moderate; three, low; four,

19   insufficient.

20   So, the results are 38 percent high;

21   42 percent moderate; 21 percent low; zero percent

22   insufficient.

1   CO-CHAIR SEPTIMUS: So, the next one

2 is -- this is a composite. No, no, keep going.

3   I think the next one is reliability.

4 So, we have already passed that.

5   Now, we are in reliability. I

6 apologize. So, any discussion? Any further

7 discussion around reliability of the measure?

8   Okay, so if you will read the

9 question, then, Laura.

10   MS. IBRAGIMOVA: Scientific

11 acceptability of measure properties, 2a,

12 reliability, including 2a1, precise

13 specifications; and 2a2, testing appropriate

14 method and scope of adequate results. One, high;

15 two, moderate; three, low; four, insufficient.

16   MS. THEBERGE: We are missing one

17 vote. If everyone could point their clicker at

18 Laura and vote again.

19   MS. IBRAGIMOVA: And the results are

20 38 percent high; 54 percent moderate; 8 percent

21 low; zero percent insufficient.

22   CO-CHAIR SEPTIMUS: Okay, the next one

1   is validity. Comments on validity. Seeing none,

2   please read the question.

3   MS. IBRAGIMOVA: Scientific

4   acceptability of measure properties, 2b,

5   validity, including 2b1, specifications

6   consistent with evidence; 2b2, testing

7   appropriate method and scope with adequate

8   results and threats address; 2b3, exclusions; 2b4

9   list adjustments and stratification; 2b5,

10   meaningful difference; 2b6, comparability in

11   multiple specifications; and 2b6, missing data,

12   eMeasures, composites, PRO-PMs. One, high; two,

13   moderate; three, low; four, insufficient.

14   So the results are 29 percent high; 63

15   percent moderate; 8 percent low; zero percent

16   insufficient.

17   CO-CHAIR SEPTIMUS: And the next

18   question? No, not a composite.

19   Feasibility. Any questions around

20   feasibility of the measure? Seeing none, read

21   the question, please, Laura.

22   Feasibility, 3a, data generated during

1   care and 3b, electronic sources, and 3c, data

2   collection can be implemented. eMeasure

3   feasibility assessment of data elements and

4   logic.

5   One, high; two, moderate; three, low;

6   four, insufficient.

7   MS. THEBERGE: We're missing one vote.

8   Please try voting again.

9   MS. IBRAGIMOVA: The results are 79

10   percent high; 17 percent moderate; 4 percent low;

11   zero percent insufficient.

12   CO-CHAIR SEPTIMUS: The next question

13   is around usability and use.

14   Comments? Seeing none, read the

15   question.

16   MS. IBRAGIMOVA: Usability and use 4a,

17   accountability and transparency used in

18   accountability within three-year, public

19   reporting within six-year, or if an incredible

20   plan; and 4b, improvement, progress demonstrated

21   if new credible rationale; and 4c, benefits

22   outweigh evidence of unintended negative

1 consequences to patients of populations.

2   One, high; two, moderate; three, low;

3 four, insufficient information.

4   So the results are 46 percent high, 33

5 percent moderate, 21 percent low, and zero

6 percent insufficient information.

7   CO-CHAIR SEPTIMUS: And now the last

8 question is whether or not this measure is

9 suitable for endorsement. So, if you would read

10 the question.

11   MS. IBRAGIMOVA: Overall suitability

12 for endorsement. Does the measure meet NQF

13 criteria for endorsement? Note: This may not

14 yet be a recommendation for endorsement. Final

15 recommendation for endorsement may depend on

16 assessment of any related and competing measures.

17 One, yes; two, no.

18   The results are 96 percent yes, four

19 percent no.

20   CO-CHAIR SEPTIMUS: Excellent. Okay,

21 so we are going to go on to the last measure of

22 the morning, 0352, Failure to Rescue In-Hospital

1 Mortality, Risk-Adjusted from CHOP. Susan, it

2 looks like you are still on the block for this.

3 Are there other developers for that?

4   DR. MOFFATT-BRUCE: Rich is going to

5 actually --

6   CO-CHAIR SEPTIMUS: You guys don't

7 want to stick around for some more abuse? Thank

8 you for your time.

9   DR. MOFFATT-BRUCE: Ed, Rich is going

10 to do this.

11   DR. BRILLI: Ed, I have this one.

12   CO-CHAIR SEPTIMUS: Oh, I'm sorry. I

13 apologize.

14   DR. MOFFATT-BRUCE: No, no, we were

15 tag teamed.

16   DR. BRILLI: So, thank you. This

17 measure has been around for quite a while.

18   CO-CHAIR SEPTIMUS: This is -- the

19 developers go first.

20   DR. MOFFATT-BRUCE: Are the developers

21 here?

22   CO-CHAIR SEPTIMUS: The developer

1 first, then Rich.

2   DR. BRILLI: Sure, I'm sorry.

3   CO-CHAIR SEPTIMUS: Are the developers

4 on the phone?

5   DR. BURSTIN: Is Orit on the phone?

6 Operator, can you see, please and make sure her

7 line --

8   The folks who work with Jeff Silver,

9 can you let the operator know you are on and open

10 your lines?

11   OPERATOR: Press *1, please. No one

12 has joined from that facility.

13   DR. MOFFATT-BRUCE: This will be

14 difficult without them.

15   CO-CHAIR SEPTIMUS: I think we can't

16 consider this measure, then. I mean are we --

17 the time we had was 11:25. We are at 11:33. So,

18 we will go to --

19   Operator, let's go to public comment

20 on this morning's discussion and then we will

21 see, maybe they will pick up.

22   Go ahead, public comment, please,

1 operator.

2 OPERATOR: For public comment, please

3 press *1, at this time.

4 CO-CHAIR SEPTIMUS: And that includes

5 folks in the room, as well as folks on the phone.

6 OPERATOR: Currently, there are no

7 public comments.

8 CO-CHAIR SEPTIMUS: We have one in the

9 room. We have dialed down the voltage. So, go

10 ahead.

11 If you will give us your name and your

12 affiliation, please.

13 DR. ADEBOGUN: Great. Good morning.

14 My name is Akeem Adebogun. I am with the

15 American Hospital Association herein D.C. and

16 thank you for the robust conversation that you

17 had about the PSI90 measure. And I just wanted

18 to add the AHA's perspective on this measure.

19 We have always thought that the notion

20 of using safety measures was incredibly important

21 for public reporting programs but we have always

22 questioned whether PSI90 is the right measure to

1   use to accomplish this purpose.

2   Our concerns really turn on two

3   questions, whether the evidence is there to

4   suggest that using these components together

5   rally results in safer care and for what purpose

6   the measure is really best suited.

7   And to answer the question of purpose,

8   we also look at issues like reliability and

9   validity.

10   I think as we heard as part of the

11   discussion this morning, there remains some

12   questions about whether the individual component

13   measures have clear and consistent evidence to

14   support them.

15   And in terms of reliability and

16   validity, certainly our compliments to AHRQ for

17   undertaking so much analysis and bringing such

18   robust testing to bear, but most of that testing

19   used the HCUP database, which is an all-payer

20   database.

21   We know that the PSI measure is used,

22   generally, on Medicare claims. The data that we

1 have available to us on testing of reliability

2 using Medicare claims is pretty suspect,

3 particularly when one looks at the individual

4 component measures, where we are talking levels

5 of reliability that are R-values and the 0.1 or

6 0.2 range, which when these measures are tied to

7 pay-for-performance programs, that is just not

8 sufficient.

9 So, certainly we commend the work that

10 was done to attempt to improve the measure. We

11 think as a measure for internal purposes, it

12 makes a lot of sense. But if answering the

13 question of whether this measure would meet the

14 test of being appropriate for internal purposes

15 and for accountability purposes, we think the

16 answer is still no.

17 Thank you, very much.

18 CO-CHAIR SEPTIMUS: Thank you. Any

19 other public comments? Has anyone joined the

20 call for Measure 0352?

21 OPERATOR: If you have, you can press

22 *1 at this time. And for public comment, press

1   *1.

2   There are no comments.

3   CO-CHAIR SEPTIMUS: Well, this may be

4   a first but I think we are finished for the

5   morning. We are going to find out what happened

6   to lunch. And then we are scheduled to resume at

7   12:30.

8   MS. THEBERGE: We are trying to get in

9   touch with them. We have emailed and we are

10 calling them now.

11   CO-CHAIR SEPTIMUS: Well, let's do

12 this. Let's take a break. If you can get them

13 on the phone, we can start at 12:15, rather than

14 12:30.

15   Yes, let's do that. So, lunch is

16 going to be in here about five or ten minutes.

17 Go ahead and take a bio break. And then if we

18 can get a hold of them, we will start at 12:15,

19 rather than 12:30. How's that? Is that okay

20 with everybody?

21   CO-CHAIR THRAEN: Sounds good, yes.

22   CO-CHAIR SEPTIMUS: Okay.

1   (Whereupon, the above-entitled matter

2   went off the record at 11:39 a.m. and resumed at

3   12:15 p.m.)

4   CO-CHAIR SEPTIMUS: Good afternoon,

5   everyone. Are the CHOP developers on the line?

6   MS. EVEN-SHOSHAN: Yes.

7   CO-CHAIR SEPTIMUS: Excellent. Okay.

8   Just before we get started, an observation --

9   wait a minute. Okay. If I can have everyone's

10   attention, I have one very important

11   announcement. How many people are going to

12   dinner tonight? As a group. I mean we're all

13   going to go to dinner tonight. Who's going to

14   dinner with the group tonight? Okay.

15   I'll remind you it's going to be at

16   Mio's at 1110 Vermont, and our time is for 6:30.

17   Those of us who are staying up at the Capitol

18   Hilton -- Washington Hilton will probably not

19   want to go all the way back to the hotel and then

20   go to the restaurant but right now, it's

21   scheduled for 6:30 so, we can be flexible with

22   that. Okay.

1   The second thing is that Helen, who

2   always has tremendous insight, went and pulled up

3   the vote for PSI 90 last year. This is just food

4   for thought. It's not a commentary, it's just

5   food for thought because my guess is this is

6   going to come back for us to vote.

7   I think by everybody's admission that

8   this is a much stronger composite than was

9   presented last year, yet the votes were lower

10 this year than last year.

11   So, I'm not sure I understand it, but

12 I'm just pointing it out for observation and

13 something to think about as we think about

14 today's date and think about the discussion this

15 morning. We'll see what the public comment is

16 and then, we'll probably have an opportunity to

17 re-discuss this on a phone call, so --

18   DR. BURSTIN: Just to add one thing,

19 I think sometimes people come up with ideas for

20 how the measure could be better, and that's

21 wonderful, and we love to see that, but you have

22 to evaluate the measure as it is before you.

1   And, you know, the mantra we often hear is,

2   "Can't let the perfect be the enemy of the good."

3   And I think sometimes people's passion

4   perhaps, maybe, you know, even though the

5   commentary suggested the measure was improved, it

6   wasn't clear the voting followed what we heard at

7   the table here. So, hopefully we'll have a

8   chance to reconsider that after we get more

9   public comment.

10   CO-CHAIR SEPTIMUS: And with that,

11   it's my pleasure after this morning, to turn the

12   moderating part for the first part of the

13   afternoon to my much better co-chair Iona.

14   CO-CHAIR THRAEN: Thank you. We're

15   teaching him how to multi-task. Okay.

16   CO-CHAIR SEPTIMUS: Men don't do it as

17   well as women.

18   CO-CHAIR THRAEN: (Laughter) Go away.

19   So we're on measure 0352, Failure to

20   Rescue and Hospital Mortality (risk adjusted).

21   And it's presented by the Children's Hospital of

22   Philadelphia. And 0353, Failure to Rescue 30-Day

1 Mortality (risk adjusted), again presented by the

2 Children's Hospital of Philadelphia. So, we'll

3 turn it over to the developer on the line.

4 MS. EVEN-SHOSHAN: Hi. I just wanted

5 to mention that Dr. Silber, who developed the

6 measure, is not on the call today, so we may not

7 be able to address all the questions. But we'll

8 take good notes, and we'll answer as many as we

9 can.

10 CO-CHAIR THRAEN: All right. Are you

11 planning on presenting a summary? You have three

12 minutes.

13 MS. EVEN-SHOSHAN: No.

14 CO-CHAIR THRAEN: No. Okay. With

15 that we'll turn it over to the team. And the

16 presenter today, for this one would be Susan,

17 right? Okay. Sorry. Dr. Brilli?

18 DR. BRILLI: So, thank you. I think

19 this is a good measure. I'll start with sort of

20 maybe the conclusion and obviously, the group

21 will have to make that final decision. It is a

22 maintenance measure, so it's been around for

1   quite a while. And as part of the packet, they

2   presented 35 publications that I think many of

3   which are pretty good that really add a lot of

4   validity and credibility to the measure.

5   You know, essentially what it does is

6   it records deaths numerator of patients who had

7   complications among all patients who had

8   complications in the denominator. And it's been

9   validated in a number of large populations.

10   It defines itself in general surgery,

11   orthopedics, and vascular surgery patients using

12   specific DRGs. It excludes patients over 90 and

13   patients under 18. Editorial comment as a

14   pediatric ICU doctor, I wish we had a measure

15   like this for pediatrics, so maybe Dr. Silber and

16   his team can do that, but this is not a pediatric

17   measure.

18   I thought the validity and reliability

19   data that they provided was good. They looked at

20   also biases, and I didn't see any problems there

21   as well. And overall, I think it's a good

22   measure that adds to our pantheon of outcomes.

1   It adds to just straight severity adjusted

2   mortality by giving us a failure to rescue

3   measure when we have complications and how many

4   of those patients ultimately die.

5   So those are my overall comments.

6   There are others in the group have other

7   comments.

8   CO-CHAIR THRAEN: Any member of the

9   team want to comment?   No? Are there any

10 questions of the group as a whole?

11   Go ahead.

12   DR. SCHULTZ: This is Leslie Schultz.

13 A question about the time frame for the data

14 being used for the reliability. Is it still 1999

15 and 2000, or are there more current data?

16   DR. BRILLI: They have something

17 that's -- at least --- what I could read, they

18 have a publication in 2015, and they also have

19 data from 2 million patients from Medicare claims

20 from 2000 to 2005. So, it's a pretty robust

21 database. And certainly the measure sponsors

22 could answer that even better than I.

1   MS. EVEN-SHOSHAN: We used data from

2   2007 in one of our recently-published papers in

3   HSR. The data that we used could be enhanced by

4   using CPT codes when available, using outpatient

5   claims information. So, every time, if we get

6   more detailed information, we can produce a

7   better measure.

8   CO-CHAIR THRAEN: All right. Yanling?

9   DR. YU: Thank you. My question is

10   very simple. I just wondering "within 30 day of

11   admission". What is the rationale for picking of

12   30 days?

13   MS. EVEN-SHOSHAN: We usually -- the

14   failure to rescue is a measure that complements

15   the death rate, and we usually look at that as a

16   30-day death rate, so that's why we chose 30 days

17   failure to rescue.

18   CHOP REP.: It's the gold standard for

19   surgical mortality measurements.

20   DR. YU: Okay.

21   DR. BRILLI: And the specific measure

22   we're talking about now, 352, is just death

1   within the hospital stay which could actually be

2   a lot longer than 30 days. And in 353, which I

3   think is the next measure, is within 30 days of

4   admission. So they're --

5   CHOP REP: Exactly.

6   DR. BRILLI: --- exactly the same

7   measures only one is within 30 days of admission,

8   353. 352 is during hospitalization which if the

9   hospital lasted 90 days, that would be included

10 as a mortality there.

11   MS. EVEN-SHOSHAN: Correct.

12   CO-CHAIR THRAEN: Steve?

13   DR. LAWLESS: Yes, Richard, the

14 developers, either one. This is Steve Lawless.

15 I was struck --- just looked in the summary, I

16 didn't see as many numbers in terms of different

17 rates and stuff. It was more descriptive in

18 articles, where other measures actually start

19 talking about rates and ratios and different risk

20 factors. Are they there somewhere I just missed

21 it, or in the publications?

22   DR. BRILLI: I agree with you. That's

1   all I saw as well, but maybe the developers could

2   comment on that?

3   MS. EVEN-SHOSHAN: We could provide

4   the new failure to rescue rates that appeared in

5   our more recent publication. For example, the

6   HSR paper that appeared in 2014 is more recent.

7   CO-CHAIR THRAEN: Steve, are you

8   making that request?

9   DR. LAWLESS: Yes, I am actually.

10   Because I have no --- by reading this, I have no

11   comprehension of the scope or size, you know --

12   MS. EVEN-SHOSHAN: Okay. Sure.

13   DR. LAWLESS: --- and then there is the

14   question of our PSI, you know, whatever, in terms

15   is; is it 20 percent, 10 percent, .1 percent?

16   CO-CHAIR THRAEN: Okay.

17   MS. EVEN-SHOSHAN: No, definitely.

18   We'll provide these rates by type of surgery as

19   well.

20   DR. BRILLI: There's a Health Services

21   paper that they reference from 2014 which I did

22   not read, but it looks like that might have -- it

1   might have the information we're looking for,

2   Steve.

3   CO-CHAIR THRAEN: Okay.

4   MS. ARDIZZONE: I just wanted to echo

5   that I would also like to see that, so --

6   CO-CHAIR THRAEN: Okay. So, if it's

7   in their documentation, is that what you're

8   referencing?

9   DR. BRILLI: Well it looks like --

10   reference 34 in the paperwork that they provided

11   is a Health Services Research 2014 paper. And

12   looking at the title, it looks like it might have

13   what we're looking for, but I didn't read that

14   paper. I didn't read all 35 papers.

15   CO-CHAIR THRAEN: Okay.

16   MS. EVEN-SHOSHAN: Yes, it does. It

17   does. Maybe we can point you to the table?

18   CHOP DEVELOPER: Yes. Table 2, I

19   believe would have -- well we'll provide it for

20   you, but we have across hospital distributions of

21   failure to rescue rates in orthopedics general

22   surgery that are directly standardized.

1   CO-CHAIR THRAEN: Thank you.

2   Charlotte?

3   DR. ALEXANDER: I'm curious how they

4   are identifying the co-morbidities. They have a

5   number that they have talked about age, sex,

6   transfer status, whether it's a high-tech

7   hospital, teaching hospital, bed size, bed-to-

8   nurse ratio, staff mix. That's not claims data

9   information, and so I'm wondering how they're

10   gathering that information?

11   MS. EVEN-SHOSHAN: Okay, first of all,

12   I have to say that we made a mistake. The table

13   that you're looking includes, in addition to

14   patient co-morbidities, hospital characteristics.

15   So, when we do the risk adjustment, we use just

16   patient characteristics which are sex, age, co-

17   morbidities, transfer status. All this is

18   available in the claims from Medicare.

19   DR. BRILLI: In the documentation they

20   submitted there's about 40 different diagnostic

21   co-morbidities that they list here;

22   thrombocytopenia, smoking, cancer, abdominal

1   cancer, major small bowel procedures. There's

2   about 35 or 40 of them that they list in the

3   thing that's this thick. So, it looks like they

4   made a pretty good multi-variate analysis on

5   this.

6   CO-CHAIR THRAEN: Okay. Josh?

7   DR. RISING: Hi there. This is Josh

8   Rising. Just a question for the developer on the

9   exclusion of patients over the age 90. Can you

10   talk us through the rationale on that?

11   MS. EVEN-SHOSHAN: Yes. We do not

12   have available DNR status. And the idea was that

13   hospitals may be less aggressive in how they try

14   to treat patients over 90.

15   DR. RISING: That makes sense. I

16   guess the question is, I mean, the measure

17   generally, is designed to identify patients who

18   have died with complications in the hospital?

19   MS. EVEN-SHOSHAN: Mm-hmm.

20   DR. RISING: Right, so, I mean, I

21   understand that the DNR order would affect how

22   much care might be provided but, you know, I

1 mean, the goal is still understanding that

2 complication rate, correct?

3   MS. EVEN-SHOSHAN: Well, the

4 complication rate, as we called it, I just wanted

5 to make a small correction the denominator

6 includes not just complications, but also the

7 number of patients who died without a

8 complication.

9   The idea being that they must have had

10 a complication that was not recorded. So, while

11 that numerator is the number of patients who

12 died, the denominator is the number of patients

13 who died with a complication plus the number of

14 patients who died without a complication.

15   CO-CHAIR THRAEN: Laura, you had yours

16 up, did you change your mind?

17   MS. ARDIZZONE: Well, I just wanted to

18 make a comment that it was a strange assumption

19 that you generally think that people over 90

20 don't get aggressive care. I would say there's

21 lots of variation in that across the country, so

22 I'm not sure if you could make that assumption,

1 unless it's based on something. I mean, is this

2 just your general impression? Or is there some

3 more data?

4 MS. EVEN-SHOSHAN: You know, we do not

5 have data, but when the measure was developed

6 years ago, I think that they put the limit at 85,

7 so as time goes on, maybe next time we'll raise

8 the limit, but --- the age limit. But that was a

9 comment that was made before. I'll bring it to

10 the attention of Dr. Silber.

11 CO-CHAIR THRAEN: Five minutes left for

12 any other discussion before we vote. Are we

13 ready to vote? All right, let's start with the

14 evidence.

15 MS. IBRAGIMOVA: So importance to

16 measure and report 1(a) evidence, health outcome

17 or PRO, question now supports the relationship of

18 the health outcome or PRO to at least one

19 healthcare structure, process, intervention, or

20 service. One yes, two no. The results are 96

21 percent yes, 4 percent no.

22 Importance to measure and report 1(b)

1 performance gap, data demonstrated considerable

2 variation and are overall less than optimal

3 performance across providers and/or population

4 groups, disparities in care. One high, two

5 moderate, three low, four insufficient. The

6 results are 21 percent high, 58 percent moderate,

7 8 percent low, 13 percent insufficient.

8 CO-CHAIR THRAEN: Reliability.

9 MS. IBRAGIMOVA: So, scientific

10 acceptability of measure properties 2(a)

11 reliability including 2(a)(1) precise

12 specifications, and 2(a)(2) testing appropriate

13 method and scope with adequate results. One

14 high, two moderate, three low, four insufficient.

15 CO-CHAIR THRAEN: Can you re-vote on

16 the reliability?

17 MS. IBRAGIMOVA: So, the results are 13

18 percent high, 67 percent moderate, 13 percent

19 low, 8 percent insufficient.

20 CO-CHAIR THRAEN: Okay, the next is

21 validity. Are there any questions that you guys

22 have before we vote? All's good.

1   MS. IBRAGIMOVA: Scientific

2   acceptability of measured properties, 2(b)

3   validity including 2(b)(1) specifications

4   consistent with evidence, 2(b)(2) testing

5   appropriate method and scope with adequate

6   results and threats addressed, 2(b)(3)

7   exclusions, 2(b)(4) risk

8   adjustment/stratification, 2(b)(5) meaningful

9   differences, 2(b)(6) comparability, multiple

10 specifications, and 2(b)(7) missing data, e-

11 measures, composites, PRO-PMs, one high, two

12 moderate, three low, four insufficient.

13   The results are 13 percent high, 71

14 percent moderate, 8 percent low, 8 percent

15 insufficient.

16   CO-CHAIR THRAEN: All right,

17 feasibility.

18   MS. IBRAGIMOVA: Feasibility, 3(a)

19 data generated during care, 3(b) electronic

20 sources, and 3 data collection can be

21 implemented, e-measure feasibility assessment of

22 data elements and logic, one high, two moderate,

1   three low, four insufficient. The results are 50

2   percent high, 42 percent moderate, 8 percent low,

3   0 percent insufficient.

4   CO-CHAIR THRAEN: And then usability.

5   MS. IBRAGIMOVA: Usability and use,

6   4(a) accountability/transparency, used and

7   accountability within three year, public

8   reporting within sixth year or, if new, credible

9   plan. And 4(b) improvement, progress

10   demonstrated if new, credible rationale. And 4 ,

11   benefits outweigh evidence of unintended negative

12   consequences to patient populations. One high,

13   two moderate, three low, four insufficient

14   information.

15   CO-CHAIR THRAEN: Okay. Try it again.

16   MS. IBRAGIMOVA: Can we try usability

17   and use again? We're still missing one vote. No

18   one stepped away, right?

19   CO-CHAIR THRAEN: Once again. Here we

20   go. And then, finally.

21   MS. IBRAGIMOVA: So the results are 29

22   percent high, 58 percent moderate, 8 percent low,

1   and 4 percent insufficient information.

2   CO-CHAIR THRAEN: So are we voting on

3   this --

4   MS. IBRAGIMOVA: Not this one.

5   CO-CHAIR THRAEN: Hold on, guys, hold

6   on.

7   MS. DANFORTH: I thought the other

8   criteria was that it showed performance

9   improvement over time, and I thought that those

10   data were missing. As Steve pointed out. I'm

11   just trying to understand, like, how to apply the

12   criteria. So, if the performance data is missing

13   and, it's never been used in an accountability,

14   how can anyone vote one?

15   DR. QUIGLEY: Accountability's got a

16   broader lens than just public reporting though,

17   so it's --

18   MS. DANFORTH: No, no, no. But the

19   second criteria I thought was performance, like,

20   it showed performance improvement over time. And

21   I thought we were missing, Steve said, the

22   performance data.

1   DR. QUIGLEY: So you don't have that

2   data either?

3   MS. DANFORTH: No, they didn't submit

4   it. They said they were going to get it to us.

5   This is just for my own information.

6   DR. QUIGLEY: Okay, okay. I thought

7   they referenced --- one of the 35 references.

8   They pointed to that as the evidence for that

9   question. Or did we misunderstand?

10   Go ahead, Steve.

11   DR. LAWLESS: No --- this Steve

12   Lawless. No, Missy's right. I didn't see it

13   until they referenced it. I mean, we just went

14   through a lot of scrutiny --

15   CO-CHAIR THRAEN: Right.

16   DR. Lawless: --- on the PSI 9

17   whatever else, and I just didn't see the data at

18   all to even say was there --- it could be a

19   snapshot, but that doesn't mean performance

20   improvement. We have nothing.

21   CO-CHAIR THRAEN: Okay.

22   DR. LAWLESS: So, it's trust but

1 verify.

2 CO-CHAIR THRAEN: Okay.

3 MS. DANFORTH: --- make sure I didn't

4 misunderstand the voting criteria.

5 CO-CHAIR THRAEN: So let's go back and

6 look at that. We want to go back and look at the

7 usability question. That's the one you're

8 referencing, right? And what the criteria is for

9 usability. No, we want the criteria for

10 usability. The question was raised whether not

11 we have information to judge usability at this

12 point in time from the developer. And if we

13 don't, how can we vote yes? Right?

14 MS. EVEN-SHOSHAN: Hi. This is Orit

15 Even-Shoshan from the Children's Hospital,

16 Philadelphia. We have not used this measure

17 specifically, to monitor performance over time.

18 However, in some of our papers we provide failure

19 rates when a certain element of providing care

20 changed.

21 For example, in the set of papers

22 about resident hours, we looked at the impact of

1   the changing in the resident hours when the new

2   law was implemented, and we compared failure to

3   rescue before and after. So, I don't know if

4   this comes as a longitudinal or monitoring

5   performance over time or over intervention. But

6   that, we do have.

7   CO-CHAIR THRAEN: Okay. So, does that

8   answer your question, Missy, or not?

9   MS. DANFORTH: It answers my question

10   but, to me, it doesn't meet the criteria of 4(b)

11   improvement which is progress demonstrated. So,

12   for 4(a), I think we agree it's not --

13   CO-CHAIR THRAEN: Applicable.

14   MS. DANFORTH: --- being used.

15   CO-CHAIR THRAEN: Right.

16   MS. DANFORTH: For 4(b) improvement

17   progress demonstrated, I think that they haven't

18   done that yet and so then, I don't know how we

19   judge 4 , so I would think that we would all say

20   --- or that it would be, like, insufficient

21   information for all of us. Again, it's so I make

22   sure I understand the criteria, so I think all

1 measures need to be compared the same way.

2   So one of the comparable measures that

3 they mentioned which we didn't talk about is PSI

4 4 which is being used in an accountability

5 program, and there's data for, so I just wanted

6 to make sure if this is a comparable measure,

7 we're judging it in the same way or evaluating

8 it, sorry.

9   CO-CHAIR SEPTIMUS: And this is a re-

10 endorsement so, for awhile so, I mean, you raise

11 an excellent question, Missy, but I think we need

12 to answer those questions, but it is a re-

13 endorsement.

14   CO-CHAIR THRAEN: So, based on the

15 argument that Missy has just put forth which is

16 she and, I think, Steve also articulated earlier,

17 there's insufficient evidence -- insufficient

18 information has been provided to the committee to

19 answer this question. Does everybody see that to

20 be true? So should we re-vote on this? You ---

21 go ahead.

22   Go ahead.

1   DR. BRILLI: No, I'm not sure I --

2   there's a difference between whether this measure

3   has been used to show improvement over time and

4   whether it's being used as an accountability

5   measure within a particular organization. They

6   have a bunch of papers that show, you know, you

7   measure it in an organization, and the

8   organization may use that as an accountability

9   measure internally. They may not have been

10   measuring that over time, so --

11   The way I think about a performance

12   improvement is not only do you use it as a spot

13   check but then, you doing it over time, and I'm

14   interpreting her question as has it been done

15   over time? I think the answer to that might be

16   no. But as a spot check, all the papers are

17   talking about using it as a measure of

18   performance as a spot check to individual

19   institutions.

20   That's what all these papers are. So,

21   that's --- to me it's very useable, and it is

22   accountable. I don't know about improvement over

1   time. If that's what (b) means. I'm not sure I

2   -- well I don't -- you can do a spot check. And

3   you can -- well --

4   CO-CHAIR THRAEN: Does the developer

5   have any response to either of those?

6   MS. EVEN-SHOSHAN: I agree with the

7   last comment. It is indeed used to compare

8   institutions before and after. It has not been

9   used as a measure of performance over time,

10   monitoring in the same institution improvement.

11   No, we haven't used it in this way.

12   CO-CHAIR THRAEN: Okay. Any other

13   thoughts about this issue? I think we need to

14   re-vote on this one.

15   MS. IBRAGIMOVA: The poll is open.

16   You can re-vote.

17   Ann and Kimberly, can you resubmit

18   your votes via chat?

19   MS. O'BRIEN: Can you repeat the

20   section we're voting on, please?

21   CO-CHAIR THRAEN: It's usability and

22   use, 4(a) accountability/transparency, used in

1   accountability with three years or public

2   reporting in six or new, has a credible plan.

3   4(b) improvement, progress demonstrated. 4

4   benefits outweigh evidence of unintended negative

5   consequences, and your options are high,

6   moderate, low, or insufficient information.

7   MS. IBRAGIMOVA: Just need one more

8   vote.

9   CO-CHAIR THRAEN: Do it again, please.

10   Okay. Go back.

11   MS. IBRAGIMOVA: So the results are 4

12   percent high, 26 percent moderate, 26 percent

13   low, 43 percent insufficient information.

14   CO-CHAIR THRAEN: So, do we proceed?

15   Okay. Proceed.

16   Okay. Now this is the yes or no

17   question.

18   MS. IBRAGIMOVA: So, overall

19   suitability for endorsement. Does the measure

20   meet NQF criteria for endorsement. Note this may

21   not yet be a recommendation for endorsement.

22   Final recommendation for endorsement may depend

1   on assessment of any related and competing

2   measures. One yes, two no.

3   CO-CHAIR THRAEN: Oh! No. Really?

4   MS. IBRAGIMOVA: Would you like to re-

5   vote?

6   It says 24 responses.

7   CO-CHAIR THRAEN: No, this is real.

8   This is real. So, what is this --- this is the

9   gray area.

10   MS. IBRAGIMOVA: So, 50 percent yes

11   and 50 percent no.

12   CO-CHAIR THRAEN: It passed on

13   everything but the --

14   DR. BURSTIN: Right. Just to be clear

15   though, I mean, the only two criteria that are

16   must pass are importance to measure and report

17   and scientific acceptability. Usability and

18   feasibility in our hierarchy, are considered

19   significantly lower. So, again, you can factor

20   these in however you'd like, but we'd at least

21   want it to reflect the hierarchy.

22   So since you passed it on the first

1   few criteria, I guess the question is does this

2   reflect your overall criteria, or are you really

3   just reflecting on your last vote?

4   CO-CHAIR THRAEN: Do you want to re-

5   vote? What are your thoughts? I hear a yes.

6   Anybody else? No, no, no. Just this final one.

7   DR. BRILLI: My only question is when

8   we've seen errors here, it's exactly 50/50 --

9   CO-CHAIR THRAEN: Same thing. Yeah.

10   DR. BRILLI: --- and so I'm just

11   wondering whether this is a technical error, or

12   not? Not trying to influence anybody's vote. I

13   don't have a dog in the fight here, just to --

14   CO-CHAIR THRAEN: All right. Again.

15   We're going to repeat. Based on the hierarchy of

16   needs here, the two required yeses are that it's

17   important, and that it passes scientific rigor.

18   So it did pass in both of those, and the rest was

19   -- the last one was the one that said no. So why

20   don't you go ahead and vote. One for yes, two

21   for no.

22   MS. IBRAGIMOVA: Still missing one.

1   Here we go, got it. So, 58 percent yes, 42

2   percent no.

3   CO-CHAIR THRAEN: All right. Moving

4   forward.

5   CO-CHAIR SEPTIMUS: Now, we're going

6   to vote on all the PSI 90s again.

7   (Laughter.)

8   CO-CHAIR THRAEN: Oh. So, one of the

9   things that we've been advised is that we want to

10   break each of the conversations down into their

11   component parts. So, we've done a summary

12   already, and so we want to have the -- is it the

13   developer, or the lead?

14   DR. PINES: So what I think we should

15   do, because I think with the way a lot of the

16   voting is going where people are voting sort of

17   the same way for each criteria. At least, that's

18   sort of what it seems, so if we can partition the

19   discussion where the developer first does a

20   presentation, we discuss -- and we'll discuss

21   their comments on the measure, and then we'll

22   assess evidence first, then vote, scientific

1 acceptability, vote, et cetera.

2   CO-CHAIR THRAEN: Okay. Developer,

3 you're on. And this is for 0353, failure to

4 rescue 30-day mortality (risk adjusted).

5   MS. EVEN-SHOSHAN: No comment.

6   (Laughter.)

7   CO-CHAIR THRAEN: All right. Smirz.

8 Who's the lead in this one? Lynda. Go ahead.

9   DR. SMIRZ: That would be me. And I

10 am delighted to see that Richard, Susan, and

11 Charlotte are part of the team here, because I'm

12 the Rodney Dangerfield specialty that gets no

13 respect as an OB/GYN. So, it look me a while to

14 go through this.

15   This is similar to what we had before,

16 except this particular measure is a failure to

17 rescue, 30-day mortality. So, basically what the

18 measure involves is a failure to rescue

19 predicting death after an adverse occurrence but

20 the hospital would have been able to improve the

21 quality of care.

22   The level of analysis was listed as

1   facility, health plan, integrated delivery

2   system, and population. However, according to

3   the measure, they only used facility. It is an

4   outcome measure. It's a patient-reported outcome

5   measure. And, you know, I don't know whether, at

6   this point in time, if the committee wants to

7   discuss that part?

8   CO-CHAIR THRAEN: Would you comment on

9   the importance of this measure?

10   DR. SMIRZ: Well, I think that the

11   measure has a theoretical importance. The

12   developers make note of the fact that knowing a

13   failure to rescue would maybe improve the

14   understanding of a hospital's mortality rate if

15   there is a variation in mortality rate.

16   And they felt that that was important,

17   since the death rate that may appear to be the

18   same one hospital to the other, as far as a

19   mortality rate, may be different if they looked

20   at a failure to rescue, and that we may be better

21   able to understand the variation in those

22   hospital mortality rates as a result of that.

1   CO-CHAIR THRAEN: How did you find the

2   evidence to support the importance?

3   DR. SMIRZ: I, personally, did not

4   feel that the evidence supported the importance

5   of this particular measure. They looked at a

6   number of different -- the developer said that

7   they were looking at various -- let me find this

8   here -- nurse-to-bed ratio, nurse mix, the number

9   of hospital beds, anesthesiologists who were

10   board certified, surgeons who were board

11   certified, the presence of house staff, and high

12   technology as, according to the developer,

13   failure to rescue is influenced by these hospital

14   characteristics. However, as a result of this

15   study, failure rate was a function only of

16   anesthesia board certification and the presence

17   of surgical house staff.

18   CO-CHAIR THRAEN: Dr. Brilli, you had

19   a comment?

20   DR. BRILLI: Just to supplement what

21   Linda's saying, they provided the exact same

22   rationale and the exact same reference list for

1   this Measure as the other one.

2   CO-CHAIR THRAEN: Okay.

3   DR. BRILLI: They really -- the only

4   thing that's different is one is 30 days and one

5   is hospital discharge. But at least as I read

6   them, they looked to be exactly the same

7   justification. We probably have the exact same

8   concerns. At least unless a developer wants to

9   disagree with me on that. But it's the same

10   reference list. It's the same 35 papers.

11   MS. EVEN-SHOSHAN: Hi. That's from

12   CHOP. That's correct. It's the same reference

13   list. I just wanted to mention that one of the

14   advantages of using failure to rescue even more

15   than using death rate is that we found that the

16   contribution of hospital characteristics to the

17   outcome is higher than for the death rate.

18   So we think that this is a very good

19   measure because it is less dependent on the

20   patient characteristics than the death rate. So

21   we found very strong correlations of the failure

22   to rescue, not only with the board certification

1   status of anesthesiologists, but also with

2   teaching status and with the nurse-to-bed ratio

3   and the nurse skill mix in a hospital.

4   DR. PINES: And just to clarify, so for

5   the evidence criteria for a health outcome

6   measure, the question is, is this outcome measure

7   related to one or more actions that providers

8   could potentially take? So it's different for a

9   process measure. So we're -- just want to

10   clarify an outcome measure.

11   CO-CHAIR THRAEN: Lillee?

12   MS. GELINAS: This is Lillee Gelinas.

13   I'm looking at our measure worksheet that we were

14   sent and I just want to clarify under evidence

15   that the developer found that failure to rescue

16   was influenced by hospital characteristics such

17   as nursing skill mix, et cetera, et cetera.

18   So I just want to affirm that what

19   were called hospital characteristics were

20   actually the characteristics of the nursing

21   workforce, including skill mix, percentage of

22   BSN, nurses present, all of those were

1   confounders in the evidence.

2   Again, I'm not going to improvement

3   gap here, but in the evidence, I just want to

4   make sure I'm reading the measure worksheet

5   correctly. I'm on Page 2 if anybody's following

6   me on the measure worksheet.

7   DR. SMIRZ: And I think that's an

8   excellent point, Lillee. Because I'm on Page 1

9   and it says, "In summary, failure rate was a

10 function of anesthesia board certification and

11 the presence of surgical staff, but not a

12 function of admission severity or illness score."

13   It does not mention nurse-to-bed

14 ratio, nurse mix. I thought that was what they

15 were hypothesizing. I didn't know that the

16 evidence showed that. So, maybe I'm reading that

17 incorrectly.

18   MS. GELINAS: So, I'm just on Evidence

19 1A on Page 2 where the -- it's towards the bottom

20 of the evidence piece, don't go to the gap piece.

21   CO-CHAIR THRAEN: Charlotte, then

22 Laura.

1   DR. ALEXANDER: I certainly agree with

2   the nursing staffing evidence that you showed. A

3   question I have, is that many of our hospitals

4   are going towards board certification

5   requirements. I'm wondering how important the

6   references they made toward board certification

7   are going to be as we move forward. I have some

8   other questions a little bit later away from the

9   evidence, I want to wait for that.

10   CO-CHAIR THRAEN: Laura?

11   MS. ARDIZZONE: Hi, Laura Ardizzone.

12   I just wanted to comment on some of their

13   evidence. Number 5, which is their Silber study,

14   anesthesiologist direction, is a highly

15   controversial and actually, in my mind, fatally

16   flawed study in how they compared outcome rates

17   as compared to nurse anesthetists.

18   So, I mean, that's not for a

19   discussion here. But just to kind of clarify

20   that I think some of the evidence that they're

21   using may be off point. I know specifically that

22   one is.

1   On top of the fact they talk about the

2   percentage of board certified anesthesiologists

3   and in 18 states, anesthesiologists are not the

4   only sole providers in 18 states. Nurse

5   anesthetists are sole providers of anesthesia.

6   So I'm just questioning some of the evidence.

7   CO-CHAIR THRAEN: Okay. Missy, you

8   started to have something. No? Okay. Any other

9   comments about the evidence? All right. We'll

10   go to the vote.

11   MS. IBRAGIMOVA: So, importance to

12   measure and report 1A evidence, health outcome or

13   PRO, Measure now supports the relationship of the

14   health outcome or PRO to at least one healthcare

15   structure, process, intervention, or service. 1

16   Yes, 2 No. Just need one more vote. So the

17   results are, 71 percent Yes, 29 percent No.

18   CO-CHAIR THRAEN: Well, we had 24

19   votes. All right. Next one is Performance Gap.

20   Do any of the leads want to talk about the

21   performance gap?

22   DR. SMIRZ: I think with respect to the

1 performance gap, they had a testing sample that

2 was the 65 to 90 year olds for general surgery,

3 but the measure is for 18 to 90 year olds for

4 general, vascular, and orthopedic surgery.

5 I also had a comment or a question

6 about the numerator. There were patients who

7 died with a complication and they also included,

8 as in the previous measure, patients who died

9 without documented complications. So I just have

10 a little concern about including them in the

11 numerator statement.

12 The denominator statement, again, is

13 general surgery, orthopedic and vascular

14 patients, and specific DRGs with complications,

15 plus patients who died in the hospital without

16 any complications. And, once again, exclusions

17 were patients over 90 and patients under the age

18 of 18.

19 CO-CHAIR THRAEN: Any comments by the

20 developer?

21 MS. EVEN-SHOSHAN: Hello. The

22 denominator includes patients who died with a

1   complication -- who died within 30 days with a

2   complication and patients who died without a

3   documented complication also within 30 days from

4   admission. This is the 30 day measure.

5   And the numerator is patients who died

6   with a complication within 30 days from admission

7   plus patients who died without a documented

8   complication within 30 days from admission. So

9   we use this measure usually with the Medicare

10   data, but it can be also used with other claims

11   data.

12   CO-CHAIR THRAEN: So we're getting into

13   the technical definition of the measure. This

14   particular criteria really is looking to see if

15   there's performance gaps. Was there any evidence

16   presented that indicated that there is

17   performance gaps in this measure?

18   MS. GELINAS: No.

19   CO-CHAIR THRAEN: No. Ed?

20   CO-CHAIR SEPTIMUS: I have a question,

21   maybe Lillee can answer this. It seems to me and

22   I was reading through this a week or so ago --

1   this is Ed Septimus by the way. It seems to me

2   that when reading through this, that was the

3   failure to rescue a relationship between nurse

4   training and ratios and, if so, and I'm asking

5   because I'm not sure how to rate this measure, is

6   that covered in other competing measures?

7   Really may be the best -- or other

8   nurses here might want to comment on that, but

9   I'm just having a problem differentiating this --

10   okay, so one's a structure and one's an outcome?

11   Okay. No, I know you do. Okay. I'm just trying

12   to understand that. Because obviously these two

13   are -- they're related. But I understand this is

14   an outcome measure. Okay.

15   CO-CHAIR THRAEN: Pat?

16   DR. QUIGLEY: Thank you. Pat Quigley.

17   I'd like to try and respond to that. In terms of

18   a performance gap, how it would drive practice to

19   improve the outcome, is that there is consistent

20   evidence from the NDNQI research that if you

21   increase the BSN prepared nurses, the patient

22   safety improves and the adverse events go down.

1   So there is that.

2   That could be associated with death as

3   well, I don't -- I'm not as literate on that.

4   But there is consistent evidence that if we -- in

5   dealing with skill mix, care delivery of the

6   nursing staff, that patient outcomes are

7   absolutely affected by nurse staffing and

8   education. That is a component of the skill mix.

9   So in that regard, there is consistent

10   evidence from NDNQI over the years that if you

11   increase the BSN prepared proportion of RNs, that

12   there is improved patient safety and reduced

13   adverse events.

14   CO-CHAIR THRAEN: Lillee, did you have

15   --

16   MS. GELINAS: I was just going to say

17   something very similar -- maybe too many

18   microphones on? That in order to improve the

19   outcome, what we do is a CAT scan of the

20   workforce first. In other words, when we're

21   looking at failure to rescue rates, we do look at

22   the skill mix, nursing hours per patient day, in

1   other words, time at the bedside, type of thing.

2   So I can see how this as an outcome

3   Measure was influenced by the characteristics of

4   the workforce that was in place at the time. So

5   the structural measure of the composition of the

6   workforce impacting the outcomes Measure of

7   failure to rescue rates.

8   CO-CHAIR THRAEN: Okay. Steve?

9   DR. LAWLESS: Yes, Steve Lawless. For

10   the developer, in looking at your 35 references,

11   where you mention a lot of the skill mix and

12   outcomes and various factors or covariates, but

13   your conclusion is down to two, anesthesia

14   presence and surgical house staff.

15   What reconciles the evidence, the

16   evidence that implies lots of other factors, but

17   then your analysis in the end says, but of all

18   the ones we've published, these are the only two

19   that really make a difference.

20   MS. EVEN-SHOSHAN: I actually want to

21   apologize, that was a mistake. We should have

22   listed all the hospital characteristics that

1   appear in the regression. And I would like to

2   take the opportunity to list them now and to make

3   a correction during the next two weeks.

4   So we take the -- what we have

5   measured as contributing to better failure to

6   rescue rates are the nursing skill mix, nurse-to-

7   bed ratio, resident-to-bed ratio, and the

8   technology level of the hospital as we look at

9   different, for example, we look at the

10   availability of CAT scans, availability of organ

11   transfer centers, and things like that. So, it's

12   not just the board certification of

13   anesthesiologists, it's all the other hospital

14   characteristics that I've just mentioned.

15   MS. ARDIZZONE: I just think it's

16   really hard for us to vote when we have a poor

17   connection to hear what she's saying. I can't

18   visually see it and I haven't had an opportunity

19   to review it.

20   MS. EVEN-SHOSHAN: We can send that

21   list of hospital characteristics that's complete

22   and includes not just the anesthesiologists board

1   certification status.

2   CO-CHAIR THRAEN: So Yanling and then

3   we have a proposal. Go ahead.

4   DR. YU: Yanling Yu. I'm new, so I'm

5   learning about all the terminology. But to me,

6   the gap to identify a measure gap is what's

7   missing in a quality measure. That's the gap,

8   what I interpret. But in term of what cause that

9   gap, that's multi-factors. That's a different

10   issue from my perspective of how to identify the

11   gaps. If I understand that correctly.

12   CO-CHAIR THRAEN: So I guess the

13   question is, do you want to proceed on this or do

14   you want to table this measure, number one? If

15   you table this measure, what are the implications

16   of the previous Measure since the previous

17   Measure is based on all the same information? So

18   what are your thoughts? Or do you want to

19   proceed forward? Steve?

20   DR. LAWLESS: I would like to, and I

21   don't know if it would take a motion or not, that

22   I think developers need to go back and clarify a

1 lot of things. Because I don't feel comfortable

2 agreeing to something and it's changing a little

3 bit and we forgot to add this. This is a pretty

4 serious, high level meeting.

5 So I would actually ask that maybe we

6 vote on the developers going back and clarifying

7 and maybe rewriting some of this so we don't have

8 the same questions. Because I don't feel

9 comfortable with a moving target.

10 CO-CHAIR THRAEN: On this only or both

11 measures?

12 DR. LAWLESS: I would say both.

13 CO-CHAIR THRAEN: Missy?

14 MS. DANFORTH: Yes. I would just ask

15 for two things. One is, after the developer's

16 last comment about the sort of finite list of

17 things that they identified as really being

18 impactful to the measure, like availability of

19 anesthesia, high tech, all of those things, if

20 they could clarify then the pretty sophisticated

21 risk-adjusted model that has 160 different

22 characteristics, so the rationale for having a

1   risk-adjustment model that has 160

2   characteristics given that it's things like the

3   availability of a CAT scan and an

4   anesthesiologist.

5   And then also if they could please

6   provide some more detail on how this is

7   calculated? They're saying that it uses

8   administrative data, but it also does seem to

9   have some patient level characteristics in the

10   risk adjustment.

11   So I'm trying to understand, is there

12   software that's been developed? How is the

13   measure actually calculated? So, like, what is

14   the math behind that? Particularly, the risk

15   adjustment piece would be extremely helpful.

16   CO-CHAIR THRAEN: Okay. Any other

17   comments to the developer before we take a vote

18   on Steve's recommendation? Charlotte and then

19   Michelle.

20   DR. ALEXANDER: There are a couple

21   things I would like clarification on. One is

22   that, often nurse staffing is variable during a

1　　patient's stay and you may not have exactly the

2　　same skill mix every time during the day, nor

3　　every day. And where is the count being taken?

4　　If they can clarify that.

5　　　　　　　　And the other is, they mention at one

6　　point gathering unlinked data so that it was

7　　patient demographic data that was unlinked. And

8　　I'm wondering how they're doing that as well.

9　　　　　　　　CO-CHAIR THRAEN: Okay. Michelle?

10　　　　　　　　DR. SCHREIBER: Thank you. A couple of

11　　other questions for the developers as you're

12　　looking to redo this. One is the collection of

13　　30 day mortality. That's not something that

14　　hospitals normally have. So is the expectation

15　　like NSQIP that you actually call all these

16　　patients and see where they are 30 days out?

17　　　　　　　　And then how you actually know that

18　　the complication that may have occurred in the

19　　hospital related to their death 30 days out? If

20　　you could clarify that as well.

21　　　　　　　　CO-CHAIR THRAEN: Any other questions

22　　to the developer? So let me repeat, the proposal

1   is that we table this measure and the measure we

2   already voted on, so that would be measures 0352

3   and 0353, asking the developer to provide more

4   detailed information and to clarify based on the

5   questions that we've provided them.

6   All those in favor, just raise your

7   hand. Any opposed? One. Okay.

8   Thank you to the developer. I believe

9   the staff is taking copious notes, so they'll be

10   able to provide you some specific feedback in

11   terms of -- documentation in terms of what we're

12   looking for in the future.

13   All right. Guess what? We're back on

14   time. Next one is 0538, which is Pressure Ulcer

15   Prevention and Care. CMS is the developer. Is

16   CMS here?

17   MS. RICHARD: Yes. This is Angela

18   Richard from University of Colorado.

19   CO-CHAIR THRAEN: All right. One on

20   the phone and we also have one present. Would

21   you like to introduce yourself?

22   DR. NUCCIO: Go ahead, Angela.

1   CO-CHAIR THRAEN: Go ahead.

2   MS. RICHARD: Yes. Do you want me to

3   introduce the measure or just myself?

4   CO-CHAIR THRAEN: Hold on, we're

5   introducing --

6   MS. RICHARD: Okay.

7   CO-CHAIR THRAEN: -- the people first.

8   Go ahead.

9   MS. RICHARD: Okay. I'm Angela Richard

10   from the University of Colorado. I'm one of the

11   measure developers.

12   DR. NUCCIO: And this is Eugene Nuccio

13   from University of Colorado. I'm one of the

14   analysts.

15   DR. MCMULLEN: Hi. It's Tara McMullen

16   from CMS. I am an analyst in the Division of

17   Chronic and Post-Acute Care. Thank you.

18   CO-CHAIR THRAEN: So would you like to

19   present on your measure?

20   MS. RICHARD: Sure. So this measure is

21   titled Pressure Ulcer Prevention and Care. It

22   has been endorsed since 2009 and we're up for re-

1   endorsement.

2   So the introduction is, while pressure

3   ulcers are relatively uncommon in home

4   healthcare, evidence shows that they have

5   significant negative impact on quality of life

6   and can be predictive of other negative outcomes.

7   They're generally thought of as preventable given

8   adequate clinical assessment of risk and

9   implementation of preventative strategies

10   As a result, pressure ulcer prevention

11   is the topic of measures that cross care

12   settings, particularly post-acute care setting.

13   This measure is intended to provide home health

14   agencies and consumers with information that will

15   enable them to monitor their quality of care

16   processes for patients, identifying risk of

17   pressure ulcers, and then also clinical

18   assessment and interventions to prevent the

19   development of pressure ulcers.

20   In addition, home health agencies are

21   -- by virtue of requiring measurements, home

22   health agencies have the incentive to encourage

1 care providers to actually go through the

2 processes of conducting a risk assessment,

3 including pressure ulcer prevention in a plan of

4 care and implementing prevention. Which could

5 have a long-term impact of reducing pressure

6 ulcers in the home healthcare patient population.

7   This measure consists of three rates,

8 each corresponding to a part of the care process,

9 assessment, a second measure for care planning,

10 and a third for intervention. We originally had

11 these separated out, but they are included in

12 this one measure at NQF's recommendation.

13   All the data for the measure are

14 collected through the OASIS at start or

15 resumption of care following the in-patient

16 facility stay and at home healthcare discharge.

17 It's currently used for public reporting and in

18 the CMS Home Health Quality Initiative, which is

19 a quality improvement reporting effort with

20 benchmarking.

21   And then the definitions of the three

22 measures are, pressure ulcer risk assessment

1   conducted is a percentage of home health episodes

2   of care in which the patient was assessed for

3   risk of developing pressure ulcers. Pressure

4   ulcer prevention included in plan of care is the

5   percentage of home health episodes of care in

6   which the physician order plan of care included

7   interventions to prevent pressure ulcers.

8   And then the third is pressure ulcer

9   prevention implemented, the percentage of home

10   health episodes of care during which intervention

11   to prevent pressure ulcers were included in the

12   physician ordered plan of care and implemented.

13   CO-CHAIR THRAEN: Thank you.

14   MS. RICHARD: That's sort of my

15   introduction. Do I need to say anything else?

16   I'm --

17   CO-CHAIR THRAEN: No.

18   MS. RICHARD: -- sorry. I'm new at

19   this.

20   CO-CHAIR THRAEN: No, that's fine. So

21   we'll go to the lead discussants. Who's the lead

22   here? Is that you, Lisa? Go ahead.

1   MS. MCGIFFERT: Okay. This is all new

2   to me. Obviously, most of the introduction has

3   been given here. And I think this is obviously

4   an important area to try to have measures on.

5   This one particularly is a process

6   measure that has been published for a number of

7   years. And from what I can see is pretty much

8   topped out, like most of the performances are

9   above 90 percent. So it doesn't give a whole lot

10   of variation among the providers.

11   It's a process, so some of it is a

12   little bit of check the box, we did this

13   assessment. And there is a component that

14   certain preventions were implemented, but it

15   doesn't really indicate what preventions were

16   implemented or whether they were the appropriate

17   preventions that were implemented.

18   And so, I think it's a very important

19   -- it's something everybody should be doing, but

20   I'm not sure that this measure is really giving

21   us a whole lot of information about quality. So,

22   when I looked at the evidence, there was some

1   evidence cited, there was a Cochrane Review that

2   concluded that there was no evidence for

3   structural assessment being superior to clinical

4   judgment.

5   And the structural assessment is the

6   first step in this. And so it did seem to me

7   that, that review showed that there was not a lot

8   of evidence that it led to reduced pressure

9   ulcers. Also, the other evidence is clinical

10 practice guidelines and all of the evidence got a

11 C rating, which means it's supported by indirect

12 evidence or expert opinion.

13   So there were lots of studies, there

14 were some studies cited including randomized

15 controlled trials, but I think those were

16 included in the Cochrane Review. Let's see. I

17 go through the -- should I just keep going or

18 stop?

19   CO-CHAIR THRAEN: So, no. So hold on

20 there.

21   MS. MCGIFFERT: Okay.

22   CO-CHAIR THRAEN: Missy and Charlotte,

1   you have your cards up? No. Charlotte? No. So

2   in terms of the evidence, how would you sum the

3   evidence at this point?

4   MS. MCGIFFERT: I would say the

5   evidence is pretty low --

6   CO-CHAIR THRAEN: Okay.

7   MS. MCGIFFERT: -- that it actually

8   leads to reduction of pressure ulcers, we just

9   don't have it.

10   CO-CHAIR THRAEN: Okay. Was there any

11   -- go ahead Ed.

12   CO-CHAIR SEPTIMUS: At least in what I

13   read, I mean, Lisa's absolutely right. I mean,

14   if you're looking at prevention, okay, there

15   doesn't appear to be any evidence. But there is

16   evidence in terms of interventions once a

17   pressure ulcer develops. So the question on this

18   measure is -- it says prevention and care. Tell

19   me if I'm reading this correctly --

20   MS. MCGIFFERT: I cannot hear you very

21   well, Ed. You're saying there is an intervention

22   component --

1   CO-CHAIR SEPTIMUS: There is an

2   intervention -- the intervention as a --

3   MS. MCGIFFERT: There is an

4   intervention component.

5   CO-CHAIR SEPTIMUS: -- the prevention

6   does not. And that's why I'm asking you for

7   clarification.

8   DR. PINES: So there is -- this is one

9   measure with three rates. And there is different

10   evidence for each of those separate process

11   measures. So it may be useful to go maybe one by

12   one through the evidence discussion for each of

13   the measures. So there is more evidence for --

14   so the plan of care is not about once someone has

15   a pressure ulcer treating it, it's a prevention

16   plan for a patient who is found to be at risk.

17   CO-CHAIR THRAEN: So there was a risk

18   assessment, a plan of care proposal, and then

19   implementation component to this category of

20   measures. The developer indicated that they were

21   advised to put those together in one. So, Pat

22   and then Victoria and then Leslie. And then

1 Chris.

2   DR. QUIGLEY: Thank you. My question

3 is related to actually indicating that this was

4 done. Because this is a requirement of CMS and

5 it's required in the OASIS database. And it is

6 simply a yes or no, is that not correct? Yes or

7 no there was an assessment. Yes or no there was

8 a plan of care. Yes or no. So yes or no is not

9 quality.

10   MS. RICHARD: Correct.

11   DR. QUIGLEY: Yes or no is a binomial

12 response, was it done or not. So I think that

13 becomes the question, even in terms of the

14 evidence. The evidence is not going to support

15 effectiveness.

16   This is essentially a binomial

17 response was it done or not. So when you're

18 looking at the strength of evidence this is going

19 to be an issue when you're looking in terms of

20 implementation and effectiveness.

21   DR. RICH: I was going to concur with

22 Pat. Also though is that the idea that this is a

1   process measure. And very, very important in

2   care to have a yes or no with this particular --

3   I understand what you're saying about the

4   evidence, but there's also on, I think it's on

5   page here, is talking about what's really

6   impacted me.

7   It says that from the TEP, that the

8   majority of the TEMP members rated the measure as

9   partially or completely meeting the criteria for

10   importance. And that impacted my opinion.

11   CO-CHAIR THRAEN: Leslie?

12   DR. SCHULTZ: Leslie Schultz. I'm

13   sorry, I'm going to tend to disagree and agree

14   with Lisa there. So there's not a lot of empiric

15   support that this really does matter. The

16   binomial issue, yes/no, you can check it off.

17   It's reliable, but that's in the simplicity of

18   it's a check off. And I do think that we

19   possibly might be asking the measure steward to

20   look at outcomes.

21   CO-CHAIR THRAEN: Chris and then we'll

22   come back to the developer.

1   DR. COOK: Yes, this is Chris Cook.

2   And I hear all the things that we're talking

3   about, but I come back to one of the general

4   principles that not all things that matter can be

5   measured. And this falls into one of those

6   categories. Because you can absolutely find out

7   whether something has been done in that binomial

8   yes or no, but you can never assess whether the

9   quality of that assessment actually occurs.

10   When we're look at the maturation of

11   measures across an area, I think that, that is

12   some of our very preliminary things that we have

13   to do. Are you actually doing these processes

14   that are needed to move there?

15   What we see within the evidence, and

16   I'm skipping ahead a little bit on this, is the

17   fact that this is now being done. We have

18   changed the behavior of practitioners to now look

19   and assess. So I think that this may be -- the

20   problem on the measure is not whether or not they

21   should be doing it and what's there.

22   I think that we may need to be moving

1 more towards an outcome type of measure that says

2 what are the outcomes of preventing pressure

3 ulcers, which is a very important issue. And

4 that this measure has served its time and has now

5 basically become topped out just on the yes/no

6 binomial.

7 DR. PINES: Just as a point of

8 clarification. So to distinguish the discussion

9 on evidence versus the scientific acceptability

10 or validity, so the question of evidence for a

11 process measure is for each of the subcomponents

12 is this action associated with some sort of

13 health outcome?

14 And what we've seen is there is

15 variable evidence for each of the subcomponents.

16 And then, I think what Pat was bringing up is the

17 validity, is whether the check box was done was

18 that associated with that action actually

19 happening?

20 CO-CHAIR THRAEN: Developer?

21 MS. RICHARD: Thank you. These are

22 excellent comments. I think clearly by virtue of

1   implementing this measure we have seen more and

2   more compliance in terms of the agencies

3   reporting that they're doing this. And in fact,

4   what we're seeing is a lot are actually putting

5   Braden Scales and putting things into their

6   forms. So I think we do feel like quality has

7   improved by virtue of measuring these processes.

8   In terms of outcomes, we actually do

9   report an adverse event outcome back to home

10   health care agencies, or CMS does that, on

11   worsening of pressure ulcers. So there is

12   currently an outcome measure that's not endorsed

13   by NQF that does get reported to the agencies.

14   I would also like to point out that as

15   a result of the IMPACT Act, there is considerable

16   work going on to develop an outcome measure for

17   pressure ulcer development that crosses provider

18   settings. And that we are also contributing to

19   that discussion.

20   So there is currently an outcome

21   measure, it's just not endorsed. And then, will

22   be an outcome measure that will be crossing

1   provider settings as directed by the IMPACT Act.

2   DR. NUCCIO: Just to provide a little

3   context about the prevalence of pressure ulcers

4   in home health agencies, only about five percent

5   of healthcare episodes in home health agencies

6   have any pressure ulcer related events. And so

7   the rate is only about five percent nationally

8   for pressure ulcers. Of the more serious

9   pressure ulcers, Stages 3 and 4, those rates are

10   approximately 1.5 percent nationally.

11   The outcome measure that, which was

12   basically an adverse event, that Angela was

13   speaking to where we have an increase in pressure

14   ulcers during the home health stay, that rate is

15   four tenths of one percent. So the prevalence of

16   this condition is extremely low in home health

17   environments.

18   CO-CHAIR THRAEN: Thank you. Pat and

19   then Yanling. No? Yanling? And then the

20   developer.

21   DR. YU: Yes, I have a question for

22   developer. Since this measure has been initially

1   endorsed in 2009 and then most recent endorsement

2   in 2012, I just wonder there's any statistic or

3   data that shows how many compliance with this

4   type of a process measure, yes/no, those binomial

5   some type of thing? Do you have some type of

6   numbers you can show us?

7   DR. MCMULLEN: Yes. This is Tara

8   McMullen from CMS. We do have compliance

9   numbers. Agencies need to report this data. So

10   they are submitting data, compliance on the data.

11   We can provide that to an extent of the

12   percentages of what's being reported to CMS.

13   Beyond that, in terms of payment or

14   survey and certification, we're not able to share

15   that data. But we can tell you the percentage

16   that -- assessments that are being submitted to

17   CMS monthly or quarterly or yearly. We do have

18   those.

19   CO-CHAIR THRAEN: Can you --

20   DR. MCMULLEN: If that's what you mean

21   in terms of compliance.

22   CO-CHAIR THRAEN: Can you also

1   demonstrate the incidence of the condition, the

2   outcome, the trend analysis of that along with

3   the change in compliance?

4   DR. NUCCIO: Yes. I have data from

5   calendar years 2011, 2012, and 2013, separated by

6   calendar year. These are episodes of care that

7   end in those calendar years. They may cross over

8   a calendar year time period. So, for example, a

9   2012 episode of care may have started in 2011.

10   CO-CHAIR THRAEN: Yes.

11   DR. NUCCIO: Just that caveat.

12   CO-CHAIR THRAEN: I do --

13   DR. NUCCIO: But for assessment, the

14   percentage has increased from 97 percent in 2011

15   to 98.5 in 2013. For plan of care, it's gone

16   from 94 percent to 97.3 percent in 2013. In

17   terms of moist/wet healing, we've gone from 80

18   percent in 2011 to 86 percent in 2013.

19   In 2011 in terms of implementation of

20   moist/wet, we've gone from 76 percent to 81

21   percent in 2013. In terms of implementation

22   during that period, again in 2011 we're talking

1   93 percent, up to 96.4 percent in 2013.

2   So in terms of compliance and

3   attention to delivering these assessments and

4   implementing the care that would be appropriate,

5   the trends have all been positive in their

6   direction.

7   CO-CHAIR THRAEN: And the trends in the

8   outcome? The actual pressure ulcer outcome at

9   the same time?

10   DR. NUCCIO: The trends in -- for

11   example, that more pressure ulcer have decreased

12   slightly. Again, we're dealing with very, very

13   small numbers. So in 2011, the rate was 0.47 and

14   in 2013, the rate was 0.44.

15   CO-CHAIR THRAEN: Did you have a

16   comment?

17   DR. MCMULLEN: Thank you. It's Tara

18   McMullen from CMS. I did want to draw back many

19   comments ago to Pat, that this is more -- we

20   collect this data to benchmark. I know everyone

21   is very interested in outcomes. We are as well.

22   The IMPACT Act was brought up. This

1   is not an IMPACT Act quality measure. The IMPACT

2   Act quality measure through the domain looking at

3   skin integrity will assess pressure ulcers, new

4   and worsened. So we are working toward that

5   ideal state of being able to collect on care

6   trends, what's really going on in a specific

7   facility setting or care setting, home setting,

8   and working towards those outcomes.

9   At this point, this is what we have in

10   terms of benchmarking. We collect this data not

11   only to improve quality measurement, but to be

12   able to report to providers, multiple levels of

13   reporting providers, beneficiaries, really what's

14   going on at a specific time, that snapshot.

15   So I did want to address the outcome

16   measure topic and let you know that we are very

17   aware of that and we are working toward that

18   ideal state for every PAC setting.

19   CO-CHAIR THRAEN: Chris and then Pat.

20   DR. COOK: Yes. This is Chris Cook

21   again. I guess one of my questions is, if we re-

22   endorse this measure, is this something that CMS

1   actually wants or, according to what CMS policy

2   typically is within its pieces, is that if you

3   have between the 75th and 90th percentile no

4   significant difference, then basically consider

5   it topped out measure and it gets retired?

6   And at this, what was reported is at

7   the 50th percentile, agencies reported 99 percent

8   for the risk assessment and plan of care and

9   98.58 percent for the prevention implemented.

10   Which to me, just guessing, that if that's at the

11   50th percentile, then you're not going to see a

12   significant difference between the 75th and 90th

13   coming back to your policy.

14   DR. MCMULLEN: Right. So Tara McMullen

15   again. We run through a rigorous process of

16   evaluating and analyzing in every PAC setting

17   really the performance of our quality measures.

18   If we see an item within an assessment instrument

19   or a measure which houses our items are topped

20   out, we do move to sunset those types of measures

21   or revise the measures basically to show

22   variation in an outcome.

1   I can tell you, because of multiple

2   mandates that have occurred in the last year that

3   affect post-acute care, we're moving in a way

4   where they're going to change. Lots of

5   assessment tool testing, instrument, OASIS, MDS,

6   so on and so forth. Lots of quality measure

7   testing. A lot of data element testing.

8   So I think the best policy for CMS is

9   to continue to analyze that. If we see that

10   something's not working and we hear from our

11   stakeholders and we hear from NQF that it's not

12   working, we take that into consideration. Your

13   opinion holds weight. And that's pretty much the

14   best response I could give you.

15   DR. COOK: So then by that, you do want

16   this to continue on and then if you all find that

17   it tops out, then you're perfectly fine to retire

18   it on your own?

19   DR. MCMULLEN: We do want it to

20   continue on, which is why we brought it to NQF

21   today. But, like I said, we're working toward

22   the ideal state of having outcomes measures. In

1   fact, Congress pushed the hand on that through

2   the IMPACT Act. So you will see the emergence or

3   the advent of other variations of pressure ulcer

4   or skin integrity quality measures --

5   DR. COOK: Thank you.

6   DR. MCMULLEN: -- inevitably.

7   DR. BURSTIN: I think part of what

8   Chris is asking though is whether since it is

9   already topped out based on, certainly, I think

10   when we bid on gap, it could be a potential for

11   reserve status. Which I think he was trying to

12   get your sense of whether that's something --

13   CO-CHAIR THRAEN: So Yanling, Pat, and

14   then Steve. And then we're going to call for

15   vote.

16   DR. YU: Just a quick, maybe a dumb

17   question. Can CMS continue to collect this data

18   without this approval of this measure?

19   DR. MCMULLEN: Yes.

20   DR. YU: Okay.

21   CO-CHAIR SEPTIMUS: CMS can do whatever

22   it wants.

1   DR. MCMULLEN: Yes, they can.

2   DR. YU: Okay.

3   DR. MCMULLEN: Right. But I can tell

4   you ask the lead analyst in Division of Chronic

5   and Post-Acute Care, what you say, again, like

6   Chris, it holds weight. If we go back and we

7   hear NQF, we go back, our leadership will

8   reanalyze and evaluate whether we should be

9   collecting on this measure or not. It's not a

10   blanket CMS can do what they want. It doesn't

11   work like that. There is a process.

12   CO-CHAIR THRAEN: They theoretically

13   can, but will they is another question. That's a

14   political will question. Pat?

15   DR. QUIGLEY: Thank you for your

16   comments. Pat Quigley. And I, as a nurse's

17   nurse, thank you for collecting this because you

18   have validated the role of nursing. It's

19   registered nurses who go in and do the

20   assessment, start the care planning. So I thank

21   you to show that there is this level.

22   But with the electronic documentation

1   OASIS, there's much more ability to be able to

2   show is it being done or not. However, this

3   measure, just like your falls measure in home

4   care, the falls measure has components of the

5   care plan, what gets assessed. It's not just yes

6   or no for each element. And that's the

7   difference when you move into quality.

8   So to continue to advance it I think

9   is really important in terms of measurement, not

10   just to measure yes or no. Because in the

11   Patient Safety Complications Steering Committee,

12   which I had an opportunity to be on before, we

13   decided not to continue to endorse just yes or no

14   responses, binomial responses. Because it's not

15   an indicator of quality in patient safety.

16   But thank you so much for doing this.

17   And I would also just like to say that there are

18   patients who are excluded in home care from this

19   based on your criteria. And the people who are

20   excluded are the people who are not in Medicaid

21   or Medicare. And the people who don't require

22   skilled nursing care.

1   So I just want to say to everybody

2   that there is exclusion criteria to making sure

3   people read this. But I thank you for measuring

4   the value of nursing. What nurses actually -- so

5   thank you.

6   CO-CHAIR THRAEN: Steve?

7   DR. LAWLESS: Yes. Steve Lawless. I

8   have question. I looked up the IMPACT Act and

9   one of the domains is about skin integrity. But

10   then you said it's not part of the IMPACT Care

11   Act Measure. What would be?

12   So my question would be, so you said

13   -- Medicare can do what they want, they can agree

14   or wait. But if you have no alternative -- if

15   you're required to do this by IMPACT Act, or it

16   looks like or something, until there's an

17   alternative, why endorse it when you're going to

18   be doing it anyway?

19   DR. MCMULLEN: Yes. Steve, this is not

20   an IMPACT Act Measure. This is an OASIS based

21   quality measure for the Home Health Quality

22   Reporting Program, for home health agencies. So

1 as we do have the IMPACT Act and it does contain

2 a domain of skin integrity, that's a different

3 topic, different quality measure.

4 DR. LAWLESS: Thank you.

5 CO-CHAIR THRAEN: All right. We're

6 stopping the conversation at this point. Jesse

7 has advised me to ask for the vote on the

8 performance gap. And if you determine that there

9 is no performance gap, that the measure can then

10 put into reserve status. Now, what that means,

11 I'm not sure. Go ahead.

12 DR. PINES: Again, we would have to

13 vote about putting it on reserve status.

14 CO-CHAIR THRAEN: Oh, and then you'd

15 have to vote about putting it on reserve status.

16 DR. PINES: We might want to tell

17 people what that means.

18 DR. BURSTIN: So reserve status is

19 essentially an endorsement status that we have

20 created for measures that are otherwise

21 excellent, high evidence, reliability, valid, all

22 the rest of it, but topped out.

1   And so the idea would be that perhaps

2   those should enter a realm of periodic

3   surveillance as opposed to being sort of front

4   and center, always measured. So they are still

5   endorsed, but with this special status.

6   CO-CHAIR THRAEN: Okay. So we're going

7   to vote on the performance gap. Laura?

8   MS. IBRAGIMOVA: So importance to

9   measure and report 1B performance gap, data

10   demonstrated considerable variation or overall

11   less than optimal performance across providers

12   and/or population groups, disparities in care. 1

13   High, 2 Moderate, 3 Low, 4 Insufficient.

14   MS. THEBERGE: Kimberly, we need your

15   vote. If you're still there.

16   MS. IBRAGIMOVA: So the results are, 0

17   percent High, 9 percent Moderate, 87 percent Low,

18   4 percent Insufficient.

19   CO-CHAIR THRAEN: And so now you're

20   going to do the question on reserve status. We

21   have to find it.

22   CO-CHAIR SEPTIMUS: We have to have a

1   motion for that.

2   DR. COOK: I make a motion that we put

3   it into reserve status.

4   CO-CHAIR THRAEN: Chris. Pat seconds

5   it.

6   MS. IBRAGIMOVA: So endorsement

7   maintenance potential for reserve status, if a

8   measure is under endorsement maintenance review

9   and did not meet importance to measure and report

10   only due to lack of performance gap 1B, does it

11   meet criteria to consider for potential reserve

12   status?

13   High performance is likely due to

14   actual improvement versus issue with measure

15   construction, strong direct evidence proximal to

16   desired outcome, high ratings for reliability and

17   validity, possibly moderate, demonstrated use,

18   and demonstrated improvement. 1 Yes, 2 No. The

19   results are 92 percent Yes, 8 percent No.

20   CO-CHAIR THRAEN: Are we good? We

21   skipped a step. Go ahead.

22   DR. BURSTIN: It's fine. I mean,

1 technically, as you can see here, you're supposed

2 to have agreed that you believe to other -- the

3 sub-things you just looked at are correct. That

4 the evidence is strong. I don't want to spend a

5 lot of time voting on this when you've got a lot

6 of other work to do. So maybe we could figure

7 out a way to do that offline.

8   But --

9   CO-CHAIR THRAEN: Okay.

10   DR. BURSTIN: -- clearly people want it

11 in reserve status. I don't think it's worth

12 belaboring each of the individual ratings at this

13 point.

14   CO-CHAIR THRAEN: All right. The next

15 one is 0679, Percent of High Risk Residents with

16 Pressure Ulcers in Long Stay. And that's also

17 CMS. Does the developer have a -- they're

18 coming. So Laura and Terry, would you like to

19 introduce yourselves?

20   MS. SMITH: Hi, my name is Laura Smith.

21 I'm from RTI International. I'm here with my

22 colleague, also from RTI, Dr. Terry Eng. And

1 we're joined by Dr. Tara McMullen, from CMS. And

2 Terry's going to do the introduction to this

3 measure.

4   DR. ENG: This measure reports the

5 percentage of long-stay residents in a nursing

6 facility who are at high risk for one or more

7 Stage 2 through 4 pressure ulcer or unstageable

8 pressure ulcers. Patients who are comatose, have

9 impaired bed mobility or transfer, or who suffer

10 from malnutrition are concerned high risk.

11   The data source for this measure is

12 the Minimum Data Set 3.0, which is mandatory for

13 all Medicare/Medicaid certified nursing

14 facilities. We want to note, this is not the

15 measure being proposed in the SNF rule for the

16 IMPACT Act.

17   The long-stay measure addresses the

18 CMS quality strategy priority patient safety as

19 pressure ulcers are serious medical conditions

20 and one of the most important measures of the

21 quality of clinical care in nursing homes.

22 Nursing facility residents are at risk for

1 developing new pressure ulcers that result from

2 prolonged periods of uninterrupted pressure on

3 the skin, soft tissue, muscle, and bone.

4 We tested this measure using data from

5 all eligible long-stay residents in all

6 Medicare/Medicaid certified nursing homes

7 nationwide, as well as previously published

8 studies. The mean facility score for this

9 measure was 6.1 percent and the median facility

10 level score was 5.4 percent in Quarter 3, 2014.

11 These figures show a downward trend in

12 continued quality improvement from the previous

13 three years, where the mean facility score was

14 7.4 percent and the median facility level as 6.7

15 percent. Critical data elements show a high

16 level of reliability and validity with kappas

17 above 0.94 when comparing ratings between pairs

18 of gold standard nurses and between facility and

19 gold standard nurses.

20 We tested the stability of this

21 measure by analyzing the quality measure score

22 change between two quarters. Overall, the scores

1   are stable from quarter to quarter. Quality

2   measure scores improved or declined by no more

3   than one standard deviation between one quarter

4   and the next. The majority of facilities

5   reporting changes in their absolute scores from

6   quarter to quarter were within one standard

7   deviation.

8   The signal-to-noise ratio suggests

9   that only eight percent of the variance for this

10   measure is explained by facility characteristics.

11   About one-third of facilities with scores for

12   this measure significantly differ from the

13   national mean over a single quarter, showing that

14   this measure is reliable in separating facility

15   characteristics from the national mean.

16   Validity testing at the quality

17   measure level indicates convergent validity

18   between this measure and the percent of resident

19   with short-stay pressure ulcers that are new or

20   worsen, which capture similar care processes.

21   In addition, a nonparametric

22   correlational analysis was performed to see if

1   facility scores for this measure were related to

2   facility five-star ratings from Nursing Home

3   Compare. Results showed a strong, significant

4   negative correlation with five-star ratings, as

5   expected.

6   Missing data do not present a threat

7   to validity of this measure as they account for

8   less than one tenth of one percent of the long-

9   stay population. Excluding low-risk residents

10   from the denominator is a risk adjustment

11   strategy. This measure was originally the high-

12   risk measure in a set of stratified measures that

13   reported on resident at high and low risk for

14   pressure ulcers.

15   Additional, risk adjustment analysis

16   was conducted identifying additional risk factors

17   for pressure ulcers, such as cognitive status,

18   but it did not result in a model with sufficient

19   predictive power to justify applying further risk

20   adjustment via the model. C-Statistics for the

21   models tested were consistently low. Applying a

22   weak risk adjustment model could introduce random

1 errors into the predicted Stage 2 through 4 and

2 unstageable pressure ulcer rates and, thus, risk-

3 adjusted scores.

4   Public reporting of this measure via

5 Nursing Home Compare provides valuable

6 information to patients and their families about

7 quality of care in nursing home facilities and

8 provides an incentive for facilities to focus on

9 improving and maintaining preventative care.

10   CO-CHAIR THRAEN: Excellent. Thank

11 you. All right. Would the lead -- who's going

12 to do the lead for this group? Okay, Theresa?

13   MS. EDELSTEIN: Okay. So bear with me,

14 I'm a rookie. So I'm not going to repeat

15 everything that the measure developer just said.

16 I just wanted to raise a couple of questions, if

17 that's okay.

18   CO-CHAIR SEPTIMUS: Please, those of

19 you who are new to this process, don't apologize.

20 You've already added significantly to the

21 conversation just by having new outside

22 perspectives.

1   MS. EDELSTEIN: Okay. So if it's okay

2   with you, I would just like to raise a couple of

3   questions rather than go over the same material.

4   Okay.

5   So my first question has to do with

6   the MDS focused surveys that CMS has now mandated

7   in every state.

8   CMS conducted a pilot, I think it was

9   in three states, 25 facilities, several months

10 ago. Issued a report. They found inaccuracies

11 in MDS coding and one of the areas of the MDS

12 where there were inaccuracies reported was the

13 skin section. Which is where this measure comes

14 from.

15   So my question is, now that you've

16 decided to implement MDS focused surveys

17 nationally, do you anticipate that your findings

18 could affect the accuracy of this measure on a

19 going forward basis? I guess my question goes to

20 whether long-term care nurses can be reliable

21 assessors of stage of pressure ulcer at the

22 bedside.

1   DR. MCMULLEN: This is Tara McMullen

2   from CMS. So the surveys were housed by our

3   Survey and Certification Group. So it's a

4   separate group from us. So I'm reluctant to talk

5   to the survey development and what they found.

6   But I can tell you, through the

7   findings that our colleagues in CMS, through the

8   data collection, things that they find, coding

9   issues that come up, White House mandates, we

10   take that seriously. We provide training for

11   providers to help back-end the coding of the MDS.

12   We look at the reliability, the validity. We

13   look at the construct validity of the MDS. We

14   are constantly testing it.

15   Do I think that the surveys will help

16   with the outcomes of this quality measure because

17   they teach us something? Yes. Through those

18   surveys, CMS is now proactively looking at how to

19   improve outcomes.

20   MS. SMITH: And if it's all right, I'd

21   like to just add one more thing. This is Laura.

22   And that sample of 25 was actually selected

1   deliberately with the thought that they were

2   looking for the types of errors that might come

3   up. So just wanted to caution, while they did

4   show inaccuracies, that was not a representative

5   sample on purpose.

6   MS. EDELSTEIN: And if I could follow

7   up with a question and I know you're not the

8   Survey and Cert folks, so you may not know. But

9   is the sample that they're using now nationally

10   in each state, is that selected the same way with

11   the idea that you're actually going to find

12   inaccuracies? Or is it a more random selection?

13   DR. ENG: Yes. We wouldn't --

14   MS. EDELSTEIN: Okay.

15   DR. ENG: -- know the answer to that.

16   Sorry.

17   MS. EDELSTEIN: Other than that, I

18   would just say, this is an important measure. As

19   a nursing home administrator by profession,

20   there's probably nothing that's more important

21   than maintaining skin integrity. It affects

22   every other area of a resident's life. And I

1 support the continued focus on this measure.

2 CO-CHAIR THRAEN: Thank you. Pat?

3 DR. QUIGLEY: Thank you. Pat Quigley.

4 I have a question related to the inclusion

5 criteria for this measure. In the numerator, you

6 have those who are identified to be high-risk for

7 pressure ulcer. And the high-risk population are

8 those people who are comatose or have impaired

9 bed mobility or transfer mobility or

10 malnutrition. So if you could just clarify, is

11 high-risk not based on what their score is on the

12 Braden Scale?

13 MS. SMITH: That's correct. It's the

14 things that you just listed out.

15 DR. QUIGLEY: So is there consideration

16 to expand this to the high-risk population based

17 on a valid and reliable risk assessment for

18 pressure ulcer? And part of why I include that

19 is in long-term care we have a huge population

20 that is wheelchair dependent. And they are

21 sitting. And they have -- and pressure --

22 immobility associated with wheelchair mobility is

1   a huge opportunity for pressure ulcer

2   development.

3   So would there be consideration for

4   maybe expanding this criteria at some point?

5   Because I know that, that can be collected in

6   your data. It might not be part of the MDS and

7   it might not be part of the RII, but it is part

8   of your medical record.

9   DR. MCMULLEN: So with the advent of a

10   lot of mandates, including the IMPACT Act that

11   was passed by Congress late 2014, we are looking

12   at standardizing across post-acute care settings

13   specific quality measures.

14   And this is not an IMPACT Act measure,

15   so I won't get into this too much, but with the

16   development of those quality measures to meet

17   that mandate, we looked at our models and looked

18   at expanding models to be able to expand the

19   models to assess for risk and different types of

20   covariates that aren't currently collected.

21   CO-CHAIR THRAEN: Charlotte?

22   DR. ALEXANDER: Are we only doing

1 evidence?

2   CO-CHAIR THRAEN: Correct.

3   DR. ALEXANDER: Okay. I'll wait.

4   CO-CHAIR THRAEN: All right. Missy?

5   MS. DANFORTH: Thanks. Can you talk a

6 little bit about how the evidence supports only

7 doing the assessment for the pressure ulcers on a

8 quarterly basis? It seems like for this

9 population, a more frequent assessment for this

10 type of condition would be appropriate. Can you

11 just talk a little bit to that specifically?

12   MS. SMITH: So the MDS is separate from

13 what the processes are that are in the facility.

14 So this is more part of the reporting

15 requirements as part of the conditions of

16 participation for CMS. And kind of how the

17 facilities are doing their monitoring is more

18 being left for the facilities to do that. But

19 the expectation, the understanding would be that,

20 that should be part of the regular practice in

21 the facility to do regular monitoring.

22   CO-CHAIR THRAEN: So the care plan can

1 require assessment on a 24 hour, weekly, whatever

2 basis. But the MDS requirement is once every 90

3 days after they've stabilized that you would go

4 in and do an assessment.

5 MS. DANFORTH: But the only cases that

6 are being counted in the numerator are those that

7 show up on these MDS forms --

8 CO-CHAIR THRAEN: Right.

9 MS. DANFORTH: -- on a quarterly basis.

10 So do you feel like you're actually capturing, I

11 guess, all of the pressure ulcers in the facility

12 is what I'm asking?

13 MS. SMITH: Oh, I see what you're

14 saying. So, I think the idea is, is that we're

15 getting a cross-section by looking at these

16 target assessments in that quarter. That allows

17 us to do some comparison on how well the

18 facilities are doing at preventing and healing

19 pressure ulcers.

20 While you're correct, we're not

21 getting every single one that's in the facility

22 given that it's more sort of about giving that

1 information across all the facilities. That it

2 is still a valid way of assessing how well

3 facilities are doing with regard to skin

4 integrity, pressure ulcers, and care.

5   DR. MCMULLEN: And, Missy, just to add

6 on to what Laura said, this is Tara McMullen. A

7 lot of those decisions quarterly are made for

8 public reporting decisions. So we have to report

9 or be able to report a larger amount of

10 assessment data for generalization purposes. So

11 what you're looking at, like Laura perfectly

12 delineated, are two different concepts. But we

13 do collect more than just once in a quarter, yes.

14   CO-CHAIR THRAEN: Okay. Any other

15 questions about the evidence? Shall we vote?

16   MS. IBRAGIMOVA: For importance to

17 measure and report 1A evidence health outcomes or

18 PRO, rationale supports the relationship of the

19 health outcome or PRO to at least one healthcare

20 structure, process, intervention, or service. 1

21 yes, 2 no.

22   MS. THEBERGE: For the folks on the

1 phone, I've just temporarily lost contact with

2 the webinar, so we're going to have to take your

3 votes either by email or verbally for this one

4 piece and then we'll be back in there in a

5 minute.

6 DR. APPLEGATE: My vote is yes. I'm

7 Kimberly Applegate.

8 MS. O'BRIEN: My vote is yes. This is

9 Ann O'Brien.

10 MS. THEBERGE: Thanks very much.

11 MS. IBRAGIMOVA: Just waiting for one

12 more vote. The results are 100 percent yes, 0

13 percent no.

14 CO-CHAIR SEPTIMUS: That's the first

15 unanimous vote.

16 (Laughter.)

17 CO-CHAIR THRAEN: All right. Moving on

18 to Performance Gap. Would the developers speak

19 to the issue of performance gap? Actually, you

20 did when you talked about the trend, didn't they?

21 So we do know. So are there any questions about

22 performance gap that you have? All right. Let's

1   vote.

2   MS. IBRAGIMOVA: Importance to measure

3   and report, 1B performance gap, data demonstrated

4   considerable variation or overall less than

5   optimal performance across providers and/or

6   population groups, disparities in care. 1 High,

7   2 Moderate, 3 Low, 4 Insufficient. The results

8   are 54 percent High, 38 percent Moderate, 4

9   percent Low, 4 percent Insufficient.

10   CO-CHAIR THRAEN: All right.

11 Reliability. Charlotte?

12   DR. ALEXANDER: So there was a

13 statement looking at the signal-to-noise that it

14 was not very reliable in separating facility

15 variance from population variance. I wonder if

16 you could speak to that, please?

17   MS. SMITH: That's correct. We did do

18 a signal-to-noise analysis and the R was 0.08.

19 We did look at a couple of other ways of looking

20 at the data, but that is what the signal-to-noise

21 analysis showed us.

22   And we did see that when you look at

1   confidence intervals, that 30 percent of

2   facilities do have values that are significantly

3   different than the mean. And we do have very

4   good results at the item level in terms of

5   reliability.

6   CO-CHAIR THRAEN: Charlotte, anything

7   else?

8   DR. ALEXANDER: I don't know how to

9   interpret that. I mean, is that going to mean

10   that the reliability is not there?

11   CO-CHAIR THRAEN: Steve's got his

12   puzzled look on and Ed's got his card up. Is it

13   related to Charlotte's question?

14   CO-CHAIR SEPTIMUS: Well, I'm not 100

15   percent sure. I'm just curious about, in terms

16   of the Stage 2 versus Stage 3 and 4. And I was

17   going to ask that question in terms of the

18   evidence, but I thought I'd wait until we started

19   talking about -- I mean, I'm having a hard time

20   that people can differentiate Stage 2.

21   So do you have reliability data on

22   that? 3 and 4, I kind of get. 2 is not usually

1   included in most reporting. If you look at the

2   HAC reporting, it's Stage 3 and 4. So 2 is what

3   bothers me about this measure.

4   MS. SMITH: In terms of the reliability

5   analyses, as Terry had alluded to that there was

6   -- oh yes. The development studies of the MDS,

7   they did two different types of inter-rater

8   analyses where they compared gold standard nurse

9   ratings to other gold standard nurses and then

10   also had staff in the facilities and comparing

11   their ratings to gold standard nurses.

12   And the results are above 0.95 for the

13   kappas for all of the items that are using in

14   calculating this measure, except for, I think,

15   malnutrition was one that had slightly lower

16   kappas. But in terms of the actual pressure

17   ulcer ones that --

18   CO-CHAIR THRAEN: So let me clarify.

19   So in terms of inter-rater reliability, strong

20   evidence.

21   MS. SMITH: Yes.

22   CO-CHAIR THRAEN: In terms of signal-

1 to-noise reliability, uncertain or low evidence.

2 Is that accurate?

3   MS. SMITH: Yes.

4   CO-CHAIR THRAEN: Okay, Steve? You're

5 puzzled, you don't have your card up.

6   DR. LAWLESS: Yes. No, I'm sorry,

7 Steve Lawless. The puzzlement was about facility

8 population again. Could you just define facility

9 versus population difference? I would have

10 thought that this would looking at differences of

11 facilities across -- I mean, practical

12 experience, there's differences in long-term care

13 facilities. Does this not distinguish that or is

14 it just, am I missing it?

15   MS. SMITH: So reliability, when you're

16 talking about it at the performance measure

17 level, has to do with sort of how much certainty

18 you have in the estimate for the specific

19 provider. And so, basically, looking at how

20 closely clustered are the values across the whole

21 entire range of providers. That is one component

22 of this concept of performance level reliability.

1   Another component is how many people

2   are in those facilities. So it's kind of similar

3   to this idea of sampling, where you kind of think

4   of the facility's denominator as a sample. So if

5   you have a small denominator then you're going to

6   have uncertainty around that estimate.

7   And so we're kind of -- basically the

8   signal-to-noise is saying that we have some

9   clustering of the facility level scores and some

10   small facilities that make it harder to

11   differentiate. But we do have very good -- when

12   you look at ratings on the actual items at the

13   individual level, we have very good results for

14   that.

15   CO-CHAIR THRAEN: Pat?

16   DR. QUIGLEY: Thank you. Pat Quigley.

17   I was just going to say the facilities with 30

18   beds or less are excluded from this measure. So

19   when you're comparing us to who can actually be

20   in this measure. But still, in terms of

21   populations, there can't be an analysis because

22   of the impaired mobility because this is based on

1   conditions. It's not based on risk for pressure

2   ulcer based on the Braden Scale.

3   So people who require help with

4   transfers or people who are immobility, I mean,

5   there still can be some analysis about what

6   happens in terms of pressure ulcer prevention.

7   So it can still be population based.

8   CO-CHAIR THRAEN: Ed?

9   CO-CHAIR SEPTIMUS: Maybe I didn't ask

10   my question well. And I apologize. I got the

11   kappa score for Stage 2, 3, and 4. I got that.

12   What I was wanting to know if you could break it

13   out by Stage and what the kappa score was by

14   Stage?

15   In other words, does Stage 2 have the

16   same level of reliability in terms of the kappa

17   score that, let's say, a Stage 3 or 4 did? Maybe

18   -- that's what I want to -- I should have asked

19   it that way and I apologize.

20   MS. SMITH: Oh, yes. We grouped them

21   together. We do have separate kappa scores for

22   each and the minimum one for across Stage 2, 3,

1 || or 4 is 0.95.

2 || CO-CHAIR THRAEN: You're saying the

3 || nurses know how to assess?

4 || DR. QUIGLEY: Exactly.

5 || CO-CHAIR SEPTIMUS: Now we need to

6 || assess the doctor's assessment.

7 || CO-CHAIR THRAEN: I understand. All

8 || right. Are there any other questions about

9 || reliability? All right, let's take a vote.

10 || MS. IBRAGIMOVA: Scientific

11 || acceptability of measure properties 2A

12 || reliability, including 2A1, precise

13 || specifications and 2A2, testing appropriate

14 || method and scope with adequate results. 1 High,

15 || 2 Moderate, 3 Low, and 4 Insufficient. The

16 || results are 29 percent High, 58 percent Moderate,

17 || 13 percent Low, 0 percent Insufficient.

18 || CO-CHAIR THRAEN: Validity.

19 || MS. IBRAGIMOVA: Scientific

20 || acceptability of measure properties 2B validity -

21 || -

22 || CO-CHAIR THRAEN: Okay. Hold on. Are

1   there any questions about validity? Any

2   additional information that you want to share

3   about validity? Any other discussion about

4   validity? Go.

5   MS. IBRAGIMOVA: 2B validity, including

6   2B1, specifications consistent with evidence,

7   2B2, testing appropriate method and scope with

8   adequate results and threats addressed, 2B3,

9   exclusions, 2B4, risk adjustment/stratification,

10   2B5, meaningful differences, 2B6, comparability

11   in multiple specifications, 2B7, missing data,

12   eMeasures, composites, PRO-PMS.

13   1 High, 2 Moderate, 3 Low, 4

14   Insufficient. Just missing one more vote. The

15   results are 21 percent High, 67 percent Moderate,

16   13 percent Low, and 0 percent Insufficient.

17   CO-CHAIR THRAEN: Okay. Next one is

18   Feasibility.

19   MS. IBRAGIMOVA: Feasibility, 3A, data

20   generated during care, 3B, electronic sources,

21   and 3C, data collection can be implemented,

22   eMeasure feasibility assessment of data elements

1 and logic. 1 High, 2 Moderate, 3 Low, 4

2 Insufficient.

3   CO-CHAIR THRAEN: Any discussion? Any

4 questions? All right.

5   MS. IBRAGIMOVA: I'm just missing one

6 vote. The results are 50 percent High, 50

7 percent Moderate.

8   CO-CHAIR THRAEN: Usability. Any

9 discussion or questions? All right.

10   MS. IBRAGIMOVA: Usability and use, 4A,

11 accountability/transparency, use and

12 accountability within three year, public

13 reporting within six year, or if new, credible

14 plan, and 4B, improvement progress demonstrated,

15 if new, credible rationale, and 4C, benefits

16 outweigh evidence of unintended negative

17 consequences to patients/populations.

18   1 High, 2 Moderate, 3 Low, 4

19 Insufficient Information. Just one more vote.

20 Still missing one vote.

21   CO-CHAIR THRAEN: Still missing one?

22 Do we need to do it again?

1   MS. IBRAGIMOVA: Yes. Just when you're

2   looking at your clicker, make sure the number

3   pops up.

4   CO-CHAIR THRAEN: All right. Once

5   again. All right. Go. Got it.

6   MS. IBRAGIMOVA: The results are 54

7   percent High, 42 percent Moderate, 4 percent Low,

8   0 percent Insufficient Information.

9   CO-CHAIR THRAEN: Okay. Final question

10 on this one.

11   MS. IBRAGIMOVA: Overall suitability

12 for endorsement, does this measure meet NQF

13 criteria for endorsement? Note, this may not yet

14 be a recommendation for endorsement. Final

15 recommendation for endorsement may depend on

16 assessment of any related and competing measures.

17 1 Yes, 2 No.

18   CO-CHAIR THRAEN: Any final comments?

19 Questions? Go.

20   MS. IBRAGIMOVA: The results are 96

21 percent Yes, 4 percent No.

22   CO-CHAIR THRAEN: Okay. It passes.

1   All right. And the next one in this group is

2   0337, Pressure Ulcer Rate (PDI 02) from AHRQ.

3   And are the developers here? Yes, they're still

4   here.

5   CO-CHAIR SEPTIMUS: So after this

6   measure, we're going to have a discussion about

7   competing measures and then we're going to take a

8   break.

9   MS. DAVIES: This is Sheryl Davies.

10   I'll be presenting on the phone, but I'll leave

11   some time for my colleagues there that I assume

12   are moving back up to the table?

13   CO-CHAIR THRAEN: That is correct.

14   MS. DAVIES: Okay.

15   CO-CHAIR THRAEN: Give them a moment to

16   settle in and then we'll have them --

17   MS. DAVIES: Sounds good.

18   CO-CHAIR THRAEN: -- introduce

19   themselves.

20   CO-CHAIR SEPTIMUS: Dr. Romano's gotten

21   --

22   MS. DAVIES: Okay.

1   CO-CHAIR SEPTIMUS: -- more grey hairs

2   since this morning.

3   CO-CHAIR THRAEN: Yes, he has.

4   (Laughter.)

5   CO-CHAIR THRAEN: It looks like the --

6   all right. Would you like to introduce

7   yourselves?

8   MS. PANCHOLI: Good afternoon. My name

9   is Mamatha Pancholi and I'm the Quality

10   Indicators Program Director at the Agency for

11   Healthcare Research and Quality. And I am joined

12   by colleagues at Stanford University, UC Davis

13   here, Patrick Romano, as well as my colleagues at

14   Truven Health, who all comprise the Quality

15   Indicator Team.

16   And we are here again this afternoon

17   to talk about PSI 15. I'm sorry, PDI 02. That's

18   tomorrow. Yes, we're here for the long haul. So

19   I'll let my colleagues on the phone, Sheryl

20   Davies and folks, introduce themselves.

21   DR. ROMANO: And this is Patrick Romano

22   again, I am a general internist and general

1 pediatrician, but I'm not leading this particular

2 effort. So our colleagues at Stanford University

3 are leading the support and enhancement of the

4 Pediatric Quality Indicator Module. So Sheryl

5 will be introducing the indicator.

6 MS. DAVIES: Yes. So this is Sheryl

7 Davies. I'm a research associate here at

8 Stanford. I think in the interest of time, I'll

9 just go ahead and introduce my colleagues on the

10 phone. We have Kathryn McDonald, the PDI Module

11 Lead and Executive Director of our center. We

12 have our clinical leads, Lee Sanders and Corinna

13 Haberland, that are joining us on the phone, who

14 are both pediatricians here at Stanford

15 University.

16 So I want to go ahead and introduce

17 the PDI Measure today. And we'll defer to

18 colleagues if we have questions along the way.

19 But this PDI 02 is a measure of Stage 3 and 4

20 pressure ulcers in pediatric patients. It is

21 stratified by high and low-risk patients.

22 I want to start by explaining a little

1   bit about the history of this PDI, which I think

2   will illuminate and answer some of the questions

3   that were raised both in the comments to our team

4   in the pre-evaluation comment period, as well as

5   perhaps clarify some of the materials that you

6   received.

7   So advanced pressure ulcers are

8   certainly a serious patient safety concern. They

9   have been a focus in children's hospitals

10   recently. They result in significant pain and

11   morbidity for patients. The ulcers may require

12   surgical intervention for debridement or

13   grafting.

14   And among children, which is slightly

15   different than adults, more than half of the

16   ulcers are related to equipment or devices. So

17   the location of those ulcers might be quite

18   different. Efforts such as manual

19   redistribution, support services, or positioning

20   devices are particularly important to prevent

21   ulcers. Head-to-toe screening on admission for

22   high-risk patients and treatment of early stage

1 ulcers to prevent progression to Stage 3 or 4

2 pressure ulcers is important as well.

3   PDI 02 was originally actually

4 designed as part of the pediatric module

5 development effort. And at that time, the

6 indicator was defined as including all pressure

7 ulcers without regard to pressure ulcer staging.

8 This was primarily because there were no codes at

9 that time for the stage of the ulcer. But rather

10 the only codes that were available relied on the

11 location of the pressure ulcer.

12   The indicator was reviewed by an

13 expert panel and those results were included in

14 the packet. The panel at that time was

15 interested in limiting the indicator to Stage 2

16 and above because of the variability in

17 diagnosing Stage 1 pressure ulcers. However, at

18 that time, we did not have staging codes to rely

19 on.

20   Since that time, and in 2009, pressure

21 ulcer staging codes were introduced into the ICD-

22 9 system. And around that same time, CMS chose

1   to focus also on Stage 3 and 4 pressure ulcers in

2   their indicators, as you've just heard. And the

3   PDI was actually aligned to include only Stage 3

4   and 4 pressure ulcers in order to align with the

5   adult PSI 03, or the adult pressure ulcer

6   indicator.

7   The indicator was last endorsed in

8   2012. At that time, this change to the

9   definition had been made. However, data were not

10   yet available to evaluate that change. So when

11   this panel last reviewed the indicator, the

12   evidence was actually based on higher rates that

13   were based on all stages of pressure ulcers.

14   So now we present and we've been able

15   to re-evaluate the indicator based on this more

16   limited definition. So some of you have noticed

17   this drastic change in the rates that we provided

18   down from 1,000 cases --- sorry, a drastic

19   reduction between 2008 and 2009. And that is

20   because prior to 2009, we actually did not have

21   staging, so we had to rely on our old definition.

22   In other words, when the software

1 calculates this indicator for data prior to 2009,

2 it actually includes all cases of pressure ulcer

3 without regard to staging. The new definition,

4 which is applicable to data 2009, is more

5 limited. And we have seen that the change is

6 drastic from 409 in 2008 to 69. We also noticed

7 that from 2009 to 2012, the latest data that

8 we've been able to test at this time, there has

9 been -- it's been relatively stable.

10   CO-CHAIR THRAEN: Thank you.

11   MS. DAVIES: The indicator --

12   CO-CHAIR THRAEN: I'm sorry, go ahead.

13   MS. DAVIES: Okay. The indicator does

14 have high reliability as tested by the signal-to-

15 noise.

16   CO-CHAIR THRAEN: Okay. I'm going to

17 stop --

18   MS. DAVIES: This is something that --

19   CO-CHAIR THRAEN: Excuse me. I'm going

20 to stop you there.

21   MS. DAVIES: Okay.

22   CO-CHAIR THRAEN: Not go into the

1   reliability question, stay with the evidence.

2   MS. DAVIES: Okay.

3   CO-CHAIR THRAEN: Does the --

4   MS. DAVIES: Sure.

5   CO-CHAIR THRAEN: -- any of the

6   discussants -- who's leading this? Okay. Tracy?

7   MS. WANG: Okay. So this Tracy Wang.

8   In terms of evidence, this is an outcomes

9   measure. It's intended to flag hospital-acquired

10   pressure ulcers. And the developers had

11   mentioned a couple of different healthcare

12   practices and interventions that can lead to

13   reduction of the pressure ulcers. So to me, it's

14   pretty strong.

15   CO-CHAIR THRAEN: Are there any

16   comments or questions about the evidence?

17   Michelle?

18   MSS: Thank you. To the developers, I

19   have a question about the preventability of

20   pressure ulcers in kids. I understand the

21   relationship very well in adults, but there is a

22   comment in your write-up that in kids up to maybe

1   50 percent, you say 49 percent, of pediatric

2   pressure ulcers aren't preventable. So is this a

3   measure actually that there is a prevention

4   strategy that's effective for?

5   MS. DAVIES: I'm sorry. I couldn't

6   quite hear the last piece of your sentence there.

7   Are you asking us to comment on the

8   preventability?

9   DR. ROMANO: Yes. So I'll start and

10   Sheryl will add. But, yes. I mean, across all

11   of the indicators of course, almost none of the

12   indicators have 100 percent preventability. That

13   particular estimate comes from a study in which

14   clinicians reviewed the medical record

15   retrospectively and made an assessment about

16   whether they thought based, on their review of

17   the medical record, the pressure ulcer could have

18   reasonably been prevented.

19   But I think people around even this

20   table might disagree about those assessments.

21   Unfortunately, in that particular study, there

22   was no inter-rater reliability assessment to know

1   if you had two different people, maybe a nurse

2   and a physician reviewing the same record, would

3   they have come to the same conclusion. So,

4   that's just the limitation of trying to determine

5   retrospectively what percentage were preventable.

6   Sheryl, did you have anything to add?

7   MS. DAVIES: Yes. I would actually

8   also like to add that that is based on the

9   definition of the indicator that includes all

10   pressure ulcers without regards to staging.

11   Certainly, you could imagine that the

12   preventability, especially when you're including

13   Stage 1 pressure ulcers, may be more tenuous.

14   However, the preventability of Stage

15   3 and 4, we do not have any research studies that

16   have evaluated this new definition, more limited

17   definition in pediatrics. And there has been an

18   effort actually to move the rate of, especially,

19   Stage 2 to 4 pressure ulcers down to zero,

20   including a tool kit which has been released by

21   what was formerly known as NACHRI, they released

22   it when they were still NACHRI, but the

1   Children's Hospital Association, in order to

2   reduce pressure ulcers among patients in the

3   hospital and in the PICU.

4   CO-CHAIR THRAEN: Yanling?

5   DR. YU: Yes. Yanling Yu. I have a

6   question about denominator exclusion. Is this

7   evidence -- discussed under evidence?

8   CO-CHAIR THRAEN: Yes.

9   DR. YU: Okay.

10   CO-CHAIR THRAEN: Yes. I think so.

11   DR. YU: Okay. My question is a

12   question for developer. There's on Page 2, it

13   says the case is excluded if they transferred

14   from a nursing home, from another health

15   facility.

16   And I was just wondering the rationale

17   on that and because some patients have been

18   transferred from a nursing home facility then

19   they develop a pressure ulcer while in the

20   hospital, that would be the secondary diagnosis.

21   And in that case, they would be excluded. I

22   wonder, what's the rationale you would do that?

1   Thank you.

2   MS. DAVIES: Sure. So the exclusions

3   that are there are there for twofold. One of

4   those is that during the clinical panel, some of

5   the clinicians actually recommended some these

6   exclusions. The caveat that's important to

7   understand here is that when we developed the

8   indicator, present on admission data was not

9   widely available.

10   And so, most of these exclusions were

11   actually created in order to decrease the

12   likelihood that we were capturing ulcers that

13   were present on admission. We're currently re-

14   evaluating this indicator.

15   We have not finished that re-

16   evaluation at this time, but we will be re-

17   evaluating to determine whether or not these

18   exclusions, in light of increased availability of

19   POA data, are still necessary.

20   CO-CHAIR THRAEN: Steve?

21   DR. LAWLESS: Yes. Steve Lawless here.

22   In Table 1 on Page 3, the mean standard deviation

1   has numbers, but up to the 95th percentile,

2   they're all blank, zeros. Is the evidence

3   showing that -- could you just explain this to me

4   in terms of where that comes -- how you can have

5   -- this is an issue for only 5 percent of

6   hospitals is how I'm interpreting this.

7   MS. DAVIES: I'm sorry. Which table

8   are you on?

9   DR. LAWLESS: It's under 1B.2, Table 1.

10   It's Reference Ranges of Observed Rates in

11   Reference Population. And it says mean 0.2,

12   standard deviation 3.13. But then it give

13   percentiles that are all zero. I just don't

14   understand -- could you just explain that?

15   MS. DAVIES: Yes. So a better way to

16   look at this is actually to look at the Measure

17   Testing Form. I think this will be a little bit

18   easier for you to see. On the Measure Testing

19   Form, under Table 4, we have listed out actually

20   the histogram of the numerators. And what you'll

21   see there is about the majority of hospitals have

22   a rate of zero.

1   So the mean is brought up because some

2   of the higher rates, but most of the -- only 189

3   hospitals have a rate. And, in fact, this brings

4   up that -- like one of the previous measures

5   mentioned, most of the indicators here, although

6   this indicator does have high reliability for

7   signal-to-noise, it actually has pretty poor

8   performance discrimination. Because most of the

9   hospitals actually have zero rate.

10   This may be an indicator to consider

11   at this time for reserve status. AHRQ is

12   considering these additional improvements to the

13   indicator, such as removing the exclusions and

14   expanding to Stage 2.

15   However, that requires extensive study

16   and the involvement of a PDI specific work group.

17   So we don't have that completed right now. So

18   this may be better for reserve status in the

19   short-term and to bring back for full endorsement

20   again once any of those improvements are

21   potentially made.

22   CO-CHAIR THRAEN: Richard?

1   DR. BRILLI: I'm privileged to co-lead

2   the solutions for patient safety work on pressure

3   ulcers in children, representing 90 children's

4   hospitals and we've actually -- so the link

5   between this data and outcomes in a bundle, we

6   have data that we're submitting for publication

7   that shows that if you implement a bundle highly

8   reliably, you will get reduction in these

9   measures.

10   So I wouldn't put this in a sustain

11   mode. I think it's a very important outcome

12   metric that needs to be out there. And there

13   will be publications that support the fact that

14   it will be an outcome measure for process

15   measures that can link to that. So this is

16   relatively new work in pediatrics, but it's going

17   to be highly reliable and I think we need to keep

18   this measure out there based on the work of 90

19   children's hospitals.

20   CO-CHAIR THRAEN: Thank you. Any other

21   comments about the evidence? All right, let's

22   vote. You have a comment?

```
 1              CO-CHAIR SEPTIMUS: Point of

 2    consideration.  If an article has not been

 3    published -- I'm sorry, Ed Septimus.  If an

 4    article has not been published and is not

 5    completely through the peer-review process, what

 6    is the NQF standard for accepting that as

 7    evidence?

 8              (Laughter.)

 9              CO-CHAIR SEPTIMUS: Don't laugh.  This

10    comes up all the time.  Things get presented at

11    meetings and then go through the peer-review

12    process, they found significant flaws.  So my

13    question -- by the way, I'm not doubting the

14    study --

15              DR. PINES: I think it's a fair

16    question.  I'm just telling you what I know.

17              CO-CHAIR SEPTIMUS: So as a federation,

18    how do we view studies that have not finished

19    going through the peer-review process?

20              MS. THEBERGE: We're actually pulling

21    Helen in to answer this question.

22              DR. BURSTIN: Of course.  Yes.  It's
```

1 like any other data a measure developer would

2 submit to us in a table or a chart. It doesn't

3 matter. It's just data.

4   CO-CHAIR THRAEN: All right. Any other

5 questions? Richard, you look like you want to

6 say something.

7   DR. BRILLI: It has been presented at

8 national meetings if that makes any difference.

9 But it hasn't been published yet. It hasn't been

10 through the full peer-review process. So I think

11 it's a very fair thing for you to bring up, Ed.

12 If I wasn't sitting here, you wouldn't have the

13 information except through abstracts and that

14 kind of thing.

15   CO-CHAIR THRAEN: Jason, then Pat.

16   DR. ADELMAN: Jason Adelman. I just

17 want to make sure I understand this correct. So,

18 I think it was the developer who just said that

19 they recommended that it be approved on a reserve

20 status because they might -- a lot of hospitals

21 don't have any events and they, themselves, are

22 thinking about tweaking it.

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1   And then Richard pointed out that he's

2   chairing a very important committee that's

3   looking at pediatric pressure ulcers and he sees

4   value in it. But it's like the tables just

5   flipped on us. And I just want to make sure that

6   I got it right and I knew who was talking on the

7   phone and that's the situation that we have. Is

8   that correct?

9   MS. DAVIES: So this is Sheryl Davies,

10   representing the measure developer. Just to be

11   clear, reserve status does not mean -- it

12   certainly is still fully endorsed. Reserve

13   status simply means that the measure has topped

14   out.

15   So it's still an important -- as we

16   understand it, it still meets importance and AHRQ

17   does maintain that these are extremely important

18   events. But we acknowledge that our ability to

19   distinguish one hospital from another or to

20   discriminate between hospital performance is

21   limited because most hospitals have no events.

22   We are considering re-evaluating and

1 increasing. We don't know that we will do that,

2 but we are re-evaluating the indicator,

3 considering expanding the definition to include

4 more numerator events. If that does happen, then

5 we might see more -- we might be able to

6 discriminate better between facilities.

7   At which case, it may not qualify any

8 more for reserve status, but would qualify

9 otherwise for endorsement. But it is our

10 understanding that reserve status is indeed full

11 endorsement, just denotes that it's topped out.

12   CO-CHAIR THRAEN: Pat?

13   DR. QUIGLEY: Thank you. Pat Quigley.

14 And I would like to always thank AHRQ for the

15 great work on it. And even though it might not

16 be a published article, AHRQ has been publishing

17 the reports in public domain on the progress of

18 the Partnership for Patients and the reduction of

19 hospital-acquired conditions. And one of those

20 conditions is pressure ulcers.

21   So even though there may not -- that

22 pressure ulcers are still occurring, there's been

1   less reduction in them, but they're still

2   occurring and we have an aging population that

3   continuing to endorse this in terms of reserve

4   status I think is very important.

5   CO-CHAIR THRAEN: But I think this a

6   pediatric --

7   DR. QUIGLEY: Oh.

8   CO-CHAIR THRAEN: -- Measure.

9   DR. QUIGLEY: Sorry. Okay.

10   CO-CHAIR THRAEN: Yanling?

11   DR. QUIGLEY: Well, same for PEDS.

12   CO-CHAIR THRAEN: No? Richard?

13   Michelle?

14   DR. SCHREIBER: My concern is that if

15   so many hospitals really are at zero, are you

16   penalizing those hospitals that maybe have a

17   larger volume because they're more likely to have

18   kids who are going to do this and, therefore,

19   they're going to perhaps look worse in the public

20   eye than those hospitals that have smaller

21   volume? So it gets back to the discrimination

22   question.

1   CO-CHAIR THRAEN: Does the developer

2   want to respond to that? Did you hear the

3   question?

4   MS. DAVIES: Yes. So we did look at

5   active -- we haven't presented all the detail

6   that we provided based on bed size. But we have

7   provided this based on the histogram of the

8   numerators, based on children's and non-

9   children's.

10   I think that the important thing that

11 we see is that the coefficient of variation,

12 which is a variation that's standardized by the

13 mean, the coefficient of variation for children's

14 hospitals is 2.0, which is fairly moderate

15 variation between children's hospitals and non-

16 children's hospitals among both the high and low-

17 risk status. It's about 10.0 or 4.0

18 respectively.

19   So we see more variation along non-

20 children's hospitals with typically lower volumes

21 and lower acuity patients. I'm not sure if

22 that's exactly getting at what you're wondering

1   about. But it certainly is consideration of that

2   and that's also why we have the low and high-risk

3   strata to get at the complexity of the patients

4   that tend to be seen in the high-volume

5   hospitals.

6   CO-CHAIR THRAEN: All right. Pat did

7   you have something else?

8   DR. ROMANO: I mean, I would just add

9   that -- so there's a wide spectrum of different

10   types of quality measures. Obviously they're

11   used for different purposes. And clearly this is

12   not a measure that has a very high level of

13   discrimination in terms of its ability to

14   discriminate hospital performance. Because most

15   hospitals are at zero.

16   Now, even the hospitals that have

17   relatively high rates, as we talked about

18   earlier, when you take the observed-to-expected

19   ratio, you put them into a risk adjustment, you

20   estimate this observed-to-expected ratio. And

21   then you shrink it based on the reliability of

22   the data from the individual hospital. So,

1   again, that will lead to a situation where you

2   have very, very few hospitals that qualify as

3   outliers.

4   And that's, again, that's why -- but

5   I think everybody agrees, this is an extremely

6   important condition and an important

7   complication. So it seems potentially well-

8   suited for reserve status. But that's obviously

9   for the committee to decide.

10   CO-CHAIR THRAEN: All right. We're

11   going to vote on the importance of the evidence

12   or the evidence.

13   MS. IBRAGIMOVA: So importance to

14   measure and report, 1A evidence, health outcome

15   or PRO, rationale supports the relationship of

16   the health outcome or PRO to at least one

17   healthcare structure, process, intervention, or

18   service. 1 Yes, 2 No.

19   CO-CHAIR SEPTIMUS: Just to clarify, I

20   just talked with Jesse. We are still going to go

21   through the elements and then at the -- because

22   this is already an endorsed measure that's coming

1   back for re-endorsement. And then we'll vote on

2   whether or not we should put this in reserve

3   status because it's topped out. Okay?

4   We're going to go through to see if we

5   want to continue to say this has the evidence and

6   endorsement. But we can go at the end, saying

7   it's topped out, we want to put this in reserve

8   status. Slightly different than what we did

9   before.

10   DR. ADELMAN: Didn't the last time we

11   do this, Helen said that we did it incorrectly

12   and we had to run through it all again?

13   CO-CHAIR THRAEN: She told me to jump

14   to the reserve status and then upon reflection,

15   they decided that we really did need to go

16   through the steps. And so we're going to come

17   back to those steps on that particular measure --

18   DR. ADELMAN: Okay.

19   CO-CHAIR THRAEN: -- later.

20   CO-CHAIR SEPTIMUS: We're trying to

21   correct what we didn't do right the first time,

22   basically.

1   (Laughter.)

2   CO-CHAIR SEPTIMUS: But we were going

3   to sort of look the other way on the other

4   measure and if we have time, we'll come back to

5   it. We want to do it right this time.

6   CO-CHAIR THRAEN: We have 22, we still

7   need two votes. Twenty-three, we've got one more

8   out there. There we go.

9   MS. IBRAGIMOVA: The results are 96

10   percent Yes, 4 percent No.

11   CO-CHAIR THRAEN: All right. Next one

12   is Performance Gap.

13   MS. IBRAGIMOVA: Importance to measure

14   and report 1B performance gap, data demonstrated

15   considerable variation or overall less than

16   optimal performance across providers and/or

17   population groups, disparities in care. 1 High,

18   2 Moderate, 3 Low, 4 Insufficient. Results are 8

19   percent High, 38 percent Moderate, 50 percent

20   Low, 4 percent Insufficient.

21   CO-CHAIR THRAEN: So that's grey?

22   Right. Proceed. 40 to 60 percent is grey. Of

1 the High or Moderate combined. Reliability. Any

2 discussion or questions that you have regarding

3 this measure in reliability? All right.

4   MS. IBRAGIMOVA: Scientific

5 acceptability of measure properties 2A

6 reliability, including 2A1, precise

7 specifications and 2A2, testing appropriate

8 method and scope with adequate results. 1 High,

9 2 Moderate, 3 Low, 4 Insufficient. One more

10 vote. The results are 29 percent High, 67

11 percent Moderate, 4 percent Low, 0 percent

12 Insufficient.

13   CO-CHAIR THRAEN: Usability. Or no,

14 excuse me, Validity.

15   MS. IBRAGIMOVA: Scientific

16 acceptability of measure properties 2B validity,

17 including 2B1, specifications consistent with

18 evidence, 2B2, testing appropriate method and

19 scope with adequate results and threats

20 addressed, 2B3, exclusions, 2B4, risk

21 adjustment/stratification, 2B5, meaningful

22 differences, 2B6, comparability in multiple

1 specifications, 2B7, missing data, eMeasures,

2 composites, PRO-PMS.

3 1 High, 2 Moderate, 3 Low, 4

4 Insufficient. The results are 13 percent High,

5 75 percent Moderate, 13 percent Low, 0

6 Insufficient.

7 CO-CHAIR THRAEN: Feasibility.

8 MS. IBRAGIMOVA: Feasibility, 3A, data

9 generated during care, 3B, electronic sources,

10 and 3C, data collection can be implemented,

11 eMeasure feasibility assessment of data elements

12 and logic. 1 High, 2 Moderate, 3 Low, 4

13 Insufficient.

14 CO-CHAIR THRAEN: Missing one. There

15 it is. We got it.

16 MS. IBRAGIMOVA: The results are 54

17 percent High, 46 percent Moderate, 0 percent Low,

18 and 0 percent Insufficient.

19 CO-CHAIR THRAEN: Okay. Usability.

20 MS. IBRAGIMOVA: Usability and use, 4A,

21 accountability/transparency, use and

22 accountability within three year, public

1 reporting within six year, or if new, credible

2 plan, and 4B, improvement progress demonstrated,

3 if new, credible rationale, and 4C, benefits

4 outweigh evidence of unintended negative

5 consequences to patients/populations. 1 High, 2

6 Moderate, 3 Low, 4 Insufficient Information.

7 CO-CHAIR THRAEN: All right. Missing

8 one. Try it again. There it is.

9 MS. IBRAGIMOVA: The results are 38

10 percent High, 50 percent Moderate, 13 percent

11 Low, and 0 Insufficient Information.

12 CO-CHAIR THRAEN: All right. So the

13 next question is endorsement. Where's the

14 question for reserve status? After this? Okay.

15 So we have to endorse it first before we

16 determine reserve status.

17 DR. PINES: So for the --

18 CO-CHAIR THRAEN: We also have some

19 disagreement.

20 DR. PINES: So for the reserve status

21 question, if something's topped out, meaning that

22 the rate is -- if you can't discriminate between

1 99 percent and 100 percent, it's different than a

2 rare safety event where your event is near zero.

3 And it's something you don't want to happen. So

4 I think we should think about it a little

5 differently.

6 The measure definitely has

7 discrimination issues between hospitals because

8 so many hospitals are zero. But thinking about

9 an analogy of a death in the waiting room in the

10 emergency department, it's an important but rare

11 patient safety event that you may want to

12 measure. But it's going to be -- not a lot of

13 hospitals are going to have that.

14 CO-CHAIR THRAEN: All right. So --

15 MS. WANG: Can I ask a question?

16 CO-CHAIR THRAEN: -- before who's ever

17 -- Tracy, go ahead.

18 MS. WANG: This is Tracy. I have a

19 question. Can you clarify the difference between

20 going to reserve status and then tabling the

21 measure until more information is provided where

22 the metric has gone through additional

1   development?

2   MS. THEBERGE: Reserve status is

3   recommended for endorsement. Tabling the measure

4   means that you haven't made a decision yet.

5   CO-CHAIR THRAEN: Charlotte, did you

6   have a question?

7   DR. ALEXANDER: Do we have to approve

8   it for endorsement to be able to go to reserve

9   status?

10   CO-CHAIR THRAEN: That's what they're

11   telling me.

12   MS. THEBERGE: Yes.

13   CO-CHAIR THRAEN: Any other questions?

14   DR. BURSTIN: I just want to make sure

15   I understand Tracy's question. So are you asking

16   -- is there additional information you would

17   want? Because you want to table it? I'm sorry,

18   I missed a part of that conversation.

19   MS. WANG: So the developer had

20   mentioned that they were thinking about this

21   metric, trying to expand the inclusion to Stage 2

22   pressure ulcers. So I just wasn't clear, would

1   that be considered as tabling because they're

2   bringing additional information?

3   DR. BURSTIN: There we go. If I hit it

4   enough, it'll let me talk. So at any point, the

5   developer can come back in what's called an ad

6   hoc review if they change the measure and ask you

7   to re-review it. So I wouldn't consider that at

8   this point. That's certainly a possibility.

9   If it's endorsed. If it's not

10   endorsed, they'd have to start all over again and

11   bring you the new measure with the modification.

12   And, again, I don't know that we've had this

13   before. But I don't know that we've ever done

14   reserve status for a low rate. I don't think it

15   really applies.

16   I mean, again, there are plenty of

17   safety events. If we went through the list of

18   some of the endorsed safety events that have

19   very, very low rates. And they're there

20   intentionally because these are rare, but serious

21   events. So it doesn't actually apply to a

22   reserve status code.

1   There are safety events that we've

2   endorsed, multiple measures, that have low rates.

3   It doesn't mean they're necessarily ones that you

4   wouldn't continue to assess and look for in the

5   way we would say something is so topped out, it's

6   built into systems, it's -- highly reliable

7   organizations have so built this into their

8   system that continuing to measure it just doesn't

9   seem worth the burden.

10   This is the flip side, these are rare

11   events, but it's not as if we've heard anything

12   to suggest they're rare because all the systems

13   are in place and et cetera. They're just rare.

14   Does that make sense? Okay.

15   CO-CHAIR THRAEN: Other questions?

16   Richard?

17   DR. BRILLI: So let me preface my

18   remarks by, if you don't want me to talk about

19   what I know through 90 children's hospitals, I

20   won't do it. But I --

21   CO-CHAIR THRAEN: That's why you're

22   here.

1   CO-CHAIR SEPTIMUS: No, we definitely

2   do.

3   DR. BRILLI: So I don't totally agree

4   with the data from the claims database. It's

5   uncommon, but I would not call it rare. We have

6   90 children's hospitals searching their

7   electronic medical records. And we get this

8   information, we have it now for two or three

9   years.

10   And I don't know how that correlates

11   with the claims database, but based on our data

12   from these 90 children's hospitals, they're

13   uncommon, but not rare. And they happen

14   regularly. And I would say, every children's

15   hospital in those 90 has at least one or two a

16   year. Not -- so that's uncommon, yes.

17   But a Stage 3 and a Stage 4 pressure

18   ulcer is a big deal. Especially a Stage 4.

19   Those are very rare. Stage 3s are also

20   significant cosmetic issues for children. So I

21   think this is an important measure.

22   I worry about putting it on reserve if

1   that implies somehow that it has less importance.

2   This is a big deal in the safety world, I think,

3   for children. And it just may be that I'm

4   looking at a different database, which is an

5   electronic medical record search, as opposed to a

6   claims database. And those two may have

7   different rates. Clearly my --

8   CO-CHAIR SEPTIMUS: No. I think Helen

9   articulated this extremely well just a moment

10   ago. About measures that are already hard-wired,

11   that have topped out. This is the opposite. And

12   so I think she articulated the issue very nicely.

13   So, yes, it's an important measure.

14   And maybe this does not qualify to go on reserve.

15   We first need to see if we're going endorse it

16   first. But I think Helen's distinction is very

17   important.

18   CO-CHAIR THRAEN: Any other thoughts.

19   Shall we vote?

20   MS. IBRAGIMOVA: Overall suitability

21   for endorsement, does the measure meet NQF

22   criteria for endorsement? Note, this may not yet

1   be a recommendation for endorsement. The final

2   recommendation for endorsement may depend on

3   assessment of any related and competing measures.

4   1 Yes, 2 No. It's just being weird.

5   CO-CHAIR THRAEN: There it is. I

6   guess we have no answer. It's not the one you

7   wanted. We have 24 votes. We'll have to vote

8   again. We have to vote again, guys.

9   MS. IBRAGIMOVA: Yes. Please vote

10 again.

11   CO-CHAIR THRAEN: Technology is

12 wonderful when it works. It sucks when it

13 doesn't. Okay. There we are.

14   MS. IBRAGIMOVA: The results are 96

15 percent Yes, 4 percent No.

16   CO-CHAIR THRAEN: All right. Are we

17 okay with not going down the reserve status

18 question? Anybody have a problem with that? All

19 right. We're done with that one.

20   We are 15 minutes behind and we're

21 scheduled for break. And the conversation

22 related to relating and competing measure

1   discussion was tabled. Is that correct?

2   CO-CHAIR SEPTIMUS: We don't have any.

3   CO-CHAIR THRAEN: We don't have any.

4   So we're good with that. So I suggest you take a

5   break. And come back in 15 minutes.

6   CO-CHAIR SEPTIMUS: Or 10 so we start

7   in 15 minutes.

8   (Whereupon the above-entitled matter

9   went off the record at 2:55 p.m. and resumed at

10   3:08 p.m.)

11   CO-CHAIR SEPTIMUS: Okay, guys. I

12   have some really great news for you here. First

13   of all, you've really been incredibly good about

14   staying on time. I mean, this is about as good

15   as you can get.

16   Second, we've moved up dinner to 6:00

17   p.m. So, that will give you an incentive to

18   finish on time and it's only a couple of blocks

19   from here.

20   And thirdly, as last time, wine is on

21   me. So, ah. I don't know if they're going to

22   have Septimus wine, but we'll have something.

1 Steve said as long as we don't have to drink the

2 Septimus Kool-aid.

3 Okay. So, we're going to start this

4 afternoon with 0204 and 0205. Apparently, the

5 presentation for those two measures are quite

6 similar, correct?

7 So, would you like to present for both

8 and then we'll discuss each of them individually?

9 Would that be okay with everybody?

10 MS. CRAMER: That's what we had kind

11 of planned, if that works for you. I think that

12 will be expedient.

13 CO-CHAIR SEPTIMUS: Sounds like it

14 might expedite things a little bit. So, go.

15 MS. CRAMER: I have never been told I

16 need to speak louder or closer to the mic.

17 Never, ever in my life.

18 I am Emily Cramer. I am with the

19 University of Kansas and I represent one of the

20 measure developers. ANA is actually -- the

21 American Nurses Association is the measure

22 steward for this for actually the next four

1 | measures on your list.

2 | And I'm here with a couple of

3 | colleagues. I'll let them introduce themselves.

4 | MS. OLDS: I'm Danielle Olds. I'm

5 | also with the University of Kansas and here as a

6 | measure developer.

7 | DR. NEEDLEMAN: And I'm Jack

8 | Needleman. I'm professor and chair of the

9 | Department of Health Policy and Management at the

10 | UCLA School of Public Health.

11 | I did some of the early research that

12 | supported the development of the staffing

13 | measures that we're talking about.

14 | I also served as a member of the

15 | Technical Advisory Panel for the committee that

16 | looked at hospital nurse staffing -- hospital-

17 | sensitive -- nurse-sensitive hospital performance

18 | measures back in 2003.

19 | And was also on the Joint Commission

20 | Technical Advisory Panel that looked at their

21 | assessment of the feasibility of the measures.

22 | MS. CRAMER: Okay. So, as we said,

1 the next two measures, which are skill mix, which

2 includes RN, LPN and LVN, which is licensed

3 practical/licensed vocational nurses, and

4 unlicensed assistive personnel measure, which is

5 Number 0204, and Number 0205, which is nursing

6 hours per patient day are very similar. So,

7 we're going to do a brief introduction to those

8 two together.

9 I would like to add that all of these

10 measures have been previously endorsed at the

11 unit level.

12 We've added a hospital-level analysis

13 and they have also been conditionally approved by

14 the Measures Application Partnership for

15 inclusion in CMS' Inpatient Quality Reporting

16 System.

17 The conditional approval is based on

18 whether or not they get the hospital-level

19 endorsement from this committee.

20 MS. OLDS: Thank you. Nursing

21 matters, and here's why. Nurses work as a core

22 service of hospital care, nurses have the

1 accountability, responsibility and authority for

2 bedside care that directly and unequivocally

3 impacts patient outcomes.

4 These outcomes include mortality,

5 failure to rescue, length of stay and numerous

6 hospital-acquired conditions.

7 Over 15 years of research has

8 demonstrated that the numbers of nurses and their

9 licensure level, that is, nursing hours per

10 patient day and skill mix, are closely linked to

11 these outcomes.

12 Nursing hours per patient day is the

13 number of productive hours worked by nurses with

14 direct patient care responsibilities per patient

15 day.

16 Skill mix is the percentage of total

17 productive nursing hours worked by each licensure

18 level, that is, RN, LPN and unlicensed personnel.

19 It's important for us to remember that

20 not all harm to patients can be captured through

21 measurable outcomes. These two structural

22 measures embody the ability of nurses to care for

1 patients and provide the surveillance needed for

2 safe and reliable care.

3 Nurses are at the sharp end of care

4 delivery intervening before errors can reach the

5 patient and mitigating harm when errors do slip

6 through the cracks.

7 Therefore, nursing hours for patient

8 day and skill mix are summary measures

9 encompassing all the work that nurses do as a

10 core function of hospitals to keep patients safe

11 and provide quality care.

12 Every patient deserves and expects

13 safe and reliable care. Both of these measures,

14 as Emily had mentioned, have MAP conditional

15 approval for CMS' Inpatient Quality Reporting

16 System for public reporting pending hospital-

17 level endorsement.

18 Hospital-level public reporting of

19 nursing hours per patient day and skill mix would

20 create increased transparency.

21 A proposed five-star quintile system

22 would allow consumers to have critical safety

1   information for decision-making regarding their

2   healthcare and would reflect the core service of

3   nursing to hospital care and safety.

4   So, to conclude, these critical safety

5   structural measures represent a foundation of

6   patient safety evaluation.

7   These measures take into account the

8   totality of nursing care and the ability of

9   nurses to deliver the highest quality care and

10   vigilance impacting safety outcomes, including

11   those that cannot be measured.

12   Public reporting of nursing hours per

13   patient day and skill mix would increase

14   transparency allowing patients and families to

15   make informed choices.

16   Nursing matters for patient safety.

17   Nursing hours per patient day and skill mix touch

18   every patient in every hospital regardless of

19   their diagnosis or procedures.

20   DR. NEEDLEMAN: If I can just add,

21   there's, I think, a preference for outcomes

22   measures and one that I, frankly, share, but

1   there is a role for structural measures. And I

2   think this is one of those cases.

3   We've got a number of outcomes that

4   are considered nursing-sensitive. And they're

5   considered nursing-sensitive because they have

6   been correlated with either the staffing hours,

7   or the skill mix or both.

8   Lisa, this morning, talked about

9   consumers needing when we were talking about

10   composite measures, talked about the need for

11   consumers to have simple summary measures that

12   will help them understand the care they're

13   getting and the risks associated with being in

14   different places.

15   The individual outcome measures that

16   are considered nursing-sensitive are both an

17   incomplete measure of the total work of nurses,

18   but also have not been put into a compiled

19   measure.

20   At the moment, the best single

21   composite measure we have to assess the

22   effectiveness and the ability of nursing systems

1 to deliver care are the number of hours and the

2 skill mix of the staff that are there. And

3 that's the reason why these measures are being

4 put up for re-endorsement and for hospital

5 compare.

6   MS. GELINAS: So, in addition to the

7 introductions by the measure developer, a couple

8 of additional comments since I'm the lead

9 discussant. And we have quite a few others in

10 the room that have worked on these measures.

11   First of all, I think it is enormously

12 important for this committee to recognize that

13 workforce determinants are a foundational element

14 in order to assure patient safety.

15   Much of the testimony that you are

16 hearing today is embellished, but is similar to

17 the same testimony we heard at the National

18 Quality Forum in 2002 and 2003, which in the fall

19 of 2004 nursing hours per patient day and skill

20 mix were endorsed. And they were subsequently

21 endorsed years later.

22   Your measure worksheet is incorrect,

1   because the original endorsement was not 2009.

2   It was actually the fall of 2003.

3   And I wanted that to be an important

4   component for you to understand that we've been

5   collecting these data longitudinally for a very

6   long period of time, but they have not been

7   shared with the public. They have not been

8   shared through public reporting. And I don't

9   know many other measures with over 15 years of

10   longitudinal history that have not been shared

11   with the public.

12   The other piece that is enormously

13   important for you to consider is the evidence is

14   robust. And we have proven that it holds up over

15   time. Now, over two decades of data.

16   So, the evidence that the measure

17   developers have submitted is on Page 14 of your

18   measure worksheet if you brought that with you.

19   Now, I am with you a hundred percent.

20   There were 1,129 pieces of paper that we had to

21   either download or consider for this meeting.

22   Now, I don't know about you, but this

1 isn't my only job and I'm not so sure that I

2 thoroughly and planfully considered every bit.

3 So, what I wanted to do for you is a

4 few high-level pieces that are in your measure

5 worksheet to make sure that you understand the

6 breadth and depth of the evidence that is before

7 you today.

8 And the measure developer evidence

9 table that is on Page 14 clearly shows you the

10 correlation between the skill mix and nursing

11 hours per patient day and patient outcomes.

12 And in order to read it, if there's a

13 minus sign, that means that the higher the skill

14 mix, the less the adverse event or the less the

15 issue. And I don't know about you, but I see a

16 lot of minus signs in that table.

17 The other piece that's enormously

18 important for you to understand is the diagram

19 that is on Page 9 which the measure developer

20 also submitted.

21 And if I am going to really summarize

22 the evidence for you in a table, it is this

1　diagram that shows nursing hours per patient day.

2　Again, this is on Page 9 of your measure

3　worksheet. Page 9. Looks like this -- I'm

4　sorry. I'm getting distracted. Would you mind

5　not typing?

6　　　　　　　You'll see nursing hours per patient

7　day on the left side as the structural measure,

8　and then the outcomes measure on the right-hand

9　side including patient outcomes.

10　　　　　　　When Jack was talking about the

11　importance of structural measures, I have to

12　admit that as a lead discussant I was perplexed

13　when I got the script, because I was supposed to

14　talk about the evidence only in terms of outcome

15　measures or process measures. And this is

16　clearly a structural measure that has been

17　endorsed and re-endorsed many, many times.

18　　　　　　　So, to make sure that we keep plenty

19　of time for you and your discussion, I wanted to

20　make sure that you knew that I do believe that

21　this is an enormous set of measures. And that

22　the evidence is not only clear, but it's robust,

1   which has stood up over time.

2   Well, I mean, those were our summary

3   comments for you. And I think we can open it up

4   for discussion, because it's my understanding

5   that we're going to vote after each piece. So, I

6   wanted to make sure that we save plenty of time,

7   because there's a number of components that we'll

8   need to vote on.

9   CO-CHAIR SEPTIMUS: Okay. So, the

10   first one is going to be evidence.

11   MS. GELINAS: Evidence, correct.

12   CO-CHAIR SEPTIMUS: Okay.

13   Missy.

14   MS. DANFORTH: Actually, can I just

15   ask you to clarify a comment about the measure

16   being available for 15 years and not being

17   publicly reported?

18   Is there any background on why that

19   is? So, like why has the measure not been

20   publicly reported if it's been endorsed since

21   2004?

22   DR. NEEDLEMAN: The measure has been

1 actually measured in a number of different ways.

2 In some of the earlier studies, it's overall

3 staffing divided by number of patient days to get

4 an estimate of that, or the reported RN/LPN mix.

5   Linda Aiken who has also done work

6 related to looking at staffing, and Jeff Silber

7 who developed the earlier measure you were

8 discussing, have used survey-based data based

9 upon the number of patients that nurses have been

10 asked to take care of on any given shift.

11   Some of us have used state-level data,

12 which has a little bit more granularity and are

13 able to better separate inpatient/outpatient

14 staffing.

15   As Lillee said, the evidence is very

16 robust. It almost doesn't matter how you measure

17 it. The same effects keep showing up in research

18 studies that use many different versions of the

19 measure.

20   NDNQI, as I understand it, have to

21 figure out a way to develop a measure that would

22 allow for comparability across hospitals. And

1   they developed their unit-based staffing measure.

2   And they report that to the members of that

3   through -- in a very standardized way.

4   And I think one of the attractive

5   features of what's being proposed here is to

6   bring a standardization and a separation of

7   inpatient from outpatient staffing in a very

8   clean way to the measurement of this that will

9   allow for standardization that would allow easy

10   reporting of it.

11   MS. GELINAS: And I do want to comment

12   that there are some states that are publicly

13   reporting these data; Illinois, Maine,

14   Massachusetts, Minnesota, New York and Vermont,

15   but they are very new to the public reporting of

16   those data. So, there's no trends yet and impact

17   hasn't been measured yet, but those states are

18   publicly reporting.

19   CO-CHAIR SEPTIMUS: So, that was --

20   we're going to get to usability, but that really

21   gets to usability. That's okay, but that's

22   correct and that's in our document.

1   MS. GELINAS: Yes.

2   CO-CHAIR SEPTIMUS: Josh.

3   DR. RISING: All right. Great. Thank

4   you.

5   So, in reading through the brief

6   description of the measure, I just was having --

7   I just wanted to make sure I was understanding

8   kind of it all correctly.

9   So, what it looks like it does, to me,

10   is it adds up the total number of nursing hours

11   at a given facility and then provides a

12   percentage of how much are provided by different

13   categories of nurses.

14   And so, in our -- so, that will tell

15   you what the skill mix is, right? But there's

16   also been a lot of discussion around, you know,

17   how robustly staffed, right, kind of what the

18   ratios are.

19   And so, my understanding is when you

20   do this by the percentage, that will give you

21   information on the skill mix, but not necessarily

22   on is that an adequate total number.

1   Is that -- is that kind of your

2   assessment as well?

3   MS. CRAMER: Well, correct. This

4   measure actually, the 0204, is strictly about

5   skill mix. We have another one, the 0205, is

6   about actual levels of staffing in terms of our

7   nursing care hours per patient day.

8   DR. RISING: Okay.

9   MS. CRAMER: And I don't know if you

10   want to speak to any additional comment.

11   DR. RISING: No, that's all right.

12   Okay. I just wanted to make sure, because the

13   evidence and the description seemed -- had a lot

14   about kind of staffing levels as well. So, I

15   just wanted to make sure. So, this is just about

16   the skill mix.

17   And the second question I had is that

18   the fourth kind of part of this measure like kind

19   of distinguishes the contract staff from, you

20   know, regular employees.

21   And so, I didn't necessarily see kind

22   of evidence kind of around that component of the

1   measure. So, I was curious to have a discussion

2   around that.

3   DR. NEEDLEMAN: Yeah. The most

4   important element to this is probably that RN/LVN

5   mix, because that number shows -- that percentage

6   shows up over and over and over and over again in

7   research as influencing outcomes.

8   The evidence, frankly, on agency mix

9   is a little bit less -- is not a little bit.

10   It's far less developed. There's some

11   conflicting evidence in the field about whether

12   or not it's associated with adverse outcomes for

13   patients.

14   There's a clearer body of evidence

15   being developed which shows it's associated with

16   the efficiency with which care is delivered,

17   things like length of stay, which should be of

18   tremendous interest to CNOs and CFOs.

19   So, given that the data is readily

20   available in the systems that would need to put

21   it in place, I think the assumption has been to

22   make it a slightly broader measure than the one

1   that is guided by the evidence because it is easy

2   to -- once you're compiling the RN and the LVN

3   data, the same data systems provide information

4   on agency and contract nurses. So, that is an

5   area that's going to be relevant in the future.

6   MS. GELINAS: And that was identified

7   as an area of future research in the initial

8   nursing-sensitive measures area when we were

9   recommending to NQF the more robust workforce

10   measures that needed to be built out. And

11   contract personnel was one of them.

12   DR. RISING: I mean, there's a lot of

13   information that, you know, theoretically could

14   be provided to patients and others about the

15   quality of care, but it sounds like there's not

16   really information to distinguish that last one

17   around the quality of care that's provided at

18   this point in time.

19   MS. GELINAS: Not that I know of.

20   CO-CHAIR SEPTIMUS: Yeah. The only

21   one that might fit the contract actually might be

22   in CLABSIs in the ICU, but I agree the data is

1   pretty soft.

2   Okay. Charlotte, Yanling and then

3   Victoria.

4   DR. ALEXANDER: So, as I look at the

5   two metrics, the skill mix seems, to me, to have

6   very good evidence to back it up.

7   When I look at the nursing hours

8   worked, I'm not seeing the same level of

9   evidence.

10   And I've got another question about

11 nursing hours work, and that's in regard to

12 intent.

13   CO-CHAIR SEPTIMUS: I think -- that's

14 0205, isn't it, or did I miss --

15   DR. ALEXANDER: Aren't we doing both

16 of them together?

17   CO-CHAIR SEPTIMUS: No, we're doing

18 0204 first. Then 0205.

19   DR. ALEXANDER: The introduction was

20 around them both.

21   CO-CHAIR SEPTIMUS: The introduction

22 was for both.

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1                    DR. ALEXANDER:  Okay.

2                    CO-CHAIR SEPTIMUS:  Okay.  So, maybe

3    -- I apologize --

4                    DR. ALEXANDER:  Sorry.

5                    CO-CHAIR SEPTIMUS:  -- if I did not

6    make that clear.

7                    DR. ALEXANDER:  I'll hold it off.

8                    CO-CHAIR SEPTIMUS:  Okay.

9                    DR. ALEXANDER:  So, we're considering

10   the evidence of 0204.

11                   CO-CHAIR SEPTIMUS:  0204 first.

12                   Yanling.

13                   DR. YU:  My questions relate to

14   nursing hours, too.  I know in Washington state

15   the nursing association and license --

16                   CO-CHAIR SEPTIMUS:  If it's about the

17   next measure, let's hold off until the next

18   measure.

19                   DR. YU:  Oh, okay.

20                   CO-CHAIR SEPTIMUS:  I'm sorry if I

21   didn't make it clear.

22                   DR. YU:  All right.
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1   CO-CHAIR SEPTIMUS: We're only talking

2   about 0204.

3   Victoria.

4   DR. RICH: I just wanted to add to the

5   contract. Linda Aiken did a study about two or

6   three years ago that looked at the Agency nurses

7   because as a CNO you always worried about how

8   safe those were.

9   And at that time, I think, Jack, you

10   would know that she found no difference. So, I

11   just wanted to add that for what it's worth.

12   DR. SCHREIBER: Just wonder if you

13   looked in this measure, maybe you will look in

14   the future, at the level of training for the RNs,

15   the bachelors prepared versus the not, if there's

16   any difference here, or might you consider that

17   in the future.

18   CO-CHAIR SEPTIMUS: Okay. Good point.

19   Okay.

20   MS. GELINAS: Well, in the NDNQI

21   database we do collect -- I know our organization

22   reports the level of education. I just don't

1 know if correlation studies and so forth have

2 been done.

3   CO-CHAIR SEPTIMUS: Okay. I see no

4 other hands. Let's vote on the evidence.

5   MS. IBRAGIMOVA: Importance to measure

6 and report, 1(a), evidence structure process

7 intermediate outcomes.

8   1(a) evidence. If quantity, quality,

9 consistency from SR was submitted box 5(a) high,

10 box -- oh, skip it.

11   Okay. So one, high. Only eligible if

12 QQC submitted. Two, moderate. Three, low.

13 Four, insufficient evidence.

14   (Voting.)

15   CO-CHAIR SEPTIMUS: One more.

16   (Pause.)

17   MS. IBRAGIMOVA: The results are 46

18 percent high. 50 percent moderate. Four percent

19 low. Zero percent insufficient evidence.

20   CO-CHAIR SEPTIMUS: Next is going to

21 be the gap, performance gap.

22   Any comments on performance gap?

1   (No comments.)

2   CO-CHAIR SEPTIMUS: Seeing none, we

3   can vote.

4   MS. IBRAGIMOVA: Importance to measure

5   and report, 1(b), performance gap. Data

6   demonstrated considerable variation or overall

7   less than optimal performance across providers

8   and/or population groups, disparities and care.

9   One, high. Two, moderate. Three,

10   low. Four, insufficient.

11   (Voting.)

12   MS. IBRAGIMOVA: Results are 38

13   percent high. 58 percent moderate. Four percent

14   low. Zero percent insufficient.

15   CO-CHAIR SEPTIMUS: Okay. The next

16   one is going to be reliability.

17   Do we have any discussion around

18   reliability?

19   MS. GELINAS: Well, referring back to

20   the previous question, remember there's a robust

21   evidence table with the link between the skill

22   mix and the outcomes.

1   And so, when it comes to reliability,

2   do the results demonstrate sufficient reliability

3   so that differences in performance can be

4   identified?

5   I want to refer you back to the table.

6   Page 14.

7   CO-CHAIR SEPTIMUS: We're on Page 14,

8   right?

9   MS. GELINAS: Uh-huh.

10   CO-CHAIR SEPTIMUS: Page 14.

11   MS. GELINAS: Yes. That's why I was

12   curious if -- where the evidence in the previous

13   --

14   CO-CHAIR SEPTIMUS: Yeah, we're going

15   to put this up so we can --

16   MS. GELINAS: I think there was some

17   confusion. I don't know, but it was a lot

18   stronger than the votes indicated. It's a

19   reality. Yes.

20   Any other comments --

21   CO-CHAIR SEPTIMUS: Can you find --

22   no, I'm looking for --

1   MS. GELINAS: -- about reliability?

2   CO-CHAIR SEPTIMUS: There we go.

3   There's Chart 14.

4   MS. GELINAS: There's Chart 14.

5   CO-CHAIR SEPTIMUS: So, we're trying

6   to pull it up as you talk.

7   So, anything else on this that you

8   want to point out on the chart?

9   MS. GELINAS: That was also what we

10   submitted, what KU submitted for 1(b).

11   CO-CHAIR SEPTIMUS: Okay. Any other

12   comments on reliability? Scroll that up. There

13   you go. This is the chart that Lillee described

14   earlier.

15   MS. GELINAS: So, if you scroll down,

16   you can see all the different patient outcomes.

17   So, scrolling down to the bottom is what they --

18   there you go.

19   CO-CHAIR SEPTIMUS: Well, that's still

20   evidence, but you said something about

21   reliability about the skill mix. Is that --

22   Well, that's the workshop. I thought

1 that there was something else on this chart that

2 you were referring to.

3   MS. GELINAS: No, this is just the

4 evidence of the association between skill mix and

5 patient outcomes.

6   CO-CHAIR SEPTIMUS: Okay. We already

7 passed the evidence. So, we're up to

8 reliability.

9   MS. GELINAS: So, do developers want

10 to say anything about the reliability testing?

11 The correlations are on Page 33 for reliability.

12   CO-CHAIR SEPTIMUS: All right.

13   MS. GELINAS: And, again, I appreciate

14 if everyone did not have a chance to look at it

15 all, because I was awash in paper myself.

16   CO-CHAIR SEPTIMUS: Well, that's why

17 we assign discussants and teams.

18   MS. GELINAS: That's great.

19   CO-CHAIR SEPTIMUS: Because it's hard

20 for all of us to --

21   MS. GELINAS: So, on Page 33 of your

22 measure worksheet, I'll just read the measures

1   also demonstrated high reliability at the

2   hospital level well within the recommended

3   thresholds recommended by CMS and others. Unit-

4   level reliability was also just as strong.

5   DR. LAWLESS: Is this --

6   CO-CHAIR SEPTIMUS: Steve, go ahead.

7   DR. LAWLESS: Is this reliability on

8   the measurement of the skill mix, or reliability

9   of the outcomes?

10   MS. GELINAS: The measurement.

11   DR. LAWLESS: The measurement. Okay.

12   CO-CHAIR SEPTIMUS: Yanling.

13   DR. YU: Yeah, I have this question.

14 Maybe just need a clarification, this productive

15 nursing care hours.

16   I know that -- I don't know how they

17 calculate it. Does it depend on how long a nurse

18 work per day, you know, long hours, or that we

19 know that -- this doesn't have RN hours built in

20 there.

21   Is RN hours also built into this mix

22 of skills and --

1   MS. CRAMER: It is a little confusing,

2   because the skill mix is calculated from the

3   total hours. So, I understand your question.

4   The definition is the same that we

5   have productive hours in both the skill mix and

6   the total RN hours measures.

7   And the productive hours is mostly --

8   it's about the time spent at the beside. So, we

9   are only collecting data from nurses who at least

10   spend a certain percentage of their time in

11   direct patient care and who are not in

12   administrative roles.

13   So, we're trying to tease out all of

14   the people who are mostly dealing with paperwork

15   that nurses deal with a lot of the time versus

16   actually providing patient care at the bedside.

17   So, that's what we mean by productive

18   hours. It's not in terms of the number that

19   they're working in a day, except in if that's a

20   total calculation.

21   DR. YU: Yeah. What I mean is, you

22   know, sometimes the long hours working even at

1   bedside can negatively affect the patient

2   outcome. There was a study shows that.

3   DR. NEEDLEMAN: Yes, it is a term of

4   art. And the two CNOs on that side of the table

5   ought to describe it, but basically it's the

6   number of hours that the nurse is on the unit as

7   opposed to away from the unit doing

8   administrative work or on vacation or doing --

9   MS. GELINAS: Or in education classes.

10   DR. NEEDLEMAN: -- in-service

11   training.

12   MS. CRAMER: Yes.

13   DR. NEEDLEMAN: So, it's basically a

14   count of the hours that nurses are available on

15   the units to provide care to patients no matter

16   how tired they are.

17   DR. SMIRZ: Lillee, I appreciate the

18   fact that you're not holding me personally

19   responsible for not reading every page there.

20   So, this question may already be in there.

21   Is there anybody that's looking at the

22   years of experience that a nurse has, or is it

1 just this whether or not they're an RN versus a

2 BSN versus an LPN, et cetera?

3   MS. OLDS: There is research looking

4 at nurse experience, but that's not included in

5 our measure.

6   MS. GELINAS: So, you're looking for

7 tenure equity.

8   CO-CHAIR SEPTIMUS: Victoria.

9   DR. RICH: What I wanted to add just

10 to tell you, it's called evidence-based staffing.

11 And it's really what as a leader now that we're

12 trying to look at.

13   And so then, you take that in

14 consideration with your education, but that's not

15 for today, but just as an FYI. Good question.

16   CO-CHAIR SEPTIMUS: Okay.

17 Reliability. I see no other names up. So, let's

18 go to a reliability vote.

19   MS. IBRAGIMOVA: So, for reliability

20 the votes are one, high; two, moderate; three,

21 low; four, insufficient.

22   (Voting.)

1   CO-CHAIR SEPTIMUS: Okay. We got it.

2   MS. IBRAGIMOVA: The results are 42

3 percent high. 54 percent moderate. Four percent

4 low. Zero percent insufficient.

5   CO-CHAIR SEPTIMUS: Okay. Validity

6 testing.

7   MS. IBRAGIMOVA: So, for scientific

8 acceptability of measure properties for validity

9 the votes are one, high; two, moderate; three,

10 low; four, insufficient.

11   CO-CHAIR SEPTIMUS: Any comments on

12 that?

13   MS. GELINAS: So, the results

14 demonstrate sufficient validity so that

15 conclusions about quality can be made. That is

16 the component that we should be considering.

17   And I agree from the materials that

18 the developers submitted that the measure should

19 be specified as an indicator of quality.

20   And I do want to talk about threats to

21 validity, because I thought what the measure

22 developer submitted was very strong.

```
 1                    And, Jack, the article that you
 2      published, you only measured bedside RN care,
 3      correct?
 4                    Nursing Economics.  I'm sorry.
 5                    DR. NEEDLEMAN:  Oh.  Yeah, I was
 6      focused on -- principally on the staff -- the
 7      hours -- I may have briefly mentioned staffing
 8      skill mix as well, but mostly hours, yes.
 9                    Lillee asked me about an editorial I
10      recently --
11                    MS. GELINAS:  Right.
12                    DR. NEEDLEMAN:  -- wrote for the
13      journal Nursing Economics looking at sort of the
14      state of the art of the staffing literature.
15                    And I've got to admit I spent a little
16      bit more time in that looking at hours per
17      patient day rather than the skill mix.
18                    MS. GELINAS:  So, for 05.
19                    CO-CHAIR SEPTIMUS:  Okay.  Seeing no
20      other comments, we will vote then on validity.
21                    (Voting.)
22                    MS. THEBERGE:  Ann, if you're on the
```

1 line, I need your vote.

2 (Pause.)

3 MS. IBRAGIMOVA: Is she not there?

4 CO-CHAIR SEPTIMUS: So, we should have

5 23 though, right? Okay. So, we need one more.

6 Okay. Got it.

7 MS. IBRAGIMOVA: The results are 29

8 percent high. 71 percent moderate. Zero percent

9 low. Zero percent insufficient.

10 CO-CHAIR SEPTIMUS: Okay. And the

11 next to the last we'll talk about usability.

12 We've already had a little bit of a discussion

13 about this in terms of what's being publicly

14 reported.

15 MS. GELINAS: Several states do

16 publicly report the data. Is there any other

17 comment that you want to make about usability?

18 Because I know in the NDNQI database that

19 hospitals -- over 2,000 hospitals have been

20 reporting well over a decade and are using that

21 data for improvement internally because it's not

22 publicly reported.

1   And I don't believe that any of the

2   states that are publicly reporting this data have

3   trending data yet, if that's correct.

4   MS. OLDS: Yeah, it's newer for the

5   states. We do a use and usability survey with

6   our -- with the hospitals that collect this data

7   and it's been very positive.

8   We, on Page 39 and 40, detail the

9   outcomes of this survey in terms of asking our

10   users about the burden of the data collection and

11   how they use the data.

12   CO-CHAIR SEPTIMUS: Have we done what?

13   Oh, we got -- oh, you're right. Thank

14   you. How did I miss that? I stand corrected.

15   We're on feasibility. Thank you, Charlotte. How

16   many times have I done this?

17   Thank you. Thank you. I apologize.

18   So, we're doing feasibility.

19   MS. GELINAS: It's okay.

20   DR. SCHULTZ: Leslie Schultz. I

21   apologize. I pored over a lot of the paperwork,

22   but not everything.

1   Are the NDNQI hospitals any different

2   from non-NDNQI hospitals? Do we know that these

3   data are reflective of those who don't report to

4   you?

5   MS. CRAMER: They do tend to be a

6   little bit different from the general population

7   of hospitals. We -- and that's for a couple of

8   reasons.

9   One, these are hospitals that have

10 obviously spent a lot of investment in this

11 quality improvement to participate in NDNQI.

12   A lot of them are magnet hospitals.

13 In fact, almost every magnet hospital in the

14 country participates with NDNQI. So, we have an

15 over representation there.

16   We also have over representation of

17 academic medical centers and larger hospitals who

18 have budgets that allow them to participate in

19 some of these things.

20   So, it's not quite a fair

21 representation of the general population, but it

22 is becoming more balanced all the time. We've

1   added a lot of critical access in smaller

2   hospitals. We're getting some decent

3   representation from the lower end in terms of

4   size.

5   CO-CHAIR SEPTIMUS: Pat.

6   DR. QUIGLEY: Thank you. Pat Quigley.

7   I'd just like to answer that question as well.

8   Recognizing that NDNQI services over 2,000

9   hospitals out of 5,000 in this great country, as

10   well as hospitals in other countries, there are

11   many hospitals in this hospital that use acuity

12   systems. And in acuity systems we have skill

13   mix, and we have hours per patient day.

14   So, they may have different

15   operational definitions which is part of what

16   sets this indicator at such high regard, is that

17   there is such incredible validity and reliability

18   in relationship to the measure.

19   So, that, I think, is really one of

20   the strengths, but this process is in place in

21   other hospitals as well. Thank you.

22   CO-CHAIR SEPTIMUS: We're on

1   feasibility. We've already discussed usability,

2   but we still have to do feasibility.

3   MS. DANFORTH: I had a question

4   related to use and usability. Can I ask that?

5   CO-CHAIR SEPTIMUS: Let's finish up

6   the feasibility --

7   MS. DANFORTH: Okay.

8   CO-CHAIR SEPTIMUS: -- since I screwed

9   it up already. Any other questions about

10   feasibility, and then we'll finish up with -- I

11   apologize. That's my error.

12   CO-CHAIR THRAEN: So, I have a quick

13   question. So, how are these data -- these data

14   are collected through the nursing-sensitive

15   indicator data systems?

16   MS. GELINAS: Correct.

17   CO-CHAIR THRAEN: Okay.

18   MS. GELINAS: By each of the

19   individual hospitals.

20   CO-CHAIR THRAEN: Okay.

21   MS. GELINAS: And then that data is

22   returned back to us quarterly and we use it for

1 internal performance improvement a great deal.

2 CO-CHAIR THRAEN: Is that a manual

3 collection, basically? So, it's not claims, it's

4 not clinical record information. This is a

5 manual --

6 MS. GELINAS: I would say it's a

7 combination of electronic and manual depending on

8 what the systems are.

9 CO-CHAIR THRAEN: Okay. Thank you.

10 CO-CHAIR SEPTIMUS: Pat, did you want

11 to comment?

12 MS. GELINAS: Did you want to comment?

13 MS. CRAMER: I was just going to

14 comment. We do -- as Danielle mentioned, we do

15 ask participants in NDNQI to tell us about what

16 the data collection process is like, because we

17 know that there's sometimes manual corrections,

18 because the way we set it up isn't exactly the

19 way it comes out of their administrative data.

20 And there's some details in that in

21 the worksheet, but most of them say it takes them

22 a little while to get it set up for their first

1   data pull, but then after that it's pretty

2   automated. So, it's not a huge burden in terms

3   of adjusting for the pulling from administrative

4   claims and then slight corrections.

5   MS. OLDS: And I just want to add that

6   93 percent of hospitals get it from some sort of

7   electronic system whether it be electronic

8   payroll account or accounting system at 61

9   percent. And 32 percent get it from electronic

10   staffing systems.

11   CO-CHAIR THRAEN: So, in follow-up of

12   that, how -- so, the research you provided is

13   basically study-based research related to

14   outcomes. You're collecting the manpower, person

15   power of that of this side of the question.

16   How are you -- what's the intent to

17   move that now towards mapping the skill bases to

18   the outcome separate from just -- from a

19   research-based approach to a surveillance kind of

20   modeling?

21   Is there any conversations around

22   that? Does that make sense? Am I asking the

1   question correctly?

2   MS. GELINAS: I don't know if I

3   understand it, because we certainly use it for

4   operational improvement pretty immediately after

5   every quarter, put data back, yes.

6   CO-CHAIR THRAEN: Okay. So, that's

7   the quality improvement methodology. But in

8   terms of the public accountability question and

9   in terms of mapping, this is not a process

10   measure, it's a structural measure to outcomes

11   even though we have individual studies, research

12   studies that indicate that there is a

13   relationship.

14   I guess my question is, where are you

15   moving in terms of being able to move this

16   forward to a point of population health

17   surveillance kind of activity, or does this stand

18   on its own, which is separate?

19   MS. GELINAS: That's Jack's question.

20   DR. NEEDLEMAN: Yes. So, this has

21   been proposed as a -- these have been proposed as

22   measures for the hospital compare dataset, which

1   is about public accountability, summary

2   reporting, assessment of quality for consumer

3   use.

4   And, frankly, my experience with most

5   public reporting systems is they do a better job

6   of shaming hospitals than the public does abusing

7   them, but that's a whole other discussion, but

8   that's the intent.

9   And the MAP endorsed it, gave a

10   conditional endorsement subject to the hospital

11   level measure that's before you now being

12   endorsed in its current form, which is the reason

13   it's here, but the long-term -- the goal and

14   intent is to move it into hospital compare to

15   deal with the accountability issue.

16   CO-CHAIR SEPTIMUS: Okay. Well, let's

17   vote -- oh, I'm sorry. Steve.

18   DR. LAWLESS: One question for you.

19   Steve Lawless. I look at it as a quadrant, per

20   se, and nursing staffing levels or hours and

21   quality.

22   So, are you also looking, are the

1 studies looking at those who are well staffed,

2 higher end, and have worse outcomes? There's a

3 problem there with other systems.

4 Are you looking at it with that much

5 scrutiny versus just skill mix by itself?

6 MS. GELINAS: So, that's for the

7 measure developer. Are you looking -- did you

8 hear -- are you looking at, I guess, the inverse

9 proportion if you're well-staffed, but you have

10 poor outcomes?

11 DR. LAWLESS: Yeah, I mean, I would

12 worry that if you had -- it's a quadrant. So, if

13 you have good staffing or high staffing and

14 despite that you have bad outcomes, for me that

15 would be a, whoa, what's going on in that place

16 more than just high outcomes.

17 And so, are you looking at developing

18 that kind of a quadrant or that kind of a skill

19 mix combination?

20 I'm going to something that she said

21 over here with that in terms of experience. So,

22 your outcomes aren't necessarily just there.

1   MS. CRAMER: We haven't done any of

2   that specifically looking at high skill mix, low

3   outcomes. Ours is mostly the whole trend line

4   rather than dividing into quadrants.

5   DR. NEEDLEMAN: So, the research

6   that's out there right now shows very strong

7   associations. And I would argue enough evidence

8   to argue causal relationships between both the

9   skill mix and the staffing hours, which we're not

10   talking about right now.

11   There are other things that have been

12   found to be correlated and interact with those.

13   The education of the nurses, which was raised

14   earlier, and the hospital work environment.

15   And there's a lot of research that's

16   looked at that, but that is all work that builds

17   upon the fact that the staffing skill mix and the

18   hours matter a lot and it modifies the effects of

19   that.

20   So, people have been looking at who

21   the negative outliers are and what other things

22   seem to be associated with being a negative

1 outlier despite having good staffing or good

2 skill mix.

3   DR. LAWLESS: So, the reason I bring

4 it up is it turns it from a structural measure,

5 which is, do you have the staff, into more of a

6 process measure or performance measure of what am

7 I doing with all this good staff.

8   And I'm asking, because it makes me

9 influence a little bit of structural measure,

10 yeah, it makes sense to do this. But if I'm

11 looking at a hospital performance, I would now

12 expect better outcomes. If I don't, that's where

13 I would like to earmark why am I not getting the

14 better outcomes.

15   I'm not - -maybe one percent or two

16 percent, but that turns it, for me, from just a

17 pure structural into something a little bit more.

18   MS. GELINAS: So, I think the answer

19 from the developer was, no, they're not looking

20 at that, but others are.

21   CO-CHAIR SEPTIMUS: Okay. Is this

22 about feasibility, because we're getting a little

1   bit off.

2   So, let's vote on feasibility so we

3   can get through this. And then I think the next

4   measure will bring up all the issue about hours.

5   MS. IBRAGIMOVA: So, the votes for

6   feasibility is one, high; two, moderate; three,

7   low; four, insufficient.

8   (Voting.)

9   MS. IBRAGIMOVA: The results are 63

10   percent high. 38 percent moderate. Zero percent

11   low. Zero percent insufficient.

12   CO-CHAIR SEPTIMUS: Okay. Now, the

13   last - next one -- I'm trying to get this right -

14   - is usability.

15   Okay. And I think we've had a lot of

16   discussion about public reporting. So, we --

17   Missy has another comment about public reporting.

18   MS. DANFORTH: I have a couple of

19   questions. So, the intent of the measures is to

20   have them used in the Inpatient Quality Reporting

21   Program.

22   Right now there are other registries

1   like NHSN where the data flows directly from NHSN

2   to CMS to be published on hospital compare.

3   Is that a similar vision, or do you

4   somehow envision CMS developing some sort of a

5   structure for the hospitals to report the data to

6   them, or do you report data directly from the

7   NDNQI database?

8   I think it's an important question for

9   hospitals related to burden.

10   MS. GELINAS: So, I know internally we

11   haven't talked about that as a process step,

12   because we already report to NDNQI.

13   So, it seems to be fairly simple to

14   transmit directly to CMS.

15   MS. DANFORTH: And that's what I'm

16   asking. And I think that applies to use and

17   usability.

18   MS. CRAMER: I see that as a

19   possibility. Although, I would hesitate to

20   require, I mean, the availability of something

21   where hospitals can report it directly was

22   probably necessary given that currently NDNQI is

1   a service that hospitals have to pay for.

2   Not everyone enrolls in it. So, it's

3   not quite the same as some of those regulatory

4   things that people are doing with like NHSN.

5   MS. DANFORTH: So, do you have a sense

6   of the burden for collecting this data for non-

7   NDNQI hospitals then?

8   So, like right now hospitals are

9   reporting this, too, electronically and then

10   you're doing the calculations for them.

11   So, if a hospital is just reporting

12   this data not to NDNQI, because they don't want

13   to pay and it becomes part of the IQR, what's

14   your sense on the burden of reporting for those

15   hospitals?

16   MS. OLDS: I would imagine that the

17   reporting would be fairly low since -- the burden

18   of reporting would be fairly low since, I mean,

19   even though NDNQI hospitals are not directly, you

20   know, they over represent in a number of

21   categories, I think the fact that we have 93

22   percent of the hospitals who are able to pull

1 this electronically that I would imagine that's

2 pretty reflective of most hospitals in the

3 country in terms of being able to pull this data

4 electronically.

5   CO-CHAIR SEPTIMUS: Pat.

6   DR. QUIGLEY: Thank you. Pat Quigley.

7 And I would like to respond, too, to Missy in

8 relationship to what gets reviewed and in terms

9 of quality improvement, program evaluation in

10 every hospital.

11   Every nurse executive has a shared --

12 has an executive group working with their chief

13 CEOs and their chief fiscal officers to be able

14 to look at staffing.

15   And while it's not part of this

16 discussion, I will say in terms of patient

17 safety, everyone looks at patient satisfaction,

18 you know.

19   Is patient satisfied with pain

20 management? Response to call light? And it all

21 comes back to nurse staffing.

22   So, you know, when you have the core

1 measures in terms of skill mix and hours, that is

2 the essential foundation to be able to even look

3 at the healthcare as delivered.

4 So, I would say in terms of the

5 usability, everybody is doing this already and

6 trying to link it to care processes and outcomes,

7 ultimately outcomes.

8 And I still go back to the original

9 definition of what patient safety practices were

10 that came out of the 1999 report, IOM report To

11 Err is Human, and we had the first AHRQ report

12 2001 on making healthcare safer, that patient

13 safety practice is a structure and a process. It

14 has the predictability to be able to predict

15 outcomes.

16 So, this is why this is so essential

17 in terms of the usability is that we have to have

18 essential, core measures to be able to measure

19 staffing and outcomes. So, thanks, Missy, for

20 that question.

21 CO-CHAIR SEPTIMUS: I'm going to try

22 to draw this to a close. We're getting a little

1 bit behind and I know at the end of the day it's

2 getting more and more difficult to focus.

3 But if we can hold it together, I

4 think we'll go through the next measure much

5 faster. So, we've had a lot of discussion,

6 except for hours, which we'll come back to, but

7 let's go through usability. And then we'll go

8 through whether or not we should endorse the

9 measure.

10 MS. IBRAGIMOVA: So, the votes for

11 usability and use are one, high; two, moderate;

12 three, low; four, insufficient information.

13 (Voting.)

14 MS. IBRAGIMOVA: The results are 38

15 percent high. 54 percent moderate. Four percent

16 low. Four percent insufficient information.

17 CO-CHAIR SEPTIMUS: Okay. This is for

18 overall suitability for endorsement. I'm not

19 sure you need to read this.

20 MS. IBRAGIMOVA: So, overall

21 suitability for endorsement. One, yes. Two, no.

22 (Voting.)

1   MS. THEBERGE: Ann, your vote hasn't

2   come through on overall.

3   (Pause.)

4   CO-CHAIR THRAEN: Do we need to vote

5   again?

6   MS. IBRAGIMOVA: The results are 96

7   percent yes. Four percent no.

8   CO-CHAIR SEPTIMUS: Okay. So, now

9   we're going to go to what a lot of people want to

10   discuss, if you haven't already discussed. So,

11   again, let's try to stay focused.

12   This one has to do with RN hours per

13   patient day. And so, we'll start off with the

14   evidence.

15   And so, I know a number of you had

16   questions, but I did ask you to hold off until

17   this time.

18   Who's the discussant for this one?

19   MS. ARDIZZONE: I am.

20   CO-CHAIR SEPTIMUS: Okay. Do you have

21   anything you want to add before we start the

22   discussion?

1   MS. ARDIZZONE: I think we've talked

2   about a lot. I just want to remind everybody

3   that this is a re-endorsement. It was originally

4   in 2003. And then 2009. And 2012 it was re-

5   endorsed most recently. This is because we're

6   adding hospital-level data that it needs a full

7   re-endorsement.

8   Again, this is number of productive

9   hours worked by RNs with direct patient care

10   responsibilities per day for each inpatient unit

11   in a calendar month.

12   The evidence, I just wanted to say,

13   again, is strong. There's a systematic review.

14   Nine longitudinal studies and one systematic

15   review were identified. The studies were

16   evaluated for effective nurse-to-patient ratios

17   on outcomes, possible harms, costs, ease of

18   implementation.

19   We conclude that the nurse-staff

20   ratios are consistently associated with a reduced

21   risk of death and all the other things we've

22   talked about before.

1   Although there was a comment from the

2   NQF staff that, you know, it's only moderate

3   level of evidence because they're not randomized

4   control trials. However, it would really not be

5   appropriate to do randomized control trials on

6   patients and change the staffing to see who did

7   better and who did worse.

8   (Laughter.)

9   MS. ARDIZZONE: Again, just to refer

10   you, there's a large table of evidence on Page 15

11   here, which is the same one as before with the

12   positives and the negatives associations.

13   So, I can't give it a high level of

14   evidence because it's not an RCT, but I think

15   it's very, very, very strong.

16   CO-CHAIR SEPTIMUS: Okay. This is

17   open for -- let's go to Charlotte.

18   DR. ALEXANDER: So, as I was looking

19   at the evidence, it looks like most of it is

20   based on staffing and not on hours.

21   And I have a similar concern about

22   hours and this may be unintended consequences

1		more than evidence, but certainly when you look

2		in the patient safety world when you start

3		working more than eight hours, you start having

4		an increase in errors.

5			And I think there's a dichotomy in

6		what we're asking our nurses to do. We ask them

7		to work over to keep our staffing levels up and

8		we're putting them in a position where they're

9		fatigued and they get burned out and errors

10		happen.

11			And so, I have a concern about a

12		measure that is measuring nursing hours that

13		might push a little bit that way. And so, I'm

14		not certain the evidence supports the hours and I

15		think it may have unintended consequences.

16			MS. ARDIZZONE: Unless the developers

17		want to take it, I mean, what I can say is I've

18		seen some of that data and I don't think what

19		they're trying to intimate here is -- they're

20		trying to quantify the nursing hours, not saying

21		you should work 12 or you should work 11.

22			They're just trying to quantify hours

1 delivering patient care, needed patient care

2 versus that -- your unit staff, but half the time

3 your nurse is at an educational meeting, at a

4 committee meeting doing some charting as a CNS.

5   You can't count that into your nurse-

6 patient hours, because that's not delivering

7 patient care.

8   I don't think it's touching the issue

9 of -- I think what you're alluding to is

10 mandatory overtime, 12-hour shifts, flex time,

11 things like that and I don't think this has

12 really much to do with that.

13   I think this is quantifying nurses

14 that you have that are giving direct, needed

15 patient care. And we should know that direct

16 patient needed care saves lives, changes

17 outcomes.

18   CO-CHAIR SEPTIMUS: Missy.

19   MS. DANFORTH: Thanks. And, again,

20 this might just be because it's late in the day,

21 but can you talk about the differences, I guess,

22 since all the evidence is based on the

1 relationship between nurse-to-patient ratios, why

2 the denominator here is patient days, not

3 patient, and then how the patient days are

4 calculated?

5 I know you offer like four methods,

6 but it was a little bit confusing to me. So, a

7 patient day within a unit could potentially be

8 like ten days, but 30 patients.

9 So, could you just talk about your

10 choice of the denominator being days instead of

11 patients when all of the evidence is about nurse-

12 to-patient ratios, and then talk specifically

13 about how you calculate the patient days?

14 DR. NEEDLEMAN: Yes. This has to do,

15 in part, with how the data is collected. We're

16 back to burden a little bit. And there are a

17 variety of different ways of doing that.

18 Because nurses -- some nurses work 12-

19 hour shifts, some work eight, many nurses in

20 hospitals are actually working part time, they

21 may pull one or two twelves rather than three a

22 week, they may work four-hour shifts or split

1 shifts, it's hard to sort of count the number of

2 patients per nurse on any -- at any given time or

3 average that out.

4 The hours that are available during

5 the day or during the week divided by the number

6 of patients represent a way to standardize the

7 different work patterns of nurses.

8 There are researchers that have looked

9 at the hours per patient day and translated that

10 into the number of patients per nurse during a

11 normalized eight-hour shift and estimated the

12 impact of that.

13 So, the Kane meta-analysis of these

14 studies that appeared in Medical Care, for

15 example, took many studies which were basically

16 hours per patient day and translated that to the

17 effect of one additional patient -- the burden of

18 one additional patient on a nurse over the course

19 of a standard shift.

20 So, the two are frequently viewed as

21 simply translations of one another taking into

22 account the variety of work forces -- variety of

1 work times that the -- kinds of work schedules

2 that nurses have. I got it eventually.

3 MS. DANFORTH: So, is it comparable?

4 So, are patient hours comparable to patients, I

5 guess, is what I'm asking.

6 And so, how is that figured into the

7 methods you have for calculating patient days?

8 MS. OLDS: That's a great question.

9 So, we classify a patient day as 24

10 hours. One of the challenges with that is if you

11 have short stay or observation units, patients

12 may not stay a full 24 hours.

13 And so, using our calculation methods

14 which we have on Page 24, units can choose the

15 method. And we make recommendations of which is

16 the most accurate way for them to count their

17 patients.

18 And so, that sort of plays in a bit to

19 the feasibility and use and usability in terms of

20 how units choose to calculate the method.

21 MS. CRAMER: And if you're interested

22 in reading lots of extra stuff, in the technical

1 report is also a reliability study of the patient

2 days indicator itself. So, we've done separate

3 reliability studies on the patient days. So, the

4 denominator has its own reliability associated

5 with it.

6 CO-CHAIR SEPTIMUS: Okay. Pat, and

7 then Steve.

8 DR. QUIGLEY: Thank you. Pat Quigley.

9 And I'd like to comment, too, and add to, Dr.

10 Alexander, to your question in that the NDNQI

11 data in measuring the hours per patient day, this

12 actually quantifies the amount of time in, as you

13 had heard, in productive hours, time at the

14 bedside. And this becomes the core anchor, the

15 structure anchor to then be able to measure other

16 metrics.

17 And I think part of what you were

18 asking is moving us into the usability, is how do

19 you use this as a core anchor to be able to look

20 at the effect of that time, as well as the skill

21 mix on patient outcomes.

22 I think that that's where you were

1 going into the relationship to the usability, but

2 this is that core anchor to be able to look at

3 those other things. And that's where the

4 performance gap is in the usability.

5 CO-CHAIR SEPTIMUS: Steve.

6 DR. LAWLESS: Yes, two. One was a

7 follow-up to something you just said about the

8 observation status.

9 I mean, the 48-hour rule. Somebody

10 being in the hospital 47 hours is not being an

11 inpatient.

12 You said people have an elective. You

13 can either use those patients or not in your

14 calculation, or are they excluded? That's one.

15 And the second thing is the definition

16 of "nonproductive time," you're defining it as

17 education hours, committee time.

18 There are -- and I'm going to use the

19 word "diversion" not in a narcotic sense, but

20 there is diverting activity for a nurse at the

21 bedside which are not -- they're at the bedside,

22 but they're still not doing direct patient care.

1   We're finding with the EMR that

2   patients are complaining more that are you

3   talking to the computer, or are you talking to

4   me?

5   So, maybe you want to consider for

6   future nonproductive bedside time which is

7   diverting actually from direct clinical time,

8   because that may become the newer generation

9   nonproductive time.

10   DR. NEEDLEMAN: Yes, there are an

11   increasing number of studies that are looking at

12   how nurses spend their productive time. And I

13   will tell you about 25 percent of it isn't

14   documentation.

15   And luckily, the EHR doesn't seem to

16   have increased that, but it hasn't decreased it

17   either.

18   So, there are studies that are

19   actually looking at the distribution of how

20   nurses spend their time, but the -- and what

21   impact that has on things like missed care and so

22   forth and those studies are going on.

1   And one of the things that's going to

2   enable them to go on is a good national database

3   on the core understanding what the staffing

4   levels are, what the hours per patient day are.

5   CO-CHAIR SEPTIMUS: Any other question

6   about the observation? They can decide yes or no

7   to include observation hours then?

8   MS. OLDS: So, at this point hospitals

9   choose which units they wish to submit data on.

10   And we do include observation patients. And we

11   have a validated unit typology that we use that -

12   - I believe it's in the scientific supplement on

13   how those units are classified.

14   CO-CHAIR SEPTIMUS: Chris.

15   DR. COOK: Yes, this is Chris Cook.

16   The issue I'm having, I guess, with both

17   measures, the last one and this one, is the fact

18   that, you know, definitely is a structural

19   measure.

20   But if you're using it by itself just

21   from what the definition is, it still doesn't

22   tell you anything. You have to still be able to

1   use it in reference with other quality measures

2   to then be able to push back. And a lot of this

3   is more of a business function as anything else.

4   And since this has been around since

5   2003, it seems to me we've got to be able to get,

6   I mean, I will say this: I applaud you guys for

7   what you've done for nursing and what's there. I

8   will say pharmacists are in the exact same boat.

9   I would say physicians are in that exact same

10   boat of being pressed further and further of how

11   many patients, you know, how many minutes you get

12   with a patient.

13   I don't know how we solve or crack the

14   nut just to solve this, but we've got to be able

15   to do something either that puts it at what is

16   your institution in as a percentile that sort of

17   gets to a point, at what point below percentile

18   do you start really seeing the negative factors,

19   you know, for patient care, or putting it in

20   association with another type of outcome measure

21   that then allows you to equate what's there.

22   But right now just by itself and

1 especially even in -- if it's reported at a state

2 level if you put those numbers out there, I have

3 no idea what that ratio mix is or what that hour

4 is, you know, the ratio between nursing hours to

5 patient unless you put it with something else of

6 some type of outcome quality. Sorry. Just a

7 statement.

8   CO-CHAIR SEPTIMUS: I think we're

9 going to go to Josh, and then Victoria, and then

10 --

11   DR. RISING: Hi, this is --

12   CO-CHAIR SEPTIMUS: Let me see if I

13 understand. When looking at the evidence, and

14 the evidence is does nursing care hours have an

15 impact on patient safety and quality of care, am

16 I correct on that? Okay. So, that's what we're

17 discussing here in terms of the evidence.

18   Is there evidence that the nursing

19 hours have an effect on patient care? I just

20 want to make sure I pose the right question.

21   Josh.

22   DR. RISING: Hi. Josh Rising. Two

1 questions that I have. So, the first has to do

2 with the ability of the hospitals to kind of

3 choose different units.

4   All right. I mean, we all know

5 different units in hospitals will have different

6 staffing ratios, you know. So, theoretically

7 hospitals that don't have, you know, intensive

8 care units or have very small ones would look

9 worse kind of on this measure compared to

10 hospitals that do have intensive care units just

11 due to their usual staffing mix; is that correct?

12   MS. CRAMER: That's correct. And

13 NDNQI initially designed this measure for unit

14 level. So, that's why we did that so that you

15 can compare critical care units to critical care

16 units.

17   When we created the hospital-level

18 measure, we actually standardize it so that each

19 unit type has a weighting based on other units of

20 that type. So, critical care units are all --

21 and then it's also that standardized score is

22 then weighted by the patient volume for that unit

1 type so that if Hospital A has four critical care

2 units and Hospital B only has one, their

3 standardized score is going to be weighted not

4 only by the unit type, but also by the number of

5 patients in that unit type.

6 And then those standardized scores are

7 aggregated to create the hospital-level metric so

8 that those two things are accounted for.

9 DR. RISING: Okay. Great. Thanks.

10 That's helpful.

11 My second question has to do with the

12 -- I know where this may be shifting at just

13 slightly, but to the disparity kind of section

14 kind of where you talk about the range kind of,

15 you know, hospital scores on this.

16 So, it looks like low-performing

17 hospitals, you know, you say it looks like about

18 five hours of nursing care per patient day. And

19 the highest hospitals are about 15 hours of

20 nursing care per patient day.

21 I mean, to me, that seems like a

22 pretty incredible spread kind of to have. So, I

1   was curious if you could kind of comment on, you

2   know, on does that really reflect the reality

3   that you're going to have some hospitals at five

4   and some at 15?

5   CO-CHAIR SEPTIMUS: Well, go ahead and

6   answer. That's going to be covered in the gap

7   question, but go ahead and answer that question

8   now.

9   MS. OLDS: So, you're asking if the

10   range of nursing care hours that's reflected here

11   at the hospital level is what --

12   DR. RISING: I mean, it's just such a

13   large range, right --

14   MS. OLDS: Yes.

15   DR. RISING: -- that you would have

16   some hospitals five hours of nursing per patient

17   day, and some would have 15.

18   So, I was wondering if you could, you

19   know, just comment on, I mean, do you think is

20   that accurate; do you think? You know, what's

21   your sense on kind of what could, you know, why

22   some hospitals would be that different kind of

1 on, you know, an assessment like that.

2 MS. OLDS: I think that that's

3 accurate. I think that you're going to have some

4 hospitals that really allocate resources toward

5 nursing, and some hospitals that, for whatever

6 reason, don't.

7 MS. CRAMER: You can also look at it

8 by the hospital type, because there's certain

9 types of hospitals that staff -- general

10 hospitals tend to staff more broadly. And, like,

11 pediatric hospitals lots of times overstaff or

12 you'll see different types of that range across

13 hospital types would be a little bit -- would be

14 kind of visible, too.

15 CO-CHAIR SEPTIMUS: Victoria.

16 DR. RICH: Some of this that might be

17 helpful is the hours of care and particularly

18 what we did at Penn was we looked at the acuity

19 of the patient. And we always looked at the CMI

20 of what was happening with the severity of

21 illness.

22 And just to share even though this is

1   a structural model, what CNOs are doing across

2   particularly the academic centers, back to kind

3   of what you're saying, Dr. Alexander, is that

4   every time I wanted to look at intuitively from

5   my shared governance that we didn't have enough

6   nurses or hours of care on a unit, we would look

7   at our outcome indicators, all our nursing-

8   sensitive outcomes, our falls, our pressure

9   ulcers and very commonly you could increase hours

10   of care based on what those quality outcomes

11   were.

12   And so, hours of care for us are very

13   important moving forward. And we benchmark those

14   with like organizations.

15   And so, they're not individual nurses.

16   They're to be the amount of the direct care

17   touched by that patient by an RN.

18   And sometimes on a 12-hour shift,

19   unfortunately, and you can't drill down, that

20   might be one or two nurses. And sometimes you

21   have two nurses with one patient, but I want us

22   all to think about its acuity and hours of care

1 are now a metric that we can benchmark to look at

2 the patient and quality safety outcome.

3   So, hours of care are very important

4 and we need to standardize those because that's

5 not only -- that also helps us with outcomes, but

6 it also helps with financial messages to non-

7 nurses within organizations.

8   CO-CHAIR SEPTIMUS: Okay. The last

9 two comments and then we have to go to vote. So,

10 we're going to go to Yanling and then to Jason.

11   DR. YU: I'm still struggling with

12 this. Definitely I see the evidence. I agree

13 the evidence is strong that you have nursing

14 hours that correlate highly with the patient

15 safety, but my concern is if you got down to the

16 facility level, how do you -- when you calculate

17 the parameter, how do you separate it that long

18 working hours versus you hire nurse versus

19 patient ratio.

20   So, you can get the same nursing hours

21 either by increasing the nurse working hours, or

22 by increasing the number of nurses per patient,

1   right?

2   So, when you're down to the facility,

3   how do you make sure that nurses are not burned

4   out and they have adequate ratio?

5   To me, the adequate ratio is more

6   robust than the hours when you come down to

7   really calculate the cumulated how long the hours

8   are worked at a facility, if I understand

9   correctly.

10   DR. RICH: I just think that -- I

11   don't think that's really the intent of what

12   we're trying to look here.

13   I hear what you're saying, but I think

14   that would be for another measure with fatigue

15   and actual bodies.

16   But with hours of care and then what

17   you're drilling down to, I don't think, is the

18   intent of what we're doing now.

19   And I think we could talk off site for

20   that, but what you're saying is there are

21   multiple layers of hours of care.

22   But for us to have hours of care to

1   begin with and start to have that as a measure,

2   it starts us to start to have more powerful

3   meaning to look at that it's not a nurse that

4   works 18 hours, but it's maybe two or three

5   nurses.

6   CO-CHAIR SEPTIMUS: Okay. Jason, and

7   then we're definitely voting and we're going to

8   move through this quickly.

9   DR. ADELMAN: Jason Adelman. I'm

10   struggling with reconciling the previous measure

11   with this measure.

12   From the perspective of the first

13   measure if you look at the numerator definition,

14   there's four numerators. It's almost as if

15   there's four measures and it's -- for nurses and

16   nurse aides there's the total hours. Each

17   numerator is the total hours over the total

18   hours.

19   And then for the second measure it's

20   let's take the sum of all those hours of all

21   those people again and look at patient days.

22   And if you want to know something

1 like, for example, how many nurse hours are

2 there, just nurses per patient day like let's say

3 you believe that the more -- if a nurse spends

4 three hours with a patient, then that will

5 decrease medication errors. And if nurses aides

6 spend two hours with patients, then maybe that

7 will decrease falls. And these are important

8 ratios.

9   You almost have to, like, multiply the

10 two measures together because of the odd way

11 they're structured to get at it. And it feels

12 like a simple change will, like, make them much

13 clearer.

14   Like, for example, why doesn't the

15 second measure also have separate numerators so

16 that I can know how many nurse hours there are

17 per nurse day, how many nurse aides hours. And

18 then I can answer the question, you know, does

19 three hours of nurse aides to help toileting

20 decrease falls?

21   It's just odd to me why the first one

22 is split in that way and the second one is -- so,

1   maybe you can answer that.

2   CO-CHAIR SEPTIMUS: Emily.

3   MS. CRAMER: Actually, we do split

4   them. It may not be clear, but NDNQI does split

5   them and report them separately.

6   So, we give them four -- hospitals

7   that participate, we give them four rates, I

8   think. It's total nursing hours, and then RN

9   hours, LPN hours and UAP hours total divided by

10   the --

11   DR. ADELMAN: So, then why would the

12   --

13   CO-CHAIR SEPTIMUS: Jason, part of the

14   reason why it's parameterized this way is much of

15   the research has been done with total hours or

16   licensed hours per patient day, and then the

17   split of those across the different levels of

18   skill mix.

19   So, you're right. They get multiplied

20   together to get the answer to how many RN hours

21   per patient day do you have, but most of the

22   research actually sort of has looked at it this

1 way. So, the measure is tracking to -- for

2 public reporting is tracking to the way the

3 research has found the effects.

4 And when we did our 2002 study, we

5 also found that these two measures, the skill mix

6 and the number of hours, were actually

7 orthogonal. They were not highly correlated.

8 So, each gives you valuable and distinct

9 information.

10 CO-CHAIR SEPTIMUS: Okay. We're going

11 to vote. And you vote on what you heard and what

12 the level of evidence is, but we need to vote.

13 I think we've got a pretty good

14 discussion. So, Laura.

15 MS. IBRAGIMOVA: So, 1(a) evidence for

16 structure process intermediate outcome. Votes

17 are high only eligible acute UC submitted; two,

18 moderate; three, low and; four, insufficient

19 evidence.

20 (Voting.)

21 CO-CHAIR SEPTIMUS: What happened?

22 MS. IBRAGIMOVA: One second.

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 1                    (Pause.)

 2                    CO-CHAIR SEPTIMUS:  Looks like a

 3        revote.

 4                    MS. IBRAGIMOVA:  Revote.

 5                    CO-CHAIR SEPTIMUS:  Okay.  Everyone

 6        revote.

 7                    (Revoting.)

 8                    MS. IBRAGIMOVA:  So, the results are

 9        high, 25 percent.  Moderate, 71 percent.  Low,

10        four percent.  Insufficient evidence, zero

11        percent.

12                    CO-CHAIR SEPTIMUS:  Okay.  So, let's

13        go to the next, which is gap.

14                    MS. IBRAGIMOVA:  Importance to measure

15        and report performance gap.  The vote is one,

16        high.  Two, moderate.  Three, low.  Four,

17        insufficient.

18                    (Voting.)

19                    MS. IBRAGIMOVA:  So, the results are

20        50 percent high.  38 percent moderate.  13

21        percent low.  Zero percent insufficient.

22                    CO-CHAIR SEPTIMUS:  Okay.  The next
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1 one, I hope I get this right. Tell me it's

2 reliability.

3 MS. IBRAGIMOVA: Scientific

4 acceptability of measure properties, 2(a),

5 reliability. The votes are one, high. Two,

6 moderate. Three, low. Four, insufficient.

7 MS. ARDIZZONE: If I could just

8 comment, on Page 33 the developers provided a

9 summary table that performed ICC at unit in

10 hospital levels and the numbers were acceptable.

11 (Voting.)

12 MS. IBRAGIMOVA: The results are 42

13 percent high. 58 percent moderate.

14 MS. ARDIZZONE: Just to comment on

15 validity on Page 36, the measures also submitted

16 a table that showed acceptable validity was done

17 at both the unit and the hospital level.

18 CO-CHAIR SEPTIMUS: Okay. Seeing no

19 questions, let's go. Vote.

20 MS. IBRAGIMOVA: So, for scientific

21 acceptability of measure properties, 2(b),

22 validity, the votes are one, high; two, moderate;

1   three, low; four, insufficient.

2   (Voting.)

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

4   (Pause.)

5   MS. IBRAGIMOVA: The results are 25

6   percent high. 75 percent moderate. Zero percent

7   low. Zero percent insufficient.

8   CO-CHAIR SEPTIMUS: Now, I hope I get

9   the next one correct. We're going to talk about

10   feasibility.

11   Any comments on feasibility?

12   (No comments.)

13   CO-CHAIR SEPTIMUS: Okay. Let's vote.

14   MS. THEBERGE: Not yet. Not yet.

15   (Pause.)

16   CO-CHAIR SEPTIMUS: There we go. Go

17   ahead.

18   MS. IBRAGIMOVA: So, for feasibility

19   the votes are one, high; two, moderate; three,

20   low; four, insufficient.

21   (Voting.)

22   MS. THEBERGE: Ann and Kimberly, we

1 need your votes.

2   (Pause.)

3   CO-CHAIR SEPTIMUS: Two more.

4   MS. THEBERGE: Ann, your vote hasn't

5 come through.

6   (Pause.)

7   CO-CHAIR SEPTIMUS: Is everybody still

8 in the room? Okay.

9   (Pause.)

10   MS. IBRAGIMOVA: So, the results are

11 52 percent high. 48 percent moderate. Zero

12 percent low. Zero percent insufficient.

13   CO-CHAIR SEPTIMUS: Okay. The next

14 element is usability. Again, this goes into

15 measure being used and reported.

16   MS. IBRAGIMOVA: So, for usability and

17 use the votes are one, high; two, moderate;

18 three, low; four, insufficient information.

19   CO-CHAIR SEPTIMUS: Okay. We'll vote.

20   (Voting.)

21   CO-CHAIR SEPTIMUS: One more. There

22 we go.

1   MS. IBRAGIMOVA: So, the results are

2   46 percent high, 46 percent moderate, eight

3   percent low, zero percent insufficient

4   information.

5   CO-CHAIR SEPTIMUS: Okay. And the

6   last question is whether or not this is suitable

7   for endorsement.

8   MS. IBRAGIMOVA: Overall suitability

9   for endorsement. One, yes. Two, no.

10   (Voting.)

11   MS. IBRAGIMOVA: Missing one.

12   (Pause.)

13   CO-CHAIR SEPTIMUS: One more.

14   (Pause.)

15   MS. IBRAGIMOVA: The results are 87

16   percent yes. 13 percent no.

17   CO-CHAIR SEPTIMUS: Great. What I

18   would -- we'll try to figure out how we use the

19   rest of our time.

20   I think everyone is getting a little

21   bit tired. So, I think let us take a short ten-

22   minute break and then we're going to sort of

1 regroup and see which measures we want to

2 consider this afternoon.

3 Probably end about a quarter of 6:00.

4 And then we do have a potential additional call

5 if we don't get to all the measures.

6 We have some people coming in from the

7 CDC in the morning. So, we have to try to be

8 sensitive to people's travel and time

9 availability.

10 So, why don't you all take a five or

11 ten-minute break and let us powwow as to what

12 measures we want to consider for the rest of the

13 --

14 MS. GELINAS: So, it's important

15 because our measure developers that were here for

16 today may not be here tomorrow. So, considering

17 --

18 CO-CHAIR SEPTIMUS: That's all --

19 thank you. That's exactly what we're talking

20 about.

21 (Whereupon, at 4:35 p.m. the

22 proceedings went off the record for a short break

1   and went back on the record at 4:41 p.m.)

2   CO-CHAIR SEPTIMUS: Okay. So if we can

3   kind of settle in, we'll tell you what we've

4   planned for the rest of your afternoon. We have

5   a lot of public comment going on in the

6   background. So what we're going to do is we're

7   going to do the next three measures.

8   And we're going to keep to a very

9   tight time frame so we can get all three in the

10   next hour. And then we're going to hold over the

11   last two for tomorrow. Okay? Everybody got

12   that? So this time, Drew is really going to be -

13   - whatever Drew says, goes. So Drew, you have

14   the authority. We're doing the next three.

15   SPEAKER: Can I ask a question?

16   CO-CHAIR SEPTIMUS: Who's asking?

17   SPEAKER: Oh, sorry. This is Apps

18   Associates, one of the Measure developers for

19   Measure 0538. I just have a question. You had

20   mentioned earlier that the process for reserve

21   status wasn't maybe followed the way it should

22   have. Is that something that will have to be

1 presented again tomorrow? Or can be done via

2 email?

3   CO-CHAIR SEPTIMUS: I think for the

4 sake of -- we'll probably do this by email.

5 Because I think --

6   SPEAKER: Okay.

7   CO-CHAIR SEPTIMUS: But thank you for

8 reminding us. Everybody knows Drew, right? So

9 whenever Drew raises that card, we're going to

10 pay attention and we'll try to get used to it

11 this afternoon so we can do it tomorrow. And

12 hopefully we'll get us back on track.

13   We've had some great discussions, but

14 obviously we're just getting a little bit tired.

15 So that's why I thought we needed to take a

16 break. All right. So, Fall with Injury, 0202.

17 I have a funny feeling it's the developers to my

18 left. Change in plans. So we're playing the

19 baby card here? I'm teasing. No, it's

20 legitimate.

21   DR. PINES: So the measure developer

22 for 0674, CMS, is here and has a baby to get home

1   to and actually has to leave. So we're going to

2   have 0674 come in next, and then we're going to

3   have 0202 and 0141. If that's okay.

4   CO-CHAIR SEPTIMUS: Still going to do

5   three. But Drew still has the axe. He's got the

6   hook. All right, 0674, Percent of Residents

7   Experiencing One or More Falls with Major Injury

8   and Long-Stays. Go developers. Clock is

9   running.

10   MS. SMITH: Hi. This is Laura Smith

11   from RTI. I'm here with Dr. Sarah Karen and Dr.

12   Tara McMullen from CMS. I'll hand it to Sarah to

13   do the introduction.

14   DR. KAREN: Good afternoon. This

15   measure captures the percentage of long-stay

16   residents in a nursing facility who have had a

17   fall that resulted in a major injury. Major

18   injuries include bone fractures, joint

19   dislocations, closed head injuries with altered

20   consciousness, or subdural hematoma.

21   The quality measure is based on

22   information from the Nursing Home Minimum Data

1   Set 3.0 and addresses the NQF Patient Safety

2   Domain. This measure is currently endorsed and

3   it is not the measure proposed for the IMPACT

4   Act. This measure has been found to be reliable.

5   The issue of falls with major injuries

6   is a significant one. Approximately three-

7   quarters of nursing facility residents fall at

8   least once a year, a rate twice that of their

9   community living counterparts. While not all

10   these falls result in a serious injury, those

11   that do are often a leading cause of death and

12   disability in this population.

13   They represent a significant cost

14   burden, both for the immediate treatment of the

15   fall-related injury, as well as for the long-term

16   increase in costs. And additionally, can result

17   in fears among residents that lead them to

18   restrict their independent function and reduce

19   engagement in social activities, thereby reducing

20   their quality of life.

21   Using data from the Second Quarter of

22   2014, we tested the measure properties for this

1   measure for long-stay residents in all Medicare

2   and Medicaid certified nursing homes nationwide.

3   We found the average facility score for this

4   measure was 3.2 percent, with a median facility

5   level score of 2.7 percent. Both of these

6   figures are slightly higher than what had been

7   found three years previously, but that rate had

8   then decreased a little bit and was stable since

9   the Third Quarter of 2013.

10   The measure captures variation in

11   performance across facilities. At least 10

12   percent of facilities had 6.6 percent of

13   residents who had fallen with a major injury, a

14   rate more than twice the facility average. And

15   about one in six facilities had had no residents

16   with falls with major injuries during this time

17   period.

18   The measure has a small, but

19   statistically significant correlation with

20   quality measure 0688, the Percent of Residents

21   Whose Need for Help with Activities of Daily

22   Living Has Increased, which offers some measure

1 of convergent validity.

2 This quality measure is not risk-

3 adjusted. The decision not to recommend risk

4 adjustment was based on careful review of the

5 literature and feedback from a technical expert

6 panel in October of 2009. The members of that

7 panel recommended strongly against risk adjusting

8 this quality measure. As one person said, by

9 admitting a resident, the facility is assuming

10 responsibility for them. If they are at high-

11 risk, the facility should deal with it.

12 The measure is unique in the

13 population outcome that it concerns. There are

14 similar NQF endorsed measures that either address

15 different populations, such as hospital

16 inpatients, or address care processes related to

17 falls, but not the outcome of falls. This

18 measure, the Prevalence of Falls with Major

19 Injury Among Long-Stay Residents, is the most

20 appropriate for this population.

21 Public reporting of this measure via

22 Nursing Home Compare offers valuable information

1   to residents and their families. And this

2   measure also is part of the CMS Five Star Rating

3   System. Thank you.

4   CO-CHAIR SEPTIMUS: Okay. So I think

5   Melissa's going to discuss this. No, Missy. I'm

6   sorry, not Melissa. She stepped out.

7   CO-CHAIR THRAEN: Who else is on the

8   team?

9   CO-CHAIR SEPTIMUS: No, she stepped

10   out.

11   CO-CHAIR THRAEN: Ann, on the phone?

12   Ann can you address this from the point of view

13   of evidence? Ann's not there. Missy?

14   CO-CHAIR SEPTIMUS: We had a slight

15   change in schedule, Missy. I'm sorry.

16   CO-CHAIR THRAEN: You're the lead.

17   They changed it up.

18   MS. DANFORTH: I'm sorry. I thought we

19   were --

20   CO-CHAIR SEPTIMUS: No, no. There's

21   someone needed to leave early, so we changed it

22   around. So it's not your fault. But you still

1 have to talk about the evidence now around this

2 measure. They've already done it, yes. And

3 we're trying to keep on time.

4   MS. DANFORTH: The developers did

5 provide a summary of a systematic review. They

6 listed several processes of care associated with

7 major falls with injury, including a

8 multifactoral falls risk assessment, management

9 programs, exercise interventions, Vitamin D

10 prescriptions -- that's the only one I'm the lead

11 discussant on.

12   CO-CHAIR THRAEN: 0674. Who's the lead

13 on this? Okay.

14   MS. MCGIFFERT: Okay. So --

15   MS. DANFORTH: No, I'm sorry. That is

16 the evidence that is with that document. Yes.

17 So I actually have it all printed out in front of

18 me. I know this is the right measure. Okay.

19   So this basically -- the evidence

20 basically suggests that there's actually lots of

21 processes the nursing homes can put into place to

22 reduce falls with major injuries, including the

1   things that I just named, are actually in this

2   document.

3   So I thought that the evidence was

4   extremely strong. They produced several articles

5   and information. So I rated the evidence very

6   high. This measure's been in place for a long

7   time. In addition, it is being public reported

8   right now in Hospital Compare. It is also a

9   standard question in the MDS.

10   CO-CHAIR SEPTIMUS: Okay. Discussion

11   on the evidence. Anybody have any comments? It

12   sounds like Missy was very satisfied with the

13   evidence. Seeing none, let's vote on the

14   evidence.

15   MS. IBRAGIMOVA: So, importance to

16   measure and report evidence, health outcome or

17   PRO, 1 Yes, 2 No.

18   MS. THEBERGE: Kimberly, we need your

19   vote. Kimberly, are you still there?

20   MS. IBRAGIMOVA: The results are, 100

21   percent Yes, 0 percent No.

22   CO-CHAIR SEPTIMUS: That is our second

1 unanimous vote. Okay. Let's move to gap.

2 Missy?

3 MS. DANFORTH: So in terms of the gap

4 in performance for this Measure, again, one of

5 the advantages is that it is being publically

6 reported on Hospital Compare. The reported rates

7 actually range from zero to 20 percent. The mean

8 for the measure is 3.2 percent, and the standard

9 deviation is 2.6 percent.

10 But I think if you look at the ranges,

11 the reported ranges, and compare that to the

12 mean, there's significant opportunities for

13 improvement. And one of the things -- and I

14 apologize for coming in late, I don't know if the

15 measure developer mentioned, but this is only a

16 measure of very serious falls.

17 And so to see this kind of significant

18 gap for things like fractures, joint

19 dislocations, head injuries with disassociation,

20 these are major injuries and the performance gap

21 is significant.

22 CO-CHAIR SEPTIMUS: Okay. So it also

1   looks like there may be some disparities in the

2   data as well.   Is that correct, Missy?

3   MS. DANFORTH: So the disparities that

4   they mentioned were two.   And I thought that, at

5   least for me, the data they provided was a bit

6   mixed.   So there is racial disparity, where some

7   studies show that white residents had higher

8   rates, but then they actually produced a counter-

9   study that showed that black residents had a

10   higher risk.

11   The other disparity was actually in --

12   they look at socioeconomic disparities and used

13   as sort of a proxy is the percentage of residents

14   that were eligible for Medicaid.   And there they

15   found that actually in facilities that had

16   greater than 75 percent Medicaid eligible

17   residents, they had a lower rate on this measure.

18   Which I honestly wouldn't have -- so

19   I don't know if you have anything to add on that,

20   but to me the racial disparities literature was

21   mixed.   Then the socioeconomic disparity was

22   somewhat surprising.

1   CO-CHAIR SEPTIMUS: Any comment?

2   DR. KAREN: You're right.

3   (Laughter.)

4   DR. KAREN: The data mix --

5   MS. DANFORTH: Okay.

6   DR. KAREN: -- and it's hard and I

7   don't --

8   MS. DANFORTH: To understand what's

9   going on.

10   DR. KAREN: -- know that we have a good

11   answer to what the explanation is and perhaps

12   more time and observing this over a period of

13   time --

14   MS. DANFORTH: Yes.

15   DR. KAREN: -- might give us some

16   information. But it's very interesting. We just

17   don't have a good explanation for it.

18   CO-CHAIR SEPTIMUS: Pat.

19   DR. QUIGLEY: Thank you. Pat Quigley.

20   And I fully support this measure and I'm so

21   thankful for you having this measure. And thank

22   you also for referencing some of the work that

1   we've done in the Department of Veterans Affairs,

2   because there is a huge performance gap here.

3   And our zero is we don't want anyone

4   to die from a fall. That is our zero. And our

5   second zero is we don't want anyone to fracture a

6   hip because, for men who fracture hips and end up

7   in long-term care have a 30 percent higher

8   mortality rate in a year.

9   So, I hope at some point in time, this

10   gets linked to structure and process. Because

11   there are interventions that can be placed to

12   reduce injury. And still to have more refinement

13   because there is no data, hardly any data at all

14   on falls with serious injuries from wheelchairs.

15   And in long-term care, we have a lot

16   of wheelchair users and falls from wheelchairs

17   are a disaster. They're very grave. So I thank

18   you so much for this measure and the opportunity

19   to be able to improve practice.

20   CO-CHAIR SEPTIMUS: Okay. Ten minutes.

21   MS. DANFORTH: Okay.

22   CO-CHAIR SEPTIMUS: No, no, there's

1   time. Drew is telling me ten minutes, so --

2   MS. DANFORTH: Are we voting?

3   CO-CHAIR SEPTIMUS: -- if no one's up,

4   let's go ahead and vote on the gap.

5   MS. IBRAGIMOVA: Importance to measure

6   and report 1B performance gap, the votes are 1

7   High, 2 Moderate, 3 Low, 4 Insufficient. The

8   results are 67 percent High, 29 percent Moderate,

9   4 percent Low, 0 percent Insufficient.

10   CO-CHAIR SEPTIMUS: Okay. Next is

11   reliability. Missy?

12   MS. DANFORTH: Yes. So the developers

13   actually provided quite a bit of detail on the

14   work they did around reliability and validity. I

15   can summarize it for you, but there's actually a

16   lot information in the packet. I believe they

17   had RTI do the work for them.

18   The one thing I'll note about the

19   reliability testing, they may have additional

20   things to add, is there was a note that the

21   measure was best at detecting outliers. So best

22   performers and worst performers. And that there

1   were slightly smaller differences with hospitals

2   who were sort of clustered around the mean.

3   Again, I think that because of the

4   significant performance variation in the measure,

5   it's still something we should be paying close

6   attention to. But I just did want to bring that

7   up. And they may have other things to add. But

8   there's an entire -- two separate reports done by

9   RTI in here for two different time periods, if

10   anyone wants to look at it in detail.

11   CO-CHAIR SEPTIMUS: Any comments from

12   the developers?

13   MS. SMITH: Thank you. And I think the

14   only thing that I would add just is we have a

15   similar situation as we had with the last measure

16   that we talked about. Which is that we have very

17   good item level reliability, but as you mentioned

18   that sort of the distinctions are more, at the

19   Measure level, are more in the tails.

20   MS. DANFORTH: But, again, this is one

21   of those measures where maybe the right number is

22   zero, so anything above zero I think is

1 definitely worth people having access to that

2 information. Vote?

3   CO-CHAIR SEPTIMUS: Pat? Oh,

4 Charlotte.

5   DR. ALEXANDER: So again I want to ask

6 about the signal-to-noise. Because it's

7 something I don't have a real grasp on. When

8 we've got these measures that are coming forward

9 where we're going to be holding facilities

10 responsible and, yet, the signal-to-noise is not

11 good, in other words they're saying, we can't

12 make meaningful statements about comparative data

13 on facilities, where does that put us as far as

14 our recommendation?

15   DR. KAREN: I think that to some extent

16 that signal-to-noise issue gets at what Missy was

17 saying. That we did find that the measure does a

18 good job of distinguishing at the extremes. So I

19 think what we're finding there is that there's a

20 lot overlap in that middle area.

21   But I think really the extremes is

22 what we care about. We want to know who are the

1   good performers that we can learn from and who

2   are the ones that are really struggling so we can

3   target our resources there.

4   CO-CHAIR SEPTIMUS: Okay. Seeing

5   nobody else, let's go ahead and vote. Drew,

6   where are we, five minutes now, Drew? Drew says

7   five minutes.

8   MS. IBRAGIMOVA: So scientific

9   acceptability of measure properties, 2A,

10   reliability, the votes are 1 High, 2 Moderate, 3

11   Low, 4 Insufficient.

12   MS. THEBERGE: Kimberly, we need your

13   vote.

14   MS. IBRAGIMOVA: The results are 35

15   percent High, 65 percent Moderate, 0 percent Low,

16   0 percent Insufficient.

17   CO-CHAIR SEPTIMUS: Next we will go to

18   Validity. Missy, anything?

19   MS. DANFORTH: I wrapped -- I talked

20   about both at the same time. I'm sorry.

21   CO-CHAIR SEPTIMUS: That's fine.

22   MS. DANFORTH: So they produced, again

1   --

2   CO-CHAIR SEPTIMUS: You don't have to

3   be --

4   MS. DANFORTH: -- two separate validity

5   studies from RTI, with very positive results.

6   CO-CHAIR SEPTIMUS: Comments? Let's

7   vote.

8   MS. IBRAGIMOVA: Scientific

9   acceptability of measure properties, 2B,

10   validity, the votes are 1 High, 2 Moderate, 3

11   Low, 4 Insufficient.

12   MS. THEBERGE: Ann and Kimberly, we

13   don't have your votes.

14   MS. IBRAGIMOVA: And the results are 52

15   percent High, 48 percent Moderate, 0 percent Low,

16   0 percent Insufficient.

17   CO-CHAIR SEPTIMUS: Okay. Feasibility.

18   MS. DANFORTH: So first, I actually

19   wanted to thank the measure developers for

20   including the MDS. So you were referring to how

21   the measure gets reported throughout the measure

22   documentation, and actually seeing the assessment

1 tool was incredibly helpful to sort of visualize

2 it. And also to get to some of the feasibility

3 issues.

4   So the measure's reported in this MDS,

5 which they included. It's a single question and

6 it asks the number of falls since admission, and

7 it defines major injury in a very specific way.

8 And so the feasibility I would say is exceptional

9 for this measure. The MDS is something that the

10 nursing homes have to do regularly, on a

11 quarterly basis, and it's built into the standard

12 assessment.

13   CO-CHAIR SEPTIMUS: Seeing no comments,

14 we will then go to vote.

15   MS. IBRAGIMOVA: Feasibility, the votes

16 are 1 High, 2 Moderate, 3 Low, 4 Insufficient.

17 The results are 75 percent High, 25 percent

18 Moderate, 0 percent Low, 0 percent Insufficient.

19   CO-CHAIR SEPTIMUS: Next is usability.

20   MS. DANFORTH: So as I mentioned, the

21 measure is used in Nursing Home Compare. It's

22 being publically reported currently. It has for

1   how many years? For seven years.

2   CO-CHAIR SEPTIMUS: I'm sorry, we can't

3   hear you.

4   DR. KAREN: Six or seven years now.

5   DR. MCMULLEN: This one of the newer

6   measures. So I think this one's just since 2012.

7   Yes. This measure was new with the institution

8   of the MDS 3.0.

9   MS. DANFORTH: Okay.

10   CO-CHAIR SEPTIMUS: Okay. Any

11   questions about usability? So, let's vote.

12   MS. IBRAGIMOVA: Usability and use, the

13   votes are 1 High, 2 Moderate, 3 Low, 4

14   Insufficient Information. The results are 71

15   percent High, 29 percent Moderate, 0 percent Low,

16   0 percent Insufficient Information.

17   CO-CHAIR SEPTIMUS: Okay. And the last

18   question, is this suitable for endorsement?

19   MS. IBRAGIMOVA: So overall suitability

20   for endorsement, does the measure meet NQF

21   criteria for endorsement? 1 Yes, 2 No.

22   MS. THEBERGE: Missing one.

1   MS. IBRAGIMOVA: Missing one vote. The

2   results are 96 percent Yes, 4 percent No.

3   CO-CHAIR THRAEN: All right. I guess

4   I'm taking over.

5   CO-CHAIR SEPTIMUS: Yes. Just one

6   quick thing though.

7   CO-CHAIR THRAEN: Okay.

8   CO-CHAIR SEPTIMUS: We're going to do

9   0202 and 0141 and then there are some relating

10   and competing measure discussion, which if we

11   have time, we'd like to do at the end. Because

12   these measures have some competing measures.

13   Well, we'll -- she almost -- go for it.

14   CO-CHAIR THRAEN: All right. We're

15   going to start with 0202, Falls with Injury,

16   sponsor development organization is American

17   Nurses Association. And what's Rich's first

18   name? Oh, Victoria. Sorry. Victoria will be

19   the lead on this. And would the developers like

20   to present your overview?

21   MS. CRAMER: Again, I'm Emily Cramer

22   with the University of Kansas. And, again, like

1 with the staffing skill mix we just did, I'll do

2 an overall introduction of both 0202 and 0141.

3 And then we can discuss them separately. But

4 they're very similar measures.

5   So these measures address patient

6 falls, and I'm sure it's not surprising to

7 anybody in this room, but patient falls and falls

8 with injury are significant patient safety

9 concerns that have substantial impacts on the --

10 physical, psychological, and financial impacts on

11 both patients and their families, as well as

12 healthcare institutions.

13   Patient falls is the most frequently

14 reported adverse event, and falls with injuries

15 is one of nine hospital-acquired conditions

16 that's been identified as preventable and has

17 been targeted for use in CMS's Partnership for

18 Patients Initiative. And the ANA patient falls

19 measures were actually reported in Partnership

20 for Patient and through that program, they showed

21 reduction in both falls and falls with injuries

22 using these measures over the three year span of

1   the project.

2   The prevention of patient falls and

3   injuries from falls is a critical safety

4   imperative given our aging population. I think

5   it's been mentioned that over 40 percent of

6   hospitalized patients are above the age of 65.

7   Frail elderly patients and vulnerable populations

8   with multiple chronic conditions are at increased

9   risk for falling. But in addition to that,

10   they're at an increased risk of sustaining an

11   injury as a result of a fall.

12   So both measures are extremely

13   important. And the robust measures to reduce

14   these preventable falls, and by extension falls

15   with injury, are extremely important. There's a

16   need for timely, robust, and clinically enriched

17   measures.

18   The data to calculate the measures

19   that we're talking about now are collected

20   predominately through electronic adverse event

21   reporting systems, which exist in most hospitals.

22   And they're fairly low burden, as indicated by

1   our hospital surveys, as well as the fact that

2   they come from electronic sources.

3   Again, I'd like to mention that these

4   measures have been previously endorsed. I think

5   they were first endorsed in 2004 and have

6   undergone a couple of re-endorsement cycles.

7   That was at the unit level. We, again, here are

8   presenting hospital level analysis in addition to

9   the unit level analysis.

10   And also, these measures were

11   conditionally approved by the MAP for inclusion

12   in CMS's Inpatient Quality Reporting System this

13   last year. Again, the conditional approval is

14   based on the hospital level endorsement by the

15   NQF.

16   Patient fall rate as a measure is

17   defined as the number of patient falls per 1,000

18   patient days. And falls with injury is the

19   number of falls per 1,000 patient days in five

20   injury categories ranging from none, minor,

21   moderate, major, and death.

22   These Measures do represent a

1   significant patient safety issue. They have been

2   used in quality and safety programs and

3   successfully reduce rates of these incidents in

4   hospitals. The data to collect the measures

5   exists electronically in most hospitals and they

6   are more timely, sensitive, and accurate than

7   claims-based measures.

8   CO-CHAIR THRAEN: Victoria?

9   DR. RICH: Excuse me. As far as the

10   evidence, there's extensive evidence, as we just

11   heard from our reporters and also from when we're

12   talking about the CMS with the elderly patients.

13   The areas that are looked upon in the evidence

14   are primary, the acute care areas, of the in-

15   patient, the short-stay, the observation, the

16   same-day surgery, and with the adult critical

17   care step-down med/surg and med/surg combined,

18   and the critical access and adult rehab.

19   The exclusions are pediatric,

20   psychiatric, and obstetrics, that I would

21   personally question that we perhaps need to do

22   that eventually. The other key to this, that

1   this is an outcome measure. And it's really

2   based on that we have strong evidence now both

3   for the structural and the process variables.

4   And if you're into the report of this,

5   on page 11, it really shows that we have

6   extensive research and we have attached about 20

7   references. And our Dr. Pat Quigley is probably

8   the world-known patient fall expert. And I said,

9   I don't know why I'm doing this Pat because

10   you're the one that knows all the literature.

11   But the structural variables are very

12   important, are the hospital characteristics, the

13   RN staffing, the skill mix, the RN environment,

14   very much to all the nursing metrics that we're

15   talking about today. And the process variables

16   are the falls risk assessment and the risk-based

17   falls. And so there lies that we're looking at

18   this as an outcome variable.

19   There is, despite all the research,

20   the concern about looking at the risk for this.

21   So there still remains gaps. And there is very

22   little evidence on the effective ways to reduce

1 falls. But what we're really showing through the

2 evidence that we are really moving the dial in a

3 positive way in prevention.

4 CO-CHAIR SEPTIMUS: Okay. So we're

5 talking about evidence now.

6 CO-CHAIR THRAEN: I'm doing this one.

7 Take my job away.

8 DR. RICH: I can quote some more, but

9 I'm trying --

10 CO-CHAIR THRAEN: No, no, it's good.

11 DR. RICH: -- to go fast. I can quote

12 a bunch if you want me to.

13 CO-CHAIR THRAEN: Is there any

14 questions? Charlotte and Lynda.

15 DR. ALEXANDER: Okay. Now I'm here.

16 And why is the therapy unit excluded if it's on a

17 nursing floor?

18 DR. RICH: I'll ask them.

19 MS. CRAMER: So the measures were

20 originally developed at the unit level and really

21 to reflect the nursing care on that unit and the

22 patient outcomes associated with it. And so we

1   didn't -- we designed it so as to not penalize

2   the unit for something that happened when it

3   wasn't on their unit and that they didn't have as

4   much control over it.

5   That is potentially something that

6   could be looked at as a future direction for the

7   measure. But as it is, we excluded those to get

8   the most reliable and valid measure of falls

9   within that unit setting. And to really

10   understand, because there's such differences

11   across unit types, to really get at what's

12   happening within that unit.

13   CO-CHAIR THRAEN: Lynda?

14   DR. SMIRZ: I'm not interested in

15   having any patients fall, but I'm just wondering

16   if you saw any unintended consequences like Foley

17   catheters being left in for longer periods of

18   time so that the patients don't get up? We know

19   that they sometimes get up to toilet whether we

20   tell them not to get up or not. Was that --

21   MS. CRAMER: I don't know. We haven't

22   looked at that directly. I don't know that

1 there's been much research done on that. And

2 maybe Pat can speak to it a little bit more. We

3 haven't seen that many unintended consequences

4 like that.

5 We do know that there are -- we've

6 seen increased fall rates in surgical units over

7 time when we did longitudinal analysis. And we

8 think that's a result of earlier ambulation to

9 try to get surgical patients up and walking

10 faster. So we do think that that's an area that

11 needs targeting for improvement. But we

12 discovered that because we're monitoring these.

13 CO-CHAIR THRAEN: Michelle?

14 MSS: Thank you. My question is if you

15 would consider either now or in the future

16 looking at neurology/neurosurgery units a little

17 bit differently? Because their rates may be

18 quite different.

19 MS. CRAMER: Yes. That's a good

20 question. I do think that's a possibility. And

21 as mentioned, in this measure, we don't yet

22 include pediatric and psychiatric falls either.

1   Those have been developed. NDNQI has developed

2   those and is in the process of collecting enough

3   data to do studies on that. And I think

4   neurology would be another direction that we

5   would look at.

6   CO-CHAIR THRAEN: Pat?

7   DR. QUIGLEY: Thank you. And I wanted

8   to answer the question as well to Dr. Smirz, to

9   share in relationship. Because this is the falls

10   with injury indicator.

11   I had added to the evidence review

12   that was provided for this in the Comments

13   section. Because there is more movement on

14   screening all patients not just for fall risk,

15   but injury risk upon admission. Or injury

16   history.

17   And in addition, there are tool kits

18   in terms of the evidence that have now, from the

19   Agency for Healthcare Research and Quality, from

20   the Institute for Clinical Systems Improvement

21   with Minnesota, that have focused on fall injury

22   reduction as a primary outcome. So this is

1   really an essential component. And this is a

2   proportion of those who fall.

3   So going back to Foley catheters,

4   absolutely. Catheters is an issue. But also

5   sequential compression devices on patients with

6   Alzheimer's who can walk and get up out of bed.

7   So that's just an aside.

8   CO-CHAIR THRAEN: Missy?

9   MS. DANFORTH: Yes. Just two quick

10   things. One is, did you look at the differences

11   between reporting this out as falls per patient

12   days versus patients? And was there something in

13   the evidence that made you choose patient days?

14   And was there something inherent about being in

15   the hospital longer that makes you more

16   susceptible to falls? Because it seems like most

17   inpatients would be at risk for falls.

18   MS. CRAMER: Very true. But the longer

19   the exposure, the more chance there is for falls.

20   So the more days you're in the hospital, the more

21   times you have to get up and the more -- and if

22   you're in particular units, if you're in a bed,

1 the more you have some loss of mobility because

2 of not being mobile. So a longer exposure in the

3 hospital does increase risk of falling and

4 potentially patient injuries.

5   MS. DANFORTH: And then one more

6 question, do you think there's any value, just

7 based on what you just said about the -- there

8 seems to be some significant distinctions within

9 a hospital, within units. So between units

10 within a hospital. Even though you're reporting

11 out this at the hospital level, having those

12 discrete rates by unit available if the sample

13 size is big enough?

14   MS. CRAMER: Okay. Sorry. Say that

15 one more time?

16   MS. DANFORTH: So I know you're

17 proposing to report this out by hospital, so a

18 hospital by fall rate. But given that you just

19 said there's actually a lot of variance between

20 units --

21   MS. CRAMER: Correct.

22   MS. DANFORTH: -- is there also - no,

1   I thought this was being reported --

2   CO-CHAIR THRAEN: Per unit. No.

3   MS. DANFORTH: I thought this was being

4   proposed as a hospital --

5   CO-CHAIR THRAEN: No.

6   DR. RICH: Given that you intended to

7   take this to the hospital level for endorsement

8   that that's based on a unit approach and then

9   you're looking to bring it up to the hospital

10   level.

11   MS. CRAMER: Correct. So similar to --

12   well, so there's two rates. We actually tested

13   two rates. The unit level, which is where the

14   data is actually collected. We collect it at the

15   unit level. And similarly to the process I

16   described for the staffing measures, we roll it

17   up to the hospital level.

18   We use a standardized process to get

19   standardized scores based on unit type and then

20   weight it by the patient population within that

21   given unit type to calculate a hospital score.

22   So it takes into account the variability of, for

1   example, critical care units, where you have a

2   low patient fall rate.

3   So a hospital with two critical care

4   units and six rehab units is expected to have --

5   so we kind of adjust for that based on patient

6   populations of those units. Both are described

7   in the methodology. Both the unit and the

8   hospital level.

9   CO-CHAIR THRAEN: So the unit --

10   MS. CRAMER: Yes.

11   CO-CHAIR THRAEN: Just for

12   clarification, the unit -- the measure tested at

13   the unit level has been endorsed historically.

14   You're bringing this forward in the maintenance

15   phase to get endorsement to do it at the hospital

16   level?

17   MS. CRAMER: Correct.

18   DR. BURSTIN: Are you also seeking it

19   at the unit level? Just to be clear?

20   CO-CHAIR THRAEN: To continue the

21   maintenance at the unit level?

22   MS. CRAMER: Yes.

1   DR. BURSTIN: Yes. So you have testing

2   at both levels?

3   MS. CRAMER: We have provided testing

4   at both levels, yes.

5   CO-CHAIR THRAEN: Okay. Go ahead.

6   MS. GELINAS: And Missy, if it helps,

7   because of the way the data are reported, for

8   those of us in large systems, I even get the

9   NDNQI rolled-up system level. And if you want

10   that to take your breath away, it will.

11   So for those of us in large systems,

12   we actually get it at three levels. Although it

13   has not been tested at the system level. But for

14   purposes of understanding trending and data

15   analysis, we have unit level, hospital level, and

16   then system level already coming at us.

17   CO-CHAIR THRAEN: Okay. Any other

18   questions for clarification and understanding?

19   All right. Let's vote on the evidence.

20   MS. IBRAGIMOVA: Importance to measure

21   and report, 1A, evidence, health outcome or PRO,

22   the votes are 1 Yes or 2 No.

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

2   MS. IBRAGIMOVA: And just to let

3   everyone know, Kimberly had to leave to do

4   clinical work, but she'll be on the phone again

5   tomorrow.

6   CO-CHAIR THRAEN: Try it again, guys.

7   Yes. There we go.

8   MS. IBRAGIMOVA: So the results are 100

9   percent Yes, 0 percent No.

10   CO-CHAIR THRAEN: Okay. Performance

11   gap. Any discussion, question, clarification,

12   need to know? All right. Let's vote. Oh, go

13   ahead Charlotte.

14   DR. ALEXANDER: So have you looked at

15   disparities and in particular, I'm interested in

16   language? Because I know in our hospital, we

17   find we'll tell people not to get out of bed,

18   wait for a nurse, et cetera, and they don't

19   understand. So have you been able to --

20   MS. CRAMER: I don't --

21   DR. RICH: No, I don't believe that we

22   have ever -- I think that's an excellent

1 question, but I don't think we've -- that's not

2 measured in any way. Now, that might be in the

3 incident reports. But I don't believe anybody's

4 really pulled that out as an aggregate.

5   Because what you usually do if you

6 have falls with injury, you have a root cause or

7 human factors study of it. The question is was

8 that ever pulled out because of not understanding

9 someone's language? I don't know if -- no, we

10 don't have that.

11   DR. ALEXANDER: Might be an

12 opportunity.

13   DR. RICH: Excellent point.

14   CO-CHAIR THRAEN: All right. Anybody

15 else? Shall we vote?

16   MS. IBRAGIMOVA: Importance to measure

17 and report, 1B, performance gap. The votes are 1

18 High, 2 Moderate, 3 Low, 4 Insufficient. The

19 results are 61 percent High, 30 percent Moderate,

20 9 percent Low, 0 percent Insufficient.

21   CO-CHAIR THRAEN: All right.

22 Reliability.

1   DR. RICH: With reliability, I'm going

2   to also go to my colleagues here. But at the

3   unit level, what we actually did three tests for

4   reliability. Signal-to-noise. We did also the

5   interclass correlation, and we actually did a

6   qualitative RN survey of falls reporting. And so

7   it's indicated there was strong reliability. I

8   don't know if you want to add to that Emily or

9   Danielle or Pat, particularly.

10   MS. CRAMER: I'll be happy to answer

11   specific questions if anybody has any.

12   CO-CHAIR THRAEN: Charlotte, do you

13   have a question? No? Any other questions or

14   discussions on reliability? We'll vote.

15   MS. IBRAGIMOVA: Scientific

16   acceptability of measure properties, 2A,

17   reliability. The votes are 1 High, 2 Moderate, 3

18   Low, 4 Insufficient. The results are 65 percent

19   High, 30 percent Moderate, 4 percent Low, 0

20   percent Insufficient.

21   CO-CHAIR THRAEN: All right. Validity.

22   DR. RICH: Okay. With validity, I

1   think again I'm going to express that there's

2   strong validity testing for it. The mean

3   hospital score percentile rank was strongly

4   associated with the rank of the true hospital

5   injury rate at a 0.98.

6   And also the idea of, what I had to

7   find out, what the experiment rank coalition

8   between the bootstrap hospital scores and the

9   true injury fall was at 0.79. And so I don't

10   know if any of you know what a bootstrap was, but

11   I sure learned what that was. But it seemed like

12   there was a strong validity, not only for face,

13   but also for construct.

14   CO-CHAIR THRAEN: Any discussions or

15   questions? Let's vote.

16   MS. IBRAGIMOVA: Scientific

17   acceptability of measure properties, 2B,

18   validity. The votes are 1 High, 2 Moderate, 3

19   Low, 4 Insufficient. And the results are 52

20   percent High, 39 percent Moderate, 4 percent Low,

21   4 percent Insufficient.

22   CO-CHAIR THRAEN: Feasibility.

1   DR. RICH: Okay. Feasibility. We

2   heard earlier that there are the eMeasures and

3   with the electronic adverse reporting with the

4   incident reports, whether they're electronic or

5   manual, is highly feasible. And the performance

6   -- we're look at probably about, what was it?

7   About 75 or 80 percent of them being reported.

8   CO-CHAIR THRAEN: Any questions? Okay.

9   Vote.

10   MS. IBRAGIMOVA: Feasibility, the votes

11   are 1 High, 2 Moderate, 3 Low, 4 Insufficient.

12   The results are 52 percent High, 48 percent

13   Moderate, 0 percent Low, 0 percent Insufficient.

14   CO-CHAIR THRAEN: Usability.

15   DR. RICH: The usability is very, very

16   keen and very important. It's currently used in

17   public reporting in several states currently.

18   It's also used by us with Magnet Organizations

19   and Pathway to Organization and probably about 80

20   to 90 percent of the hospitals. It's used --

21   it's very, very important.

22   I would say in acute care setting, if

1 not the top, the second important to pressure

2 ulcers and how we prevent injury and how we do

3 care. It is also one of the highest malpracticed

4 areas. And I know we don't talk about dollars,

5 but the idea of that impact being there, it's

6 usability is absolutely imbedded in the nursing

7 profession.

8 CO-CHAIR THRAEN: All right. Any

9 questions? Charlotte?

10 DR. ALEXANDER: Sorry. Is there a

11 definition of injury? I mean, is it clearly

12 stated exactly what the injury is?

13 DR. RICH: I think you're best to go

14 through this. Yes, there's different degrees of

15 injury. Absolutely. I think there's six -- what

16 are they Pat? I'm thinking minor --

17 MS. CRAMER: We have different

18 categories and in each category we provide a

19 definition of what a minor versus a moderate is

20 and then we also give examples. And I can --

21 DR. RICH: No, it's in there. There's

22 also -- what they updated is the definition of a

1   fall. Because if you're walking and you just go

2   down to your knees or do you fall to the floor?

3   And so, I really say that we've really gotten

4   excellent more tools to describe so that we can

5   report more effectively.

6   MS. CRAMER: And we've done separate

7   reliability or validity studies that, I mean,

8   that are published now that were done prior to

9   this to really outline the definitions and test

10   specifically for the definitions. Rather than

11   some of this just signal-to-noise analysis that

12   we've done for this particular project.

13   CO-CHAIR THRAEN: Pat?

14   DR. QUIGLEY: Thank you. And I'd just

15   like to add and confirm in terms of usability,

16   that the falls with injury and related immobility

17   was one of the hospital-acquired conditions that

18   CMS went after in the HACs for the Partnership

19   for Patients.

20   So this really was a focus and there

21   was reporting of it for the first three years.

22   It was pulled from 2015, but it's still being

1 reported. But this was -- the focus was

2 injurious falls.

3   CO-CHAIR THRAEN: Any other question?

4 Shall we vote?

5   MS. IBRAGIMOVA: Usability and use.

6 The votes are 1 High, 2 Moderate, 3 Low, 4

7 Insufficient. And the results are 57 percent

8 High, 43 percent Moderate, 0 percent Low, 0

9 percent Insufficient Information.

10   CO-CHAIR THRAEN: And the last one is

11 endorsement.

12   MS. IBRAGIMOVA: Overall suitability

13 for endorsement, does the measure meet NQF

14 criteria for endorsement? 1 Yes, 2 No.

15   CO-CHAIR THRAEN: There we go.

16   MS. IBRAGIMOVA: The results are 100

17 percent Yes, 0 percent No.

18   CO-CHAIR THRAEN: Three.

19   (Laughter.)

20   CO-CHAIR SEPTIMUS: Four.

21   CO-CHAIR THRAEN: Four? Okay.

22   CO-CHAIR SEPTIMUS: Four.

1   CO-CHAIR THRAEN: Four. All right.

2   And 0141, Patient Fall Rate. The developer is

3   American Nurses Association. And Schreiber,

4   who's -- there we are Michelle, okay.

5   Developers, do you have anything you want to add

6   to the earlier presentation?

7   MS. CRAMER: I think the earlier

8   introduction holds for this measure as well. So

9   I'll let them go ahead and start stepping us

10   through it.

11   CO-CHAIR THRAEN: Michelle?

12   DR. SCHREIBER: In a way, the prior

13   measure was really a subset of this measure.

14   That was falls with injury and this is all falls.

15   And this is really the rate of all falls

16   regardless of whether or not there was injury,

17   regardless of whether or not the patient was

18   assisted.

19   But other than that, it looks at very

20   similar things. It's collected in the same way.

21   It has the strength of evidence that the other

22   measure had as well. It has been extensively

1 studied, has been used by NDNQI as well. There

2 is extensive reliability and validity testing.

3 So the big difference here is that this is all

4 falls regardless of injury and regardless of

5 assistance.

6 CO-CHAIR THRAEN: Questions? Or -- go

7 ahead. Helen?

8 DR. BURSTIN: There we go. Just a

9 quick question because I remember this going

10 through CSAC last time. And so, since we know

11 we're going to go through that process again and

12 a lot of the same players are there, this measure

13 had a significantly harder time the last round.

14 And I think there were concerns about

15 -- and I just want to make sure we at least put

16 those questions on the table so we can start

17 talking about it. What is the additive value of

18 having both? Was a major issue.

19 And I remember the hospitals at the

20 table in particular had concerns about the burden

21 of collecting all of them and of the squishiness

22 of the ones without injury. So I'm just putting

1   it on the table, and I can find the exact details

2   if we want it. But just so we can inform the

3   discussion and have a -- since time is limited.

4   MS. CRAMER: Certainly. Yes. There

5   was some concern about the additive value of

6   collecting total falls in addition to injury

7   falls. Injury falls are often viewed as the more

8   important measure because of the cost associated

9   with that and obviously the patient harm.

10   Our argument is that the total fall

11   rate really informs the injury fall rate and

12   that's prevention of all preventable falls, if

13   you can prevent the fall, you can prevent the

14   injury. So we're not just trying to stop injury,

15   we're trying to stop the falls. And I know Pat's

16   got some thoughts on this too, so I'd be happy to

17   let her take the floor on it.

18   CO-CHAIR THRAEN: Okay.

19   DR. QUIGLEY: Thank --

20   CO-CHAIR THRAEN: Pat, then --

21   DR. QUIGLEY: Thank you. I will be

22   brief.

1   CO-CHAIR THRAEN: -- then Lisa and then

2   Steve.

3   DR. QUIGLEY: I would say the reason in

4   working with hospitals in relationship to falls

5   is that falls overall remains the top adverse

6   reported event in terms of incident reports. And

7   to be able to prevent falls, there has to be an

8   interdisciplinary approach to it. So hospitals

9   need to be able to step up to the plate and get

10   the best of the team there to be able to go after

11   fall prevention.

12   Fall prevention is different than

13   injury prevention. If someone doesn't fall, they

14   don't get injured. But falls remains the top

15   reported adverse event in incident reports. So

16   it is the measure, it is the measure for patient

17   safety. And that's in the literature.

18   CO-CHAIR THRAEN: Lisa?

19   MS. MCGIFFERT: I would just add that

20   I think if you're looking at all falls, that

21   injury is more of a function of the condition of

22   the patient. And so often if you have a patient

1 who is very, very ill and they fall, that injury

2 is greater than if you have a patient who's not

3 very, very ill and falls. But still, they fell.

4 And that's what you want to prevent.

5   CO-CHAIR THRAEN: Okay. Steve?

6   DR. LAWLESS: Just a question about

7 definition of fall. Because I could see falling

8 with injury, I mean, the injury is the earmark.

9 If I'm falling and caught, my knee doesn't hit

10 the ground, I mean, it might've been hit, but I

11 sprain my back. Is that counted?

12   MS. CRAMER: Yes. The definition is

13 really specific. It includes assisted falls. So

14 if you don't necessarily hit the ground or if

15 somebody catches you, we still count that.

16 There's specific things in the definition about

17 whether you fell back onto the bed versus fell

18 out of bed onto the floor.

19   All of these are counted in the

20 definition. And it lays it out very

21 specifically. And we've refined the definition

22 over the years to include all of those issues.

1   DR. LAWLESS: And is the data then, I

2   mean, because I haven't read all the details of

3   it, has there been an inter-rater reliability on

4   the definition of fall?

5   MS. CRAMER: There has been. Yes.

6   DR. LAWLESS: Okay.

7   CO-CHAIR THRAEN: Lynda?

8   DR. SMIRZ: Okay. So, I think you

9   probably already answered my question. As an

10   OB/GYN, I've had a lot of patients with

11   epidurals. First time they get up, they've got a

12   nurse on each side because we're not convinced

13   that their legs are going to be able to support

14   them. Turns out they can't, they're lowered to

15   the floor, that's considered a fall in this

16   measure?

17   MS. CRAMER: Yes. But we would count

18   that as an assisted fall. NDNQI tracks them as

19   assisted falls.

20   CO-CHAIR THRAEN: Pat?

21   DR. QUIGLEY: Thank you. The other

22   comment that I really wanted to make in

1   relationship to why hospitals need to be able to

2   prevent all falls is because we still do not know

3   what a best practice is. And that's the

4   opportunity for improvement in relationship to

5   the gap. Is we don't know what needs to be done,

6   what combination, what dose, what intensity verus

7   what population. So there's just a lot of

8   opportunity.

9   CO-CHAIR THRAEN: Anything else? Shall

10   we vote?

11   MS. IBRAGIMOVA: Importance to measure

12   and report, 1A, evidence, health outcome or PRO,

13   1 Yes, 2 No.

14   CO-CHAIR THRAEN: Try again. We're

15   missing one.

16   MS. IBRAGIMOVA: The results are 100

17   percent Yes, 0 percent No.

18   CO-CHAIR THRAEN: All right.

19   Performance gap.

20   MS. IBRAGIMOVA: Importance to measure

21   and report, 1B, performance gap. The votes are 1

22   High, 2 Moderate, 3 Low, 4 Insufficient.

1   CO-CHAIR THRAEN: Charlotte, did you

2   have a question?

3   DR. ALEXANDER: Just another plea to

4   put language in this one. When we're looking at

5   disparities.

6   CO-CHAIR THRAEN: We're missing some

7   responses. Try again.

8   CO-CHAIR SEPTIMUS: I think Helen may

9   want to comment. This certainly is an interest

10   and a push for NQF, I think, to make sure that we

11   include disparities. Would that be correct,

12   Helen?

13   DR. BURSTIN: It's a major issue.

14   Absolutely.

15   CO-CHAIR SEPTIMUS: They share your

16   comments.

17   MS. IBRAGIMOVA: The results are 57

18   percent High, 35 percent Moderate, 9 percent Low,

19   0 percent Insufficient.

20   CO-CHAIR THRAEN: All right.

21   Reliability. Any comments, questions,

22   assertions? Then we will vote. Charlotte?

1   DR. ALEXANDER: I'm sorry.

2   CO-CHAIR THRAEN: It's all right.

3   DR. ALEXANDER: We're not gathering

4   incident reports is what I understand and as I

5   read this. Is that a place where we're missing

6   some opportunity?

7   DR. RICH: Repeat what you said about

8   the incident reports?

9   DR. ALEXANDER: So as I'm reading this,

10   I'm seeing that we're not gathering information

11   from incident reports.

12   MS. CRAMER: Well, that's one of the

13   mechanisms that hospitals use to actually collect

14   this data, yes. Is their incident reports.

15   DR. ALEXANDER: Okay.

16   DR. RICH: Yes. Because -- no, we're

17   not publically reporting it, but how we give our

18   data to NDNQI is primarily through our electronic

19   incident reports or our paper incident reports.

20   CO-CHAIR THRAEN: Okay. Any other

21   questions, thoughts? Lynda, you threw something

22   there. Okay. Shall we vote?

1   MS. IBRAGIMOVA: Scientific

2   acceptability of measure properties, 2A,

3   reliability. The votes are 1 High, 2 Moderate, 3

4   Low, 4 Insufficient. The results are 48 percent

5   High, 48 percent Moderate, 4 percent Low, 0

6   percent Insufficient.

7   CO-CHAIR THRAEN: All right. Validity.

8   Any comments? Questions? All right. Vote.

9   MS. IBRAGIMOVA: Scientific

10   acceptability of measure properties, 2B,

11   validity. The votes are 1 High, 2 Moderate, 3

12   Low, 4 Insufficient. The results are 57 percent

13   High, 39 percent Moderate, 4 percent Low, 0

14   percent Insufficient.

15   CO-CHAIR THRAEN: Feasibility. Any

16   questions? Keep going. Wait, wait, we don't

17   vote yet. We're still on composite. There we

18   go.

19   MS. IBRAGIMOVA: Feasibility. The

20   votes are 1 High, 2 Moderate, 3 Low, 4

21   Insufficient. Just one more vote.

22   CO-CHAIR THRAEN: Try again, guys.

1   We're missing one. All right. Go.

2   MS. IBRAGIMOVA: The results are 53

3   percent High, 43 percent Moderate, 4 percent Low,

4   0 percent Insufficient.

5   CO-CHAIR THRAEN: All right.

6   Usability. Any questions, comments? Let's vote.

7   MS. IBRAGIMOVA: Usability and use.

8   The votes are 1 High, 2 Moderate, 3 Low, 4

9   Insufficient Information. The results are 61

10   percent High, 35 percent Moderate, 4 percent Low,

11   0 percent Insufficient Information.

12   CO-CHAIR THRAEN: And finally,

13   endorsement.

14   MS. IBRAGIMOVA: Overall suitability

15   for endorsement, does the measure meet NQF

16   criteria for endorsement? 1 Yes, 2 No. And the

17   results are 96 percent Yes, 4 percent No.

18   CO-CHAIR THRAEN: So staff have a

19   comment about competing and related measures.

20   You want to go ahead and chair?

21   MS. THEBERGE: Sure. So we have two

22   measures that were recommended, Falls with Injury

1   0202, and then 0674, Percent of Residents

2   Experiencing One or More Falls with Major Injury.

3   And we just have to have a quick conversation

4   about whether those are related measures or

5   they're competing.

6   Competing would be if they have the

7   same measure focus and target population. Okay.

8   So, yes, that's what I thought, just had to --

9   yes, okay. Conversation is done.

10   DR. BURSTIN: But they are still

11   related measures. So in that instance, the key

12   issue here is harmonization. So a lot of the

13   discussion you've just had about the definitions

14   of falls, et cetera, an injury should be --

15   ensure that they are in fact comparable across

16   settings.

17   Particularly if you heard what CMS

18   said earlier about the IMPACT Act and if they

19   need to in fact harmonize and have a set of

20   measures that flow with patients across all

21   settings, that's probably an exercise worth doing

22   the side-to-side, and Pat could probably do it

1   over drinks tonight.

2   DR. QUIGLEY: Thank you. But you know,

3   the issue with harmonization for CMS and

4   hospitals is CMS gets their data from MDS. So

5   their falls data is falls per person year. It is

6   not falls per person day. So that's the issue.

7   Is the -- yes.

8   DR. BURSTIN: I think the bigger issue,

9   and it's probably okay based on the discussions

10   we've already had today, is a couple of key

11   definitions. Are they defining falls in the same

12   way? Are they defining --

13   DR. QUIGLEY: No.

14   DR. BURSTIN: -- injury in the same

15   way?

16   DR. QUIGLEY: They're not, and they

17   don't define severity of injury the same way. We

18   have --

19   DR. BURSTIN: It's just an opportunity

20   to -

21   DR. QUIGLEY: Yes.

22   DR. BURSTIN: -- at least put out some

1   side-by-sides --

2   DR. QUIGLEY: Yes.

3   DR. BURSTIN: -- so that the two groups

4   can inform each other going forward.

5   DR. QUIGLEY: Absolutely.

6   DR. BURSTIN: It's not going to get

7   solved today.

8   DR. QUIGLEY: Right.

9   DR. BURSTIN: But again, if you think

10   about an IMPACT Measure coming forward on falls,

11   which you heard, it would likely -- well, that

12   was pressure ulcers, but I assume falls is

13   probably -- they're nodding back there, yes.

14   Then it's logical that they're going to want to

15   make sure with the care tool, for example --

16   DR. QUIGLEY: Yes.

17   DR. BURSTIN: -- and the IMPACT Act,

18   that in fact those definitions start to do this.

19   DR. QUIGLEY: Well, if I can help, let

20   me know.

21   DR. BURSTIN: Okay.

22   DR. QUIGLEY: I am here.

1   MS. CRAMER: I will say that ANA did

2   start to pull these falls measures that are in

3   NQF and sort of line them up side-by-side. So

4   there's still some work to be done, but I think

5   that there is probably the beginnings of a report

6   out there. It needs a lot more work. But we at

7   least lined the measures up next to each to see

8   where there were differences.

9   CO-CHAIR THRAEN: There's also supposed

10   to be public comment. So does anybody from the

11   public want to come up and comment?

12   CO-CHAIR SEPTIMUS: Operator, can you

13   ask?

14   OPERATOR: Okay. At this time, if

15   you'd like to make a comment, please press Star

16   then the Number 1. And there are no comments

17   from the phone line.

18   CO-CHAIR THRAEN: Go ahead.

19   CO-CHAIR SEPTIMUS: We have a comment.

20   DR. BURSTIN: And there's also a

21   comment on the call when we're done.

22   DR. NEEDLEMAN: Okay. So I apologize,

1   I know I'm the last thing between you and dinner.

2   DR. BURSTIN: We still have the comment

3   on the phone.

4   DR. NEEDLEMAN: So I'm the next to the

5   last thing between you and dinner, and I

6   appreciate how hard everybody has worked, and

7   it's been an incredible day watching you work. I

8   want to speak to the Failure to Rescue Measure

9   that was voted on.

10   I'm speaking now as the developer of

11   PSI 04, the Failure to Rescue Measure that's

12   included in the AHRQ data set. That measure and

13   the CHOP Measure are sometimes considered

14   competing measures. There's enough philosophical

15   difference between them in terms of the

16   underlying philosophy of who gets counted and why

17   that I think at this point they're complementary

18   Measures, and it's not at all obvious that one

19   should pick one versus the other for endorsement.

20   I saw Jeff Silber at the Academy

21   Health Meeting and he was very, very upset that

22   he was not, because of prior commitments, he was

1 not going to be able to join you. And between

2 you and me, his staff did not serve him well.

3 Jeff has been very -- I appreciate that. I knew

4 that, Helen. And I will stand by that statement.

5   The key thing is, one of the reasons

6 that people tend to often pick the AHRQ PSI is

7 because the code is available and everything is

8 automated in it. Jeff has been extraordinarily

9 good about sharing his code with people.

10   So recent -- and the main use of his

11 Measure and a substantial use of the PSI 04

12 Measure is to look for structural and process

13 correlates with mortality, particularly among

14 surgical patients. And it's been very effective

15 as a use of that. We can argue about individual

16 studies. I have some arguments with his

17 anesthesia studies. But it sheds a light on

18 where to look and suggest things that are in fact

19 actionable.

20   And it has been a usable study. It's

21 been used in some very important ways. The

22 Future of Nursing Study of 2010 endorsed a move

1 towards 80 percent baccalaureate degrees among

2 RNs. And the principle study that led the

3 Institute of Medicine to do that was a study that

4 used failure to rescue as the dependent variable

5 and the proportion of nurses that were

6 baccalaureate prepared in the hospitals as the

7 right-hand side, the independent variable.

8   With that -- so I think if you think

9 about usability in terms of the research base

10 that's going to let us analyze what kinds of

11 structural and process measures make a

12 difference, so we find things to act on, this is

13 a very important measure to have in the

14 portfolio. And I would encourage you to consider

15 that when it comes up again after it comes off

16 the table. Thank you.

17   CO-CHAIR THRAEN: Someone on the phone

18 has a comment.

19   OPERATOR: We have a comment from

20 Hardeep Singh.

21   MR. SINGH: Yes. Hi. This is Hardeep

22 Singh. Can you hear me?

1   CO-CHAIR THRAEN: Hardeep. Yes. We can

2   hear you.

3   MR. SINGH: Okay. Wonderful. Thank

4   you. My name is Hardeep Singh. I'm actually a

5   patient safety researcher at the Houston VA

6   Center for Innovation and the College of

7   Medicine. I'm also the co-chair of the recently

8   formed NQF Health IT Safety Committee.

9   I'm calling in to support Jason

10   Adelman's Wrong Patient Retrack and Reorder

11   Measure that you're going to be discussing

12   tomorrow. Just a little bit of background on why

13   this is relevant. We implemented electronic

14   health records many years ago, thinking we're

15   going to use them to improve patient safety.

16   But now we're finding is we also have

17   some new risks and new unintended consequences

18   that have been introduced with the use of

19   electronic health records. We actually never

20   predicted the risks so I think it's important

21   that we have sort of measures that can be used to

22   find problems for us to fix, new types of

1   problems.

2   So before we use health IT to improve

3   patient safety, we need to make sure the

4   technology's safe and that the technology is used

5   safely. Within the last five years, as everybody

6   knows, health IT has changed the way we deliver

7   healthcare. And this measure is so unique

8   because it addresses a gap in patient safety

9   that's not met by the other current measures.

10   And I would strongly -- you're going

11   to hear about the measure in a lot more detail

12   tomorrow, but it's been well-tested and it sort

13   of addresses a unique area that is unmet by the

14   other current measures. Most of the health

15   systems right now are just trying to sort of

16   follow meaningful use, and they don't know how to

17   measure the unintended consequences and the risks

18   that come with health information technology use.

19   So it would be a good measure to have

20   on the table so that they can start getting aware

21   of these risks. Thank you very much. And that's

22   all I have to say. Thank you for considering it.

x

1 CO-CHAIR SEPTIMUS: Well, thank you for

2 that comment. How much did Jason pay you to say

3 that?

4 (Laughter.)

5 MR. SINGH: Not enough, I guess.

6 CO-CHAIR THRAEN: Are there any other

7 public comments to be made? Either in the room

8 or on the phone?

9 OPERATOR: There are no comments from

10 the phone line.

11 CO-CHAIR THRAEN: Thank you.

12 CO-CHAIR SEPTIMUS: I think -- well,

13 no. The real thanks go to the NQF staff.

14 Without them, we couldn't get it. So to the NQF

15 staff.

16 (Whereupon, the above-entitled matter

17 went off the record at 5:51 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Patient Safety Standing Committee

Before: NQF

Date: 06-17-15

Place: Washington, DC

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Court Reporter