

NATIONAL QUALITY FORUM

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ALL CAUSE ADMISSIONS AND READMISSIONS  
STEERING COMMITTEE

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TUESDAY  
May 6, 2014

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The Steering Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:00 a.m., Bruce Hall and Sherrie Kaplan, Co-Chairs, presiding.

PRESENT:

BRUCE HALL, MD, PhD, MBA, Co-Chair  
SHERRIE KAPLAN, PhD, Co-Chair  
KATHERINE AUGER, MD, Msc, Cincinnati Children's Hospital  
FRANK BRIGGS, PharmD, MPH, West Virginia University Healthcare  
JO ANN BROOKS, PhD, RN, Indiana University System  
JOHN BULGER, DO, MBA, Geisinger Health System  
MAE CENTENO, DNP, RN, CCRN, CCNS, ACNS-BC, Baylor Health Care System  
HELEN CHEN, MD, Hebrew Senior Life  
ROSS EDMUNDSON, MD, Adventist Health System  
W. WESLEY FIELDS, MD, FACEP, CEP America  
STEVEN FISHBANE, MD, North Shore University Hospital and LIJ Medical Center  
LAURENT GLANCE, MD, University of Rochester  
ANTHONY GRIGONIS, PhD, Select Medical  
LESLIE KELLY HALL, Healthwise  
PAUL HEIDENREICH, MD, MS, FACC, FAHA, Stanford University School of Medicine  
KAREN JOYNT, MD, MPH, Brigham and Women's Hospital

PAULA MINTON-FOLTZ, RN, MSN, Harborview  
Medical Center; UW Medicine  
CAROL RAPHAEL, MPA, Subject Matter Expert  
PAMELA ROBERTS, PhD, MSHA, ORT/L, SCFES,  
FAOTA, CPHQ, Cedars-Sinai Medical Center

ALISON SHIPPY, MPH, Consumer-Purchaser  
Alliance, National Partnership for Women &  
Families

THOMAS SMITH, MD, FAPA, American Psychiatric  
Association

RONALD STETTLER, United Health Group

CRISTIE TRAVIS, MHA, Memphis Business Group on  
Health

NQF STAFF:

CHRISTINE CASSEL, MD, NQF CEO

TAROON AMIN, Special Assistant to the  
President and CEO

HELEN BURSTIN, Senior Vice President,  
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ANNE HAMMERSMITH, General Counsel

ANDREW LYZENGA, Senior Project Manager,  
Performance Measurement

ADEELA KHAN, Project Manager, Performance  
Measurement

KAREN PACE, PhD, RN, Senior Director,  
Performance Measurement

ZEHRRA SHAHAB, Project Analyst

ALSO PRESENT:

SUSANNAH BERNHEIM, MD, MHS, Yale University

JEPHTHA CURTIS, MD, Yale University

NIHAR DESAI, MD, MPH, Yale University

ELIZABETH DRYE, MD, MS, Yale University

JANE HAN, Society of Thoracic Surgeons\*

LEIN HAN, PhD, CMS

LORI GEARY, MPH, Yale University\*

JEFF JACOBS, MD, FACS, FACC, FCCP, All  
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JOHN MULDOON, MHA, 3M Health Information  
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SEAN O'BRIEN, PhD, Duke University

ROBERT McNAMARA, MD, MHS, Yale University

ISURU RANASINGHE, MD, PhD, Yale University

DAVE SHAHIAN,, MD, Society of Thoracic  
Surgeons\*

MARK SCHUSTER, MD, MPH, Center of Excellence  
for Pediatric Quality Measurement\*

LARA SLATTERY, MHS, American College of  
Cardiology

LISA SUTER, MD, Yale Center for Outcomes,  
Research and Evaluation

ALAN ZASLAVSKY, PhD, Harvard Medical School

LEORA HORWITZ, MD, MHS, Yale University

\* present by teleconference

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

7:57 a.m.

MR. AMIN: Good morning, everyone.

Welcome back to day 2 of the Readmissions In-Person Steering Committee meeting.

Thank you again for all of your work yesterday. It was quite a day reviewing all the measures that we got through but we were successful.

I wanted to welcome Christine Cassel, our CEO at NQF for a quick welcome to the committee.

DR. CASSEL: Thanks, Taroon. And thanks, Sherrie and to Bruce too for chairing this important work.

I was able to sit in and eavesdrop on some of your conversation yesterday. And so really especially appreciate the thoughtfulness and care and openness, the spirit really of open debate and discussion that goes on here at NQF.

And it was what makes the

1 deliberations but also the conclusions of this  
2 work carry the weight that they do. Not only  
3 in government programs but increasingly in  
4 private sector programs as well.

5               So, we just always need to stop  
6 just for a moment and recognize all of the  
7 volunteers and the expertise around this table  
8 that has made the commitment to actually make  
9 this multi-stakeholder model of healthcare  
10 quality measurement actually work for the  
11 nation. So we really appreciate that.

12              I wanted to just -- I take every  
13 opportunity I can to meet with our committees  
14 and talk with you about your work but also to  
15 let you know what's in a nutshell happening at  
16 NQF.

17              We are as you probably have seen  
18 recently right in the center of lots of really  
19 important discussions and debates about what  
20 our board is calling measurement science,  
21 really at the forefront of measurement  
22 science. Just in the last few weeks all the

1 attention to whether or not and if so how to  
2 risk-adjust measurement for sociodemographic  
3 status I think has ignited a needed national  
4 debate.

5 Carol Raphael and I were talking  
6 about this on the elevator, that these issues,  
7 many of these issues just are never done.  
8 We're just marching towards a better state, a  
9 better measurement science and a better way of  
10 implementing quality measurement. And I think  
11 that's a really good example.

12 We also are internally at NQF  
13 moving to a way of recognizing that endorsed  
14 measures -- there's more to say about whether  
15 a measure should be endorsed or not.  
16 Sometimes it's not just, you know, an up or  
17 down decision. But it's a kind of it depends.  
18 And often it depends on what it's being used  
19 for and whether it's for trial use.

20 We haven't really had the ability  
21 to make those kind of distinctions because we  
22 haven't really had the ability to do rapid



1 cycle feedback and follow-up.

2 And we now are actually moving to  
3 a place where we can do that with an open  
4 pipeline for measure submission, a model of  
5 standing committees so that it doesn't take us  
6 six months to assemble a committee every time  
7 we have a group of new measures.

8 We're not there yet, but with the  
9 full support of CMS we are piloting some of  
10 these approaches with some of the contracts we  
11 have this year. And I'm very hopeful and  
12 optimistic that it's going to give us a way of  
13 reducing the cost and the length of time that  
14 it takes to get this process through and to be  
15 able to be more adaptive then to what's  
16 happening in the scientific world as well as  
17 to what the clinical world really needs from  
18 us.

19 Another thing that is happening is  
20 that you know we have a process to evaluate  
21 the measures and endorse them or not. And  
22 then we have a process called MAP, the Measure

1 Applications Partnership, which selects which  
2 measures should be used for which federal  
3 programs.

4 And a lot of the discussion that  
5 goes on at the MAP is very similar to this  
6 discussion that goes on here. And in many  
7 ways we think it could be much more efficient  
8 if the two were sort of streamlined more to be  
9 able to identify what purpose -- maybe at this  
10 stage what purpose measures should be used for  
11 and feed that into the MAP process so that it  
12 makes that whole process more streamlined.

13 And in order to do that within the  
14 staff we're taking advantage of staff  
15 expertise in Lean and Six Sigma reengineering.

16 I don't know if you realize that  
17 Taroon is a black belt among us here. So, in  
18 his spare time he's actually helping us with  
19 the staff process of finding ways to cut the  
20 waste out of our process and become more lean  
21 and more efficient and effective in what we  
22 do. So we're very fortunate to have that kind

1 of expertise on our staff as well.

2 So you'll be hearing more about  
3 many of these things that are developing at  
4 NQF. But in the meantime the policies are the  
5 policies and it's really important that we  
6 adhere to these publicly available and  
7 carefully established policies which you're  
8 helping us to implement here today.

9 So let me just stop there,  
10 Sherrie, and see if anybody has any quick  
11 questions. I know you have a lot of work to  
12 do so I don't want to hold you up too long.

13 CO-CHAIR KAPLAN: Questions or  
14 comments for Chris? Dr. Cassel.

15 DR. CASSEL: Okay, thank you.

16 CO-CHAIR KAPLAN: Well, thank you.  
17 That was very, very helpful, especially the --  
18 knowing that on the horizon there may be some  
19 of the synergy between the MAP process and  
20 this process I think helps with some of the  
21 frustrations that many feel for the purpose of  
22 measurement and a little concern about how

1     these things are going to be applied. So that  
2     was very, very helpful. Thanks, Chris.

3             So, I'm going to ask Taroon to  
4     kick off in a second, but yesterday it was  
5     noted that we laid out a bunch of ground rules  
6     and then assiduously ignored all of them.

7             And so today we are going to  
8     adhere to some ground rules hopefully more  
9     closely. We did a lot of hard work and you  
10    were extremely efficient but I think it will  
11    help if we can make the questions and the  
12    comments very concise. And then hopefully  
13    from the measure developers also the responses  
14    concise. And so that will keep us on track to  
15    make sure -- because we're going to start  
16    losing people as their plane flights and so on  
17    get going.

18            So if we can crisp up our comments  
19    and questions, and then also the responses  
20    from the measures developers, if those can be  
21    a little bit more concise will get us through  
22    today's agenda in a timely and hopefully full-

1       throated discussion way.

2                       So, Taroon?

3                       MR. AMIN:  So, if we can -- as we  
4       get started here I would welcome the  
5       developers from STS to join us at the table as  
6       we get started.

7                       But I'll actually turn it over to  
8       Adeela if you can just walk through a quick  
9       summary of day 1 here and then just quickly  
10      walk through the agenda for day 2.

11                      MS. KHAN:  Sure.  So we actually  
12      were able to get through the agenda for day 1  
13      and evaluate all the measures that were  
14      supposed to be.

15                      Just a quick recap of where each  
16      measure is.  2502, the all-cause unplanned  
17      readmission measure for 30 days post discharge  
18      from inpatient rehab facilities passed.

19                      2512, all-cause unplanned  
20      readmission measure for 30 days post discharge  
21      from long-term care hospitals was a measure  
22      where we weren't able to reach consensus.  And

1     so we'll be following up with those developers  
2     but that measure will still be going out for  
3     public and member comment.

4             2375, PointRight OnPoint 30 SNF  
5     rehospitalizations passed.

6             2510, skilled nursing facility 30-  
7     day all-cause readmission measure passed.

8             2496, standardized readmission  
9     ratio for dialysis facilities was another  
10    measure where consensus was not reached.

11            2503, hospitalizations per 1,000  
12    Medicare fee-for-service beneficiaries was  
13    consensus not reached.

14            2504, 30-day rehospitalizations  
15    per 1,000 Medicare fee-for-service  
16    beneficiaries was consensus not reached.

17            2505, emergency department use  
18    without hospital readmission during the first  
19    30 days of home health passed.

20            2380, rehospitalization during the  
21    first 30 days of home health passed.

22            And 0327, risk-adjusted average

1 length of inpatient hospital stay was another  
2 measure where consensus was not reached.

3           Quickly we're going to be going  
4 over the following hospital measures today.  
5 We have two CABG measures, one risk-adjusted  
6 vascular procedure, two pediatric measures,  
7 one all-cause, one lower respiratory  
8 infection. And we have a PCI, AMI and  
9 outpatient colonoscopy.

10           MR. AMIN: Okay, thanks. Thanks,  
11 Adeela. I just wanted to point out two other  
12 things for today.

13           Again, a sincere try all for  
14 yesterday. There was a lot of work that was  
15 done. Again, NQF would not be able to achieve  
16 its goals without volunteers like you spending  
17 time through the workgroup calls and time that  
18 we had yesterday and today.

19           I just wanted to also follow up  
20 that we'll try to do an evaluation or just a  
21 discussion around the dry run results on the  
22 1789 all-cause measure today.

1                   And given the recommendation for  
2                   endorsement on the two measures yesterday that  
3                   were -- had the same measure focus and the  
4                   same target population we will likely have a  
5                   follow-up call to have a discussion around  
6                   best-in-class/competing in addition to the  
7                   potential two measures that are up for  
8                   discussion today.

9                   But we'll first evaluate them  
10                  independently and then have that discussion  
11                  later on.

12                 So again, I'll turn it over to the  
13                 chairs if there's any other reflections on  
14                 yesterday. Otherwise, you guys can lead us  
15                 directly into the conversation.

16                 Is there anything else you wanted  
17                 to add, Helen? Okay, thank you.

18                 CO-CHAIR KAPLAN: And my earlier  
19                 comments were not meant to truncate anything.  
20                 I just want to make sure everybody gets a  
21                 chance to say what they have to say about the  
22                 measures under consideration and do so and get



1       their points made and considered.

2                       With respect to the reviewers, if  
3       you could each time you make a comment state  
4       your name because the people recording this  
5       can't see you. And they know which  
6       microphones we're sitting at so they can hear  
7       who we are but they can't hear who you are.

8                       So if you could each time say your  
9       name. We're going to ask yourself to  
10      introduce yourself and your background quickly  
11      and then give a two-minute summary of the  
12      measure.

13                      But if you could, when you're  
14      talking, after your introductions repeat your  
15      name again that will be very helpful. So  
16      could you introduce yourselves and then the  
17      measure.

18                      DR. JACOBS: My name is Jeff  
19      Jacobs and I'm a cardiac surgeon from Johns  
20      Hopkins and All Children's Hospital in St.  
21      Petersburg, Florida. And I'm joined today by  
22      Sean O'Brien.

1 DR. O'BRIEN: Hi, my name's Sean  
2 O'Brien. I'm a statistician at Duke  
3 University Medical Center. And we serve as an  
4 analytic center, the STS database.

5 DR. JACOBS: We also have on the  
6 phone with us two members from the Society of  
7 Thoracic Surgeons, Dave Shahian who's a  
8 cardiac surgeon from Harvard, and Jane Han who  
9 is staff at Society of Thoracic Surgeons.

10 CO-CHAIR KAPLAN: Cathy, can we  
11 just make sure that those people have open  
12 lines?

13 OPERATOR: Yes, ma'am, their lines  
14 are open.

15 DR. JACOBS: So, the measures that  
16 are before the group today, actually the next  
17 two were developed in parallel. There's the  
18 Risk-adjusted Coronary Artery Bypass Graft  
19 Readmission Rate from the Society of Thoracic  
20 Surgeons and there's the Hospital 30-day All-  
21 cause Unplanned Risk-standardized Readmission  
22 Following Coronary Artery Bypass Graft Surgery

1 from Yale.

2           These two measures were developed  
3 in parallel and in collaboration between the  
4 two groups as part of a process in  
5 collaboration with CMS.

6           And the two measures are somewhat  
7 different in that the Yale measure is based on  
8 administrative data and the Society of  
9 Thoracic Surgeons measure is based on clinical  
10 data from a clinical database, a clinical  
11 database that currently has a penetrance of  
12 between 90 and 95 percent of hospitals in the  
13 United States, but not 100 percent.

14           And I think both groups, the Yale  
15 group and STS, view these two measures as  
16 complementary with strengths and weaknesses  
17 that complement the other measures.

18           And I think the way I kind of look  
19 at this simplistically is that the Yale  
20 measure is based on administrative data. An  
21 advantage and a strength of the Yale measure  
22 is that 100 percent of hospitals in the United

1 States that do coronary artery bypass surgery  
2 participate in the administrative data sets  
3 which the Yale measure is developed.

4 Meanwhile, in the Society of  
5 Thoracic Surgeons only 90-95 percent of the  
6 hospitals participate. But we feel that the  
7 actual risk adjustment in the measure is  
8 somewhat enhanced because of increased ability  
9 to use clinical variables both for defining  
10 the model of patients, the cohort of patients,  
11 isolated CABG patients, and for the variables  
12 used to risk-adjust.

13 I think that's a brief summary of  
14 how these two measures fit together and what  
15 we've done. And I think we'd be happy to  
16 answer any questions.

17 CO-CHAIR KAPLAN: Thank you very  
18 much. Bruce and Paul were the discussants on  
19 this measure. With respect to the evidence,  
20 Bruce, do you want to go first?

21 CO-CHAIR HALL: I think overall  
22 this is an outstanding measure and in terms of

1 evidence the evidence is strong.

2 DR. HEIDENREICH: I would agree.

3 While I think it should be classified as an  
4 intermediate clinical outcome I think there's  
5 a strong rationale.

6 CO-CHAIR KAPLAN: Other comments  
7 and questions from the group? Are we ready to  
8 vote evidence?

9 MS. SHAHAB: So, we're going to  
10 vote on 1(a) evidence, 1 for yes, 2 for no.  
11 And your time begins now. I think we have all  
12 22 votes. 1(a) evidence, 22 yes, zero no.

13 CO-CHAIR KAPLAN: Thank you very  
14 much. Onto performance gap.

15 CO-CHAIR HALL: I'll jump in  
16 front, Paul, and then you can follow.  
17 Overall, about a 13.5 percent readmission rate  
18 depending on exactly which set and period and  
19 so on that you look at.

20 In terms of risk-standardized rate  
21 it comes out to about 17 percent with a range  
22 of 12.5 to 34.2. The interquartile being

1       about 15 to 18.

2                       So, about a 3 percentage point  
3       spread in the interquartile range. So, at  
4       least, you know, comparable if not as good or  
5       better than many of the other measures that  
6       we're dealing with. In terms of the  
7       performance gap.

8                       DR. HEIDENREICH: I would agree.  
9       I would say it's at least a moderate level of  
10      potential for improvement.

11                      CO-CHAIR KAPLAN: Other comments  
12      from the committee? Hearing none are we ready  
13      to vote?

14                      MS. SHAHAB: Voting for 1(b)  
15      performance gap, 1 high, 2 moderate, 3 low, 4  
16      insufficient. Time begins now. Just one  
17      more.

18                      We have all 22 votes for 1(b)  
19      performance gap: 6 high, 16 moderate, zero  
20      low, zero insufficient.

21                      CO-CHAIR KAPLAN: Great. For  
22      scientific acceptability we're going to move

1 to reliability first. Sorry, priority.

2 Priority.

3 CO-CHAIR HALL: In terms of  
4 priority the developers make the case that  
5 it's between two and three hundred million  
6 dollar target roughly as a subset of all  
7 readmission costs that are a burden on  
8 Medicare.

9 So, again, I think it's -- that's  
10 probably an understatement of the magnitude of  
11 the issue in terms of priority. So, my  
12 feeling on priority was at least moderate if  
13 not better.

14 CO-CHAIR KAPLAN: Paul?

15 DR. HEIDENREICH: I would agree on  
16 moderate. It's not as common as readmission  
17 -- as some of the other medical diagnoses, but  
18 still substantial.

19 CO-CHAIR KAPLAN: Other comments?  
20 Are we ready to vote on priority?

21 MS. SHAHAB: Voting for 1(c) high  
22 priority, 1 high, 2 moderate, 3 low, 4

1       insufficient and your time begins now.

2                   We have all 22 votes, 1(c) high  
3       priority. Five voted high, seventeen  
4       moderate, zero low, zero insufficient.

5                   CO-CHAIR KAPLAN: Thank you. Now  
6       onto scientific acceptability and first  
7       reliability.

8                   CO-CHAIR HALL: So I think the  
9       developers have provided outstanding  
10      information. I think in terms of reliability  
11      actual implementation cutoffs for distinction  
12      and whatnot are actually not described. Those  
13      would be determined at a later date. So in  
14      terms of the most kind of classic rigorous  
15      signal-to-noise it's not really possible to  
16      comment on that until some of those later  
17      details would be specified.

18                   In the background I think every  
19      other aspect of data field reliability,  
20      consistency, reproducibility, and so on are  
21      met by what has been submitted in the  
22      material.



1 CO-CHAIR KAPLAN: Paul?

2 DR. HEIDENREICH: I did see, maybe  
3 you can correct me, but it looks like you did  
4 compare, say, one year and three years worth  
5 of data. If I got that right. And that had  
6 reasonable correlations. It looks like -- it  
7 looked like you had a score-out of 0.78 if you  
8 had 300 hospitals included. I don't know if  
9 you have any further clarification.

10 DR. O'BRIEN: This is Sean O'Brien  
11 from Duke University.

12 One thing we did with respect to  
13 reliability was to estimate the proportion of  
14 variation that was explained by true signal  
15 variation as opposed to random statistical  
16 fluctuations.

17 And for that type of analysis we  
18 basically used the sample of all of the  
19 hospitals, there's approximately 1,000  
20 hospitals in the development data set.

21 And when you included all the  
22 hospitals that have at least 30 cases which

1 might be a very common, inclusive threshold  
2 for reporting results of a hospital, the  
3 reliability, the percentage of explained  
4 variation by signal was 47 percent.

5 And then we looked at thresholds  
6 of what if we only reported results for  
7 subsets of hospitals that have at least 50  
8 cases, at least 100, or at least 200 and those  
9 are respectively around 50 percent, 55 percent  
10 and 65 percent.

11 So I think the results  
12 demonstrated the potential for higher  
13 reliability with -- even with a very inclusive  
14 threshold as being kind of, you know, adequate  
15 or moderate, and the potential to have very  
16 high reliability in the subset with larger  
17 volumes.

18 In terms of the comparing one year  
19 versus three year, that may be -- I think  
20 basically we saw high agreement between  
21 different outcomes done across different time  
22 periods. But actually I don't have the

1 details up in front of me.

2 CO-CHAIR HALL: So I'd like to  
3 support but back up and clarify something that  
4 Sean said.

5 So indeed, Paul, as you point out  
6 there was good consistency and reproducibility  
7 of fields and data.

8 With respect to the reliability  
9 that you talk about, Sean, again, I respect  
10 your numbers. When an institution submits a  
11 30-case estimate you had a number of 0.47.  
12 For 200 cases it would be 0.641. The  
13 development was on a 3-year data set, right?

14 So, again, if that's how the  
15 measure were going to be implemented then  
16 those would be good reflections of the  
17 reliability.

18 But those -- the actual sort of  
19 application of the measure is not yet  
20 determined. And so, again, those are good  
21 numbers. As Sean correctly phrased it that  
22 represents great potential for high

1 reliability. And so I support what he said.

2 But those numbers reflect a 3-year  
3 data set and an example of a development, an  
4 example of the potential that could be  
5 achieved.

6 CO-CHAIR KAPLAN: Other comments  
7 from the group? Go ahead, Larry.

8 DR. GLANCE: So, I have a comment  
9 about specification. I have great respect for  
10 the fact that there is a tremendous amount of  
11 clinical expertise as well as statistical  
12 expertise that went into the development of  
13 this outstanding measure.

14 The comment that I have is that  
15 this is a measure for isolated CABG surgery.  
16 And as part of the specification it also  
17 includes patients who underwent a combined  
18 CABG and ventricular assist device placement.

19 The rationale as I understand it  
20 for including the VAD patients is that there  
21 are occasions where because of a quality issue  
22 a patient is unable to separate from the

1 heart-lung machine and requires a ventricular  
2 assist device.

3 On the other hand at many heart  
4 failure centers there is an intention going  
5 into the surgical procedure that these are  
6 very, very high-risk patients and that there  
7 is a high likelihood that the patient will in  
8 fact, although the planned procedure is a  
9 CABG, that the patient will in fact probably  
10 need to undergo ventricular assist device.

11 The reason this is important is  
12 because the readmission rate for CABG patients  
13 is very, very different from the readmission  
14 rates for ventricular assist device patients.  
15 So my question for the developers is, knowing  
16 this, why would you have included VAD patients  
17 as part of the specification for this measure.

18 DR. JACOBS: Well, thank you.  
19 This is Jeff Jacobs. And first of all, that's  
20 an excellent question and some excellent  
21 observations.

22 A couple of clinical facts that I

1 think would help understand the rationale for  
2 the way this was developed.

3 First of all, substantially less  
4 than 1 percent of all coronary artery bypass  
5 grafts performed in the United States are  
6 associated with the use of a ventricular  
7 assist device. Ninety-nine percent of them  
8 are not.

9 Of those that are associated with  
10 ventricular assist device usage most of them  
11 are unplanned. And a patient is taken to the  
12 operating theater, undergoes coronary artery  
13 bypass grafting, cannot separate from the  
14 bypass machine, a variety of interventions are  
15 tried including a machine called an intra-  
16 aortic balloon pump.

17 After all of those things failed  
18 then really the only option is to put the  
19 patient on a ventricular assist device. And  
20 most of the time that's in an unplanned  
21 situation.

22 It is true that in some heart

1 failure centers patients go to the operating  
2 theater for planned ventricular assist device  
3 insertion after coronary artery bypass  
4 grafting but that's rare. It's extremely  
5 rare.

6 That being said, it is a fact that  
7 patients who get a ventricular assist device  
8 either planned or unplanned after a coronary  
9 artery bypass grafting, should they survive  
10 and go home have a higher rate of readmission  
11 than those without a ventricular assist  
12 device, no doubt.

13 When the measure was developed the  
14 measure was developed using a data set where  
15 we just knew that the CABG was associated with  
16 ventricular assist device insertion.

17 Since that time the STS database  
18 has been modified so that ventricular assist  
19 devices are now tracked as to whether or not  
20 the insertion is planned or unplanned. And  
21 that's a change in the database since the  
22 measure was developed.

1                   Therefore, moving forward we  
2                   certainly can implement this measure with the  
3                   definition of isolated CABG that would include  
4                   patients who had an unplanned ventricular  
5                   assist device but excluded those with a  
6                   planned ventricular assist device.

7                   CO-CHAIR KAPLAN: Thank you. I  
8                   think this discussion shades into validity  
9                   because we're talking then about the accuracy  
10                  of the application of the measure rather than  
11                  the reproducibility of it. So, anymore  
12                  questions on reproducibility? Go ahead, Paul.

13                  DR. HEIDENREICH: Well, I have a  
14                  question about that, but we can hold it.

15                  CO-CHAIR KAPLAN: Can we hold it?  
16                  Yes, for the validity question. Because right  
17                  now I'd like to stick to reproducibility.

18                  So, we've heard the  
19                  reproducibility is in the zone. And actually  
20                  for some of us who look at these kinds of  
21                  signal-to-noise numbers for those hospitals  
22                  that have a fairly large number that's a good



1     number.  It's a reasonable number to have  
2     given the database.

3             Any other comments on  
4     reproducibility?  Are we ready to vote?

5             MS. SHAHAB:  Voting for 2(a)  
6     reliability - 1 is high, 2 moderate, 3 low, 4  
7     insufficient and your time begins now.

8             We have all the votes for 2(a)  
9     reliability.  Eight high, fourteen moderate,  
10    zero low, zero insufficient.

11            CO-CHAIR KAPLAN:  Thank you.  Now  
12    we're onto validity.  So, Bruce, do you want  
13    to?

14            CO-CHAIR HALL:  I have a couple of  
15    points, but Paul, you were about to go ahead.

16            DR. HEIDENREICH:  Well, just a  
17    follow-up to your comment that you can now  
18    have a field for a planned ventricular assist  
19    device is how can you -- are you confident  
20    that that won't be gamed?  That seems very  
21    hard to control.

22            DR. JACOBS:  Absolutely.  I

1 anticipated that being the next question.

2 I've got the word "gaming" written right here.

3 (Laughter)

4 DR. JACOBS: Oh, this is Jeff  
5 Jacobs. I'm supposed to identify myself.

6 Well, that's a great question.

7 And I think one potential tradeoff of  
8 including patients with unplanned ventricular  
9 assist device and excluding patients with  
10 planned ventricular assist devices is that the  
11 system then is subject to gaming.

12 I think the way that can be  
13 addressed is through a combination of proper  
14 definitions, proper documentation and then  
15 audit of that documentation.

16 The Society of Thoracic Surgeons  
17 database is one of the most rigorously audited  
18 clinical databases in the United States with  
19 multiple sites undergoing site visits with  
20 audit every single year.

21 And it would be a relatively  
22 simple process during that audit to audit this

1 field and to make sure that the documentation  
2 is in place to document that the patient truly  
3 went to the operating theater with a planned  
4 ventricular assist device insertion.

5 And that would simply require a  
6 note in the chart that says that the family  
7 was consented for a planned ventricular assist  
8 device and that the clinical team felt it was  
9 likely that that might be needed because of  
10 the patient's severe heart failure.

11 So I agree with you that gaming is  
12 a potential problem. The solutions to  
13 addressing that are good definitions,  
14 documentation and good audit.

15 CO-CHAIR KAPLAN: Thank you. I  
16 think that may get to -- so Paul, you might  
17 want to bring that up again, or at least  
18 remind people of it when it comes to the use.  
19 Because unintended consequences is one of the  
20 use parameters. Bruce?

21 CO-CHAIR HALL: So in terms of  
22 reliability I thought I would present my 20-

1 second summary for the group. This is a risk-  
2 standardized readmission ratio. Ninety-five  
3 percent intervals are provided. Medicare fee-  
4 for-service greater than 65 then obviously but  
5 matched to the STS data. So matching between  
6 the programs is one of the prominent features.

7 This is isolated CABG. We've  
8 already heard some comments about that. The  
9 definition of isolated CABG is provided and  
10 well specified with note to that issue that  
11 we've already heard about.

12 Patients have to be discharged  
13 alive and then readmitted within 30 days from  
14 discharge.

15 The exclusions include under 65,  
16 patients that they were not able to match  
17 between the data programs, cases that are not  
18 deemed standalone by their definition which  
19 we've touched on, patients who died in the  
20 hospital or were discharged to AMA.

21 Now, patients who died in the  
22 hospital, there's some small controversy about

1     how to handle a death in the hospital with  
2     respect to readmissions because obviously that  
3     was not a good outcome and yet that patient is  
4     not eligible for readmissions.

5             Suffice to say that because that  
6     is controversial and there's probably a lack  
7     of 100 percent consensus within healthcare  
8     about how to do that at least as many people  
9     are excluding deaths as taking any other  
10    approach. So this is consistent with that.

11            If patients were not fee-for-  
12    service, excluded index more than 365, not  
13    first admission, all exclusions, all specified  
14    well.

15            Race and sociodemographics were  
16    not included but the developers provide good  
17    information about those variables. Again,  
18    this -- the information we're seeing is a 3-  
19    year development set. If it were a 3-year  
20    measure that might be questioned but it's not  
21    clear that in practice it would be a 3-year  
22    measure.

1                   And the readmission is attributed  
2                   to the first institution in the case where  
3                   patients are transferred between acute  
4                   institutions. And only one readmission would  
5                   be counted.

6                   So I think overall excellent  
7                   specifications and high validity on all the  
8                   aspects that I mentioned.

9                   CO-CHAIR KAPLAN: Do the  
10                  developers want to respond to that?

11                 DR. JACOBS: Is there a particular  
12                 question?

13                 CO-CHAIR KAPLAN: Never mind.  
14                 Paul?

15                 DR. HEIDENREICH: I'd say the only  
16                 concern for validity I would have, it's not a  
17                 big concern, is the matching to CMS. I think  
18                 given right now you're not allowed to match on  
19                 Social Security number, is that correct? But  
20                 obviously CMS could do that in the future.  
21                 So, I assume there's not a 100 percent  
22                 matching to the readmission to CMS.

1 DR. JACOBS: Right, so the issues  
2 we've had with Social Security number relate  
3 to our matching of the STS database to the  
4 Social Security Death Master File.

5 And that matching process worked  
6 quite well. We've published several papers  
7 and all was well until the Social Security  
8 Death Master File was modified. And with  
9 changes in the Social Security Death Master  
10 File a substantial portion of the deaths in  
11 the Social Security Death Master File are no  
12 longer re-disclosed. So that's not very  
13 useful for outcomes research.

14 As far as our matching with CMS, I  
15 think that it's -- I'll let Sean address the  
16 overall numbers but my understanding is that  
17 the overwhelming majority of patients over the  
18 age of 65 in the STS database are matched  
19 successfully to the CMS registry.

20 DR. O'BRIEN: This is Sean  
21 O'Brien. Yes, Jeff, that's correct. Using an  
22 indirect record linkage around 85 percent are

1 linked. But then if you look within the  
2 subset of sites that are actively  
3 participating it depends which direction  
4 you're linking from among the subset in  
5 Medicare what percent linked to the STS  
6 database within sites that are actively  
7 participating in the database, high nineties,  
8 97 percent, 98 percent. So it's fairly  
9 complete.

10 And then going the other direction  
11 of course you don't pick up the Medicare  
12 Advantage plans, the HMOs. Of course those  
13 wouldn't show up in the claims-based measure  
14 either.

15 DR. O'BRIEN: Can I just -- this  
16 is Sean O'Brien again. Just to respond to the  
17 question about the time frame.

18 All aspects of the measure were  
19 really developed with consistency with other  
20 CMS readmission measures in mind. So a lot of  
21 the other readmission measures for AMI and  
22 pneumonia, et cetera, they were originally



1 developed with a 1-year time frame and they  
2 were subsequently in subsequent iterations  
3 converted to a 3-year time frame. So I think  
4 the measure developers had a 3-year time frame  
5 in mind just for consistency with CMS.

6 CO-CHAIR KAPLAN: Thanks for that  
7 clarification. Any other comments on  
8 validity? Go ahead.

9 MS. SHIPPY: I had a quick  
10 question about the specification. So, you had  
11 noted in your introduction that you had worked  
12 in collaboration with CMS. Can you discuss  
13 the choice for 65 and older for the patient  
14 denominator and CMS has 18 and older.

15 DR. O'BRIEN: CMS has 18 and  
16 older?

17 MS. SHIPPY: I understand that  
18 this is probably harmonization but it felt  
19 like it was an opportunity to have them  
20 discuss it.

21 DR. JACOBS: My understanding is  
22 that to be eligible for Medicare one has to be

1     either over the age of 65 or in renal failure.  
2     So, to be in the Medicare database and having  
3     undergone a CABG the two ways to get in there  
4     is either being younger and being in renal  
5     failure, or being over the age of 65. So  
6     that's why the age of 65 is part of this  
7     measure.

8                   I'm not sure why a claims-based  
9     measure would be developed for over the age of  
10    18 that's based on the Medicare data because  
11    I don't think a patient would be eligible for  
12    that unless they're on dialysis.

13                  CO-CHAIR KAPLAN: Okay, when you  
14    put up your cards if you can turn them  
15    sideways so I can see them. They disappear  
16    when they're this way. Paul?

17                  DR. HEIDENREICH: I know the Yale  
18    group has occasionally used the California  
19    data to test their model that was developed  
20    for 65 and older in Medicare but then to have  
21    it on a claims base for 18 and above. So I  
22    didn't deal with that measure but I know

1       they've done that with other measures.

2                   CO-CHAIR KAPLAN:   Thank you.

3       Other comments?   Okay, we're ready to vote  
4       validity.

5                   CO-CHAIR HALL:   So I have a  
6       question though.   Is -- are we asking that the  
7       developers clarify that in the future the VADs  
8       would be so specified as planned or unplanned.  
9       Do we have that ability to request that?   If  
10      they agree?

11                  DR. JACOBS:   We're very  
12      comfortable with that.   We have the skills to  
13      do it and we're comfortable doing that.

14                  CO-CHAIR KAPLAN:   So how are we  
15      approving the measure though?   As specified,  
16      as is.   We can recommend that they make this  
17      change but we are approving or not approving  
18      the measure as it is currently presented.  
19      Ready to vote?   Okay.

20                  MS. SHAHAB:   Voting for 2(b)  
21      validity, 1 high, 2 moderate, 3 low, 4  
22      insufficient and your time begins now.   Just

1 one more vote.

2 We have all the votes for 2(b)  
3 validity. Four voted high, seventeen voted  
4 moderate, one low and zero insufficient.

5 CO-CHAIR KAPLAN: Okay, we're onto  
6 feasibility.

7 CO-CHAIR HALL: I thought the  
8 feasibility was very reasonable. The main  
9 issues I guess that popped into mind would  
10 again be the penetration of the STS program  
11 into all CABG procedures across the country  
12 which I think is very, very high.

13 And then the issues around  
14 matching that have already been raised which  
15 might create some limitation around perfect  
16 matching. But again, the matching seems to be  
17 done at a very high level.

18 So otherwise, I did not see any  
19 major obstacles to feasibility. I defer to  
20 Paul.

21 DR. HEIDENREICH: I agree with  
22 that.

1 CO-CHAIR KAPLAN: Any other  
2 comments? Go ahead.

3 MS. HALL: I had a question about  
4 the proprietary nature and the potential fees  
5 and could that cause barriers for use by other  
6 organizations or particularly those who might  
7 be reporting to the public for public good or  
8 consumer organizations who might have an  
9 interest. Could you comment on that, please?

10 DR. JACOBS: So, the Society of  
11 Thoracic Surgeons is the largest professional  
12 organization of cardiac surgeons in the world.  
13 And almost all cardiac surgeons in the United  
14 States are members.

15 STS is a strong advocate of public  
16 reporting, a huge advocate. And currently our  
17 outcome data is publicly reported on two  
18 platforms, one through Consumers Report. And  
19 we partner with Consumers Report because that  
20 allowed public reporting from a respected  
21 organization at an arm's length from STS.

22 So, Consumers Report publicly

1 reports our outcomes measures with a web  
2 platform designed by Consumers Report and  
3 using STS data.

4 STS also reports our outcome data  
5 on our own website, [www.sts.org](http://www.sts.org). That  
6 information is available to anyone through the  
7 internet for free. So there's methods to  
8 access the results of our NQF-endorsed  
9 measures through our website for free and also  
10 through Consumers Report at an arm's length  
11 from us.

12 So I think the issue of public  
13 reporting and the proprietary nature of the  
14 database becomes essentially a non-issue  
15 because there's two ways to get that  
16 information from the website of STS or  
17 Consumers Report. And we're certainly a big  
18 advocate of transparency in public reporting.

19 CO-CHAIR KAPLAN: Thank you.

20 Other questions or comments? Okay, we're  
21 ready to vote.

22 MS. SHAHAB: Voting for number 3,

1 feasibility. One is high, two moderate, three  
2 low, four insufficient and your time begins  
3 now.

4 We have all the votes for  
5 feasibility. Eleven voted high, eleven  
6 moderate, zero low and zero insufficient.

7 CO-CHAIR KAPLAN: Thank you. Now  
8 we're on the issue of usability and use.

9 CO-CHAIR HALL: I felt the  
10 usability was high myself. I did not see any  
11 major obstacles.

12 CO-CHAIR KAPLAN: Paul?

13 DR. HEIDENREICH: There's always  
14 the potential that with a procedure that's  
15 elective you could have surgeons not doing the  
16 cases. Although, as you say, you've been  
17 reporting data for a long time so I don't  
18 think this would have any significant  
19 incremental impact on selecting cases based on  
20 risk of readmission.

21 And then it just has the  
22 limitation I think that all the CMS 3-year

1     based measures have in that it just takes --  
2     you can't see a rapid change in your program  
3     through those data.

4                   CO-CHAIR KAPLAN:   So the issue of  
5     gaming was raised.   And I want to make sure  
6     we're all having a discussion about unintended  
7     consequences.   Karen?

8                   DR. JOYNT:   Just two quick  
9     comments.   I think one, just to get back to  
10    the ability of these models to sort of reduce  
11    the information that you can get from low-  
12    volume hospitals.   And for two reasons, in  
13    case you're looking for a safety signal and  
14    also for consumers as we talked about  
15    understanding what the difference is between  
16    an average hospital that's small and a  
17    hospital about which we just don't know their  
18    performance.

19                   Again, this all gets back to  
20    usability as opposed to the validity and I'm  
21    sorry to be a broken record on this.

22                   And I forget what my other comment



1 was.

2 CO-CHAIR KAPLAN: Thank you. Do  
3 the developers want to comment on that? I  
4 mean, this is -- excuse me for interrupting.

5 This is going to be -- I mean,  
6 low-volume hospitals are going to have the  
7 same plaguing problem we've all talked about  
8 and will probably continue to debate for the  
9 majority of our remaining careers.

10 So it is one of these perplexing  
11 problems. Do you just not evaluate the low-  
12 volume hospitals? Do you evaluate them and  
13 give them the mean? Do you do all the things  
14 that we've talked about that they're going to  
15 always have problems associated with the error  
16 of estimation.

17 Developer?

18 DR. JACOBS: This is Jeff Jacobs  
19 again. And I think this recent dialogue  
20 raised three issues. One, risk aversion as an  
21 unintended consequence, two, gaming, and  
22 three, how to manage low-volume hospitals.

1 And I'll say a couple of sentences about each  
2 one and then I can answer more questions.

3 Certainly with any form of outcome  
4 reporting risk aversion is a possibility. The  
5 solution to that is a good risk adjustment  
6 methodology. And I think this measure as well  
7 as all of our isolated CABG measures  
8 implemented by STS have a very vigorous risk  
9 adjustment methodology that's designed to  
10 prevent risk aversion.

11 I think it's extremely unlikely  
12 that this particular measure would lead to any  
13 new risk aversion because isolated CABG is a  
14 group of patients that are already subject to  
15 multiple other NQF-endorsed measures including  
16 a mortality/morbidity/multi-domain composite.

17 So I think that although risk  
18 aversion is possible with any measure it's  
19 mitigated by proper risk adjustment.

20 Regarding gaming of the system  
21 which came into context in this discussion  
22 with the planned versus unplanned VAD but

1 certainly could also become an issue with  
2 other components of any risk adjustment  
3 methodology I think the solution to gaming is  
4 having, again, good definitions for all the  
5 fields, having proper documentation of those  
6 definitions, and the application of those  
7 definitions and having a solid audit program.

8 And as I said before, I think our  
9 audit program of the STS database is as good  
10 as any and better than most clinical  
11 registries in the country.

12 Finally, related to the issue of  
13 low-volume hospitals, this is a challenging  
14 problem for almost any measure, especially  
15 measures that deal with relatively rare  
16 procedures and relatively rare operations.

17 And I think within STS we've done  
18 a lot to make sure that appropriate confidence  
19 intervals are utilized so that the low-volume  
20 hospitals and their unique situations are  
21 respected and accounted for.

22 And I think I'll turn this over to

1 Sean to maybe make an additional comment about  
2 what we do to deal with low-volume hospitals.  
3 It's a topic we discussed on frequent phone  
4 conferences.

5 DR. O'BRIEN: This is Sean  
6 O'Brien. I don't think there's a magic bullet  
7 for dealing with the problem of small sample  
8 sizes.

9 As Jeff mentioned we report  
10 measures with measures of uncertainty so I  
11 think that's about the best you can do is to  
12 say what the evidence is and report that  
13 there's a range of possible performance that's  
14 consistent with the observed data.

15 CO-CHAIR KAPLAN: Thank you.  
16 Bruce?

17 CO-CHAIR HALL: So I would like to  
18 add that with respect to this particular  
19 measurement access isolated CABG the  
20 developers do shed light on this for us in  
21 their reliability information.

22 For instance, portraying that the

1 signal-to-noise version of the reliability  
2 assessment down to 30 cases gives a metric  
3 about 0.47.

4 So with 30 cases assessed that  
5 level of reliability is as good or better than  
6 probably anything you see in healthcare which  
7 I don't know if that's a reflection that  
8 isolated CABGs end up being a pretty  
9 homogenous reproducible query into quality I  
10 guess is one way to put it.

11 For whatever the explanations are  
12 I think we can be at least somewhat comforted  
13 by the notion that the reliability, the  
14 signal-to-noise assessment of this specified  
15 measure remains as good or better than  
16 anything else we see down to levels of 30  
17 cases assessed and perhaps below.

18 So, I personally take that as some  
19 comfort and reassurance around the  
20 specification of the measure.

21 CO-CHAIR KAPLAN: Thank you.

22 DR. JACOBS: This is Jeff Jacobs.

1 I agree with everything you just said and just  
2 to provide some clinical context.

3 A hospital doing 30 cases a year  
4 of coronary artery bypass grafting is a really  
5 low-volume hospital. I mean that's --

6 CO-CHAIR HALL: Jeff, this is 30  
7 cases over three years.

8 DR. JACOBS: Yes, I'm getting to  
9 that. So 30 cases a year since you're doing  
10 about 2 a month, a little over 2 a month.  
11 Thirty cases over three years means that it's  
12 one of the most low-volume hospitals on the  
13 planet. It's not where I would go for my  
14 coronary artery bypass graft.

15 CO-CHAIR KAPLAN: I think we're  
16 getting the drift. Larry, can you make a  
17 concise comment?

18 DR. GLANCE: Always.

19 (Laughter)

20 DR. GLANCE: So, this is very  
21 concise. I think the point that Karen makes  
22 is a really important one. And it is

1 crosscutting.

2 And the point is, and it will need  
3 to be looked at at some point because it's  
4 applicable to all the measures.

5 When you use shrinkage estimators  
6 what you end up doing is classifying virtually  
7 all of the low-volume providers as if they  
8 were average and grouping them together with  
9 other higher-volume centers that may in fact  
10 be average. So that is a problem and I think  
11 it will need to be addressed at some point.

12 CO-CHAIR KAPLAN: Absolutely.  
13 There is absolutely no disagreement that low-  
14 volume hospitals remain a perplexing and  
15 problematic issues for all of these outcome  
16 measures. And we probably aren't going to  
17 resolve that here now.

18 On the other hand, for this  
19 measure it looks like the low-volume issue is  
20 probably as not problematic as we're going to  
21 get.

22 So, having said that, any other

1        comments or questions? Okay, are we ready to  
2        vote usability? Go.

3                    MS. SHAHAB: Voting for usability  
4        and use, 1 high, 2 moderate, 3 low, 4  
5        insufficient information. And your time  
6        begins now. One more vote, please.

7                    We have all the votes for  
8        usability and use. Thirteen high, nine  
9        moderate, zero low, zero insufficient  
10       information.

11                   CO-CHAIR KAPLAN: Thank you. So  
12       now we're onto endorsement.

13                   CO-CHAIR HALL: I have no  
14       additional concerns.

15                   CO-CHAIR KAPLAN: Other comments  
16       or questions? Larry, did you have your gizmo  
17       up? Okay. Other comments? Are we ready to  
18       go? Voting.

19                   MS. SHAHAB: Voting for overall  
20       suitability for endorsement, 1 yes, 2 no.  
21       Time begins now.

22                   All votes are in for overall



1       suitability for endorsement. For measure 2514  
2       Risk-adjusted Coronary Artery Bypass Graft  
3       Readmission Rate, 22 yes, zero no.

4                   CO-CHAIR HALL: We thank our  
5       developers for their input. I guess we  
6       neglected to ask whether Dr. Shahian or Jane  
7       Han had anything to add, but too late for  
8       those of you on the phone. We thank you for  
9       your input.

10                   And we'd like to ask the next  
11       developers, Yale, CMS to come to the table.  
12       Thank you. We have our developers for the  
13       next measure 2515 to the table. Lein, Lisa  
14       and Elizabeth are with us.

15                   So if you wouldn't mind briefly  
16       introducing yourselves and then your measure.

17                   DR. SUTER: My name is Lisa Suter.  
18       I'm from the Yale Center for Outcomes,  
19       Research and Evaluation. And we're  
20       introducing the measure 2514.

21                   CO-CHAIR KAPLAN: Lisa, can you  
22       move just a tad closer to the mike? Thanks.

1 DR. SUTER: Sure. Can you hear me  
2 now? Great.

3 So I think the overall --

4 CO-CHAIR HALL: Lisa, I'm sorry.  
5 Did you say 2514? 2515?

6 DR. SUTER: 2515. My apologies.

7 CO-CHAIR HALL: Fifteen, thank  
8 you.

9 DR. SUTER: I think the discussion  
10 with the STS measure very nicely summarized  
11 the collaborative process which CMS allowed us  
12 to engage in with STS to develop these two  
13 measures.

14 They are as harmonized as two  
15 measures I think could possibly be. And the  
16 success with which the claims-based measure  
17 was able to achieve cohort and risk adjustment  
18 validation is certainly due to the close  
19 collaboration that we were able to participate  
20 with STS's surgeons and their workgroup.

21 And I think we've talked about how  
22 important CABG is as a readmission measure so

1 I'm not going to speak to that individually.

2 This measure differs slightly from  
3 the registry-based measure in that it measures  
4 all-cause unplanned readmissions after  
5 isolated CABG procedures. And similarly to  
6 use as a vetted guideline concordant approach  
7 to measure development that's been supported  
8 by the MAP.

9 As I mentioned the measure was  
10 developed in close collaboration with STS and  
11 every step of the measure development was  
12 performed in parallel with the STS measure  
13 developers and clinical experts.

14 I think as Dr. Jacobs mentioned  
15 both measure developers recognized that there  
16 are pros and cons to each measure, and that  
17 they each have a place in the measurement  
18 process.

19 The registry measure noting, as he  
20 said, a clinical-based risk adjustment model  
21 that I think has a greater face validity among  
22 clinicians but a lower penetrance in terms of

1 the number of hospitals that can be captured  
2 and assessed without burden upon the  
3 hospitals.

4 And as noted before we have  
5 reached over a 97 percent agreement in the  
6 cohort definition with the only discrepancies  
7 either being distinct measure decisions such  
8 as MAZE procedures which were made in concert  
9 with the measure developers, or with  
10 incongruities that can be ascribed neither to  
11 the claims nor to the registry data  
12 specifically and could represent errors in  
13 either data source.

14 I think the other clarification  
15 I'd just like to offer, and I'm sure we'll  
16 have other discussions as we move on, is that  
17 while this measure was developed in the over-  
18 65 population I think it was noted that we  
19 have assessed it in a California all-payer  
20 data source.

21 This is to allow flexibility for  
22 other users of this measure to use it in an

1 all-payer data source. But it was in fact  
2 developed in a full national Medicare over-65  
3 population data set.

4 And finally, just to remind people  
5 that for other readmission measures that CMS  
6 has implemented regarding the low-volume  
7 hospital discussion there has been -- always  
8 been an opportunity for hospitals to be noted  
9 either that they are no different from  
10 average, or that they are too small-volume to  
11 be ascribed to a particular category. So that  
12 that inability to categorize due to small  
13 sample size is transparent to users. Thank  
14 you very much.

15 CO-CHAIR HALL: Thank you, Lisa.  
16 Lein, any comments or anything else to add?

17 DR. HAN: Hi. I am Lein Han from  
18 CMS. And I just want to say that we  
19 appreciate very much the collaboration with  
20 STS. The working relationship was very good  
21 and I really appreciate that. So thank you.

22 CO-CHAIR HALL: Thank you. So

1 we're in the category of evidence. I would  
2 like to turn to our primary discussants Ross  
3 and John and ask them to open the discussion.

4 DR. EDMUNDSON: Yes, this is  
5 ground that we covered here. But the evidence  
6 is pretty compelling that there is a  
7 readmission problem in this population and  
8 that there's opportunity for improvement in  
9 that. So I think that's well established.

10 DR. BULGER: I don't have anything  
11 to add. From an evidence standpoint it's very  
12 similar to the last measure which we looked  
13 at.

14 CO-CHAIR HALL: I'm not seeing any  
15 other cards so we'll vote evidence.

16 MS. SHAHAB: Voting for 1(a)  
17 evidence, 1 yes, 2 no. Time begins now. Just  
18 one more vote.

19 We have all the votes for 1(a)  
20 evidence. Twenty-two yes, zero no.

21 CO-CHAIR HALL: Performance gap.  
22 Any additional commentary above and beyond

1       what we've reviewed?   John?

2                   DR. EDMUNDSON:   Just on the  
3       information provided that they have a mean of  
4       16.8 percent readmission in the range of 12 to  
5       22.1 percent.   But again it's information  
6       that's redundant as to what we discussed  
7       before.

8                   CO-CHAIR HALL:   Wes?

9                   DR. FIELDS:   Yes, a question you  
10      can either answer now as developers or later  
11      in the process if you think it's more  
12      appropriate.

13                          But I'm just curious if analysis  
14      of claims data reveals whether there is a  
15      greater degree of variation or less than  
16      optimal outcomes among the sites that don't  
17      participate in STS or not.

18                          So I'm just curious about whether  
19      or not that's been part of your analysis and  
20      whether you think there may be greater  
21      variation in those few remaining sites that  
22      aren't part of the STS registry.

1 DR. SUTER: This is Lisa Suter  
2 from Yale. It's an excellent question.  
3 Because of the proprietary nature of the STS  
4 data we do not have the ability -- we at Yale  
5 do not have the ability to identify individual  
6 hospitals that either matched or did not  
7 match.

8 I can't actually speak to whether  
9 or not STS has investigated that among the  
10 hospitals that they were unaware that did not  
11 match to the Medicare data.

12 I know that many of the hospitals  
13 that were not included in the validation  
14 process because they did not link or match did  
15 not have active participation in the STS  
16 registry which represents about 10 percent of  
17 hospitals in the nation.

18 DR. FIELDS: But do you know any  
19 ballpark on the number of total CABGs in  
20 Medicare that did not appear to have an STS  
21 case match?

22 DR. SUTER: So, speaking to the



1 isolated CABG cohort that we identified,  
2 approximately 30,000 patients or one-fifth of  
3 the national isolated CABG patients identified  
4 in claims approximately did not link or match.

5 DR. FIELDS: To an STS case.

6 DR. SUTER: To the STS. I don't  
7 know the outcome rate among -- we did not  
8 investigate the outcome rate among those  
9 patients.

10 CO-CHAIR HALL: Wes, does that  
11 answer your question or is it as close as  
12 we're going to get for now?

13 DR. FIELDS: Well, we'll probably  
14 talk more about it. I just find it  
15 fascinating. I mean if ultimately what we're  
16 trying to do is to reduce the remaining  
17 variation.

18 You know, I have a lot of respect,  
19 regard for the STS process and registry and  
20 measure, but it raises a question about which  
21 measure is most likely to actually reduce  
22 variation going forward.

1 CO-CHAIR HALL: Great. Any other  
2 additional comments? I'm not seeing any cards  
3 raised for performance gap.

4 MS. SHAHAB: Voting for 1(b)  
5 performance gap, 1 high, 2 moderate, 3 low, 4  
6 insufficient. Time begins now.

7 We have all the votes for 1(b)  
8 performance gap. Nine voted high, thirteen  
9 voted moderate, zero low and zero  
10 insufficient.

11 CO-CHAIR HALL: Priority, John?

12 DR. BULGER: So this has a similar  
13 priority to the last measure. And as noted  
14 before this is one of MedPAC's targeted  
15 diagnoses for readmissions priority.

16 CO-CHAIR HALL: Okay, any  
17 additional comments? Not seeing any.

18 MS. SHAHAB: Voting for 1(c) high  
19 priority. One is high, two moderate, three  
20 low, four insufficient. Your time begins now.

21 We have all the votes for 1(c)  
22 high priority. Eighteen voted high, four

1       voted moderate, zero low and zero  
2       insufficient.

3                   CO-CHAIR HALL:   Moving into the  
4       scientific realm, reliability and validity.  
5       John, Ross, you want to open the discussion?

6                   DR. EDMUNDSON:   Okay, reliability.  
7       This is a test/retest split sample.   And with  
8       intraclass correlation coefficient here.  
9       Large numbers.

10                   What I found interesting -- and  
11       they used Medicare claims for the years 2008,  
12       09 and 10 as well as the Society of Thoracic  
13       Surgeons.   But I believe this is on the claims  
14       data that you're doing the split samples, is  
15       that correct?

16                   DR. SUTER:   That's correct.

17                   DR. EDMUNDSON:   And then on that  
18       the random split samples for each hospital was  
19       the intraclass correlation coefficient was  
20       0.331 which was judged as fair.   Could  
21       developers comment on that relationship?

22                   DR. SUTER:   Yes, we heard during

1 the workgroup the concerns about the low  
2 intraclass correlation coefficient during the  
3 split sample retest.

4 So, trying to understand the  
5 stability of the measure result, we think that  
6 the most robust and conservative assessment is  
7 to fully separate the sample of patients so  
8 that in an individual hospital there is no  
9 overlap between the two samples.

10 So we randomly split each  
11 hospital's patients into equal portions and  
12 then we calculate the risk-standardized  
13 readmission rate at the hospital level in each  
14 of those samples.

15 And using a 3-year data set which  
16 was what was available to us we received -- we  
17 yielded an ICC of 0.33 which you would agree  
18 is outside of the range of 0.4 to 0.7 which is  
19 usually interpreted as fair to good or  
20 moderate for intraclass correlation  
21 coefficients.

22 Although in many, most of the

1 readmission measures other than the hospital-  
2 wide readmission measure that CMS has  
3 implemented use three years of data in order  
4 to achieve a sample size. And this is  
5 particularly true in a procedural-based  
6 measure such as CABG.

7 In response to the concerns about  
8 the ICC and based on some recommendation from  
9 prior NQF discussions for other measures using  
10 a method similar to John Adam's paper which  
11 was referenced in regards to RAND's method  
12 using the Spearman-Brown prophecy formula --  
13 and we have this information available to the  
14 committee if you'd like to see it -- we  
15 estimated what would the intraclass  
16 correlation coefficient be if we were actually  
17 able to create a 3-year sample that could be  
18 split into two equal 3-year samples. So that  
19 you had the volume of the 3-year sample but  
20 you still had two completely independent and  
21 non-overlapping samples.

22 And when we perform that analysis

1 for CABG the ICC rises to 0.5. It rises for  
2 all of the readmission measures that our  
3 measure developer has in front of the  
4 committee today and we'd be happy to share  
5 this information. We have copies that we can  
6 provide to you.

7 CO-CHAIR HALL: Additional  
8 comments on this area, reliability?  
9 Reproducibility. Not seeing any -- go ahead.

10 CO-CHAIR KAPLAN: I would say that  
11 for these intraclass correlation coefficients  
12 this is roughly in the range of the things you  
13 see.

14 And in part -- and we were just  
15 having a dialogue about it. In part it's  
16 because within hospitals when you're looking  
17 across patients within hospitals you're  
18 dealing with a dichotomous variable of  
19 readmitted/not readmitted. So it's a little  
20 bit of a compressed variance problem.

21 But having said that there are,  
22 you know, this is in the zone where you --

1 exactly what you would see when you look at  
2 other kinds of measures we've already  
3 considered for the intraclass correlation  
4 coefficient.

5 CO-CHAIR HALL: Not seeing any  
6 cards we'll vote on reliability.

7 MS. SHAHAB: Voting for 2(a)  
8 reliability, 1 is high, 2 moderate, 3 low, 4  
9 insufficient and your time begins now.

10 We have all the votes for 2(a)  
11 reliability. One voted high, twenty-one  
12 moderate, zero low and zero insufficient.

13 CO-CHAIR HALL: And validity?  
14 Ross, John, opening comments.

15 DR. BULGER: So a couple of  
16 questions on validity. In general, the C  
17 statistic was 0.63 which is similar to the  
18 last measure.

19 This is administrative data, not  
20 clinical data so I wondered if you at some  
21 point could speak to that.

22 The other question that came up

1 with the last data was with the LVAD patients.  
2 And they are in this group. And we had just  
3 talked about the ability to exclude one subset  
4 of those.

5 But my assumption, and you can  
6 speak to this, that because of the  
7 administrative -- yours is administrative data  
8 that you could only exclude them totally or  
9 not exclude them, but not subset them into  
10 elective and non-elective LVAD patients.

11 The face validity from the panel I  
12 think was strong as well. In looking at your  
13 exclusions they were similar to the last one  
14 we looked at.

15 There was a question of excluding  
16 patients from the panel in our discussions  
17 from the workgroup of excluding patients who  
18 died in the 30 days.

19 And I think you had mentioned, you  
20 made some comments back on that already that  
21 they were in because that was what was similar  
22 to the there Yale measures, to keep those in.



1 But I was wondering if you could speak to that  
2 as well.

3 DR. SUTER: Great, thank you. And  
4 I also just wanted to correct an answer. I  
5 had responded to the question of capture. My  
6 off-the-cuff math was off. So instead of  
7 being 20 percent it's 10 percent non-capture  
8 rate. I apologize for that error.

9 In regards to post-discharge  
10 mortality. So patients who die within the  
11 hospital obviously are not at risk for  
12 readmission. They are in fact excluded from  
13 the measure.

14 There are a small proportion of  
15 patients who die after discharge from the  
16 hospital. That is about 1.4 percent of  
17 patients. They do as expected have a higher  
18 readmission rate.

19 This measure is paired with a  
20 mortality measure which is in front of the  
21 surgery committee and will be reviewed by the  
22 NQF later this year.

1                   We think that that allows the  
2                   capture of a full spectrum of quality  
3                   outcomes. So to prevent any unintended  
4                   consequences of measuring readmission in this  
5                   cohort of patients.

6                   In regards to the VAD issue, as  
7                   has been previously noted we do include VAD  
8                   procedures based on the recommendation of a  
9                   host of cardiothoracic surgeons who are  
10                  involved in this measure development. And it  
11                  is harmonized with the STS measure.

12                  As you noted we do not have the  
13                  ability to finesse the -- the ability to  
14                  identify unplanned versus planned VAD  
15                  procedures. In a cohort of about 150,000  
16                  patients with isolated CABG only 90 have VAD  
17                  procedures.

18                  About 50 percent of them have  
19                  percutaneous VAD procedures and they have a  
20                  readmission rate very close to the mean 17.5  
21                  where the average hospital readmission rate is  
22                  16.5 in non-VAD patients.

1           Those that have more invasive VAD  
2       procedures do have a higher readmission rate  
3       around 30 percent.

4           Because they represent 0.03  
5       percent of the entire cohort of isolated CABGs  
6       and they are not clustered in any one  
7       particular hospital or type of hospital we as  
8       measure developers are open to bringing back  
9       to our workgroup the recommendation from NQF  
10      to remove these procedures if there's a strong  
11      feeling that they misrepresent the quality of  
12      hospital performance using this measure.

13          We went ahead with the best  
14      recommendations from the largest group of  
15      cardiothoracic surgeons so we felt confident  
16      in that recommendation and we are eager for  
17      the NQF's advice.

18          And I will also talk about risk  
19      adjustment. I don't know if people wanted to  
20      comment on VADs before I move onto risk  
21      adjustment.

22          So, in the materials that we

1 submitted we also submitted a technical  
2 report. And on page 81 and 82 there are two  
3 graphs that I think are particularly helpful  
4 to understand the risk adjustment validation  
5 that was performed with the Society of  
6 Thoracic Surgeons.

7 And this is in a matched cohort of  
8 patients as was previously discussed.

9 And I know that it's not easy to  
10 see this, but these are all of the hospitals  
11 that were identified as outliers among all of  
12 the thousand or so hospitals included in the  
13 validation process.

14 And each pair of lines and dots  
15 represent the risk-standardized readmission  
16 rate achieved with the claims-based measure  
17 and that achieved with the registry-based  
18 measure.

19 And while it's I know impossible  
20 for you to see across a room, the gray area  
21 represents -- the top of the gray area  
22 represents the national rate.

1                   And what I hope is visually  
2           apparent is that those paired lines are  
3           extremely overlapping. So in addition to  
4           achieving an ICC of 0.9 something depending on  
5           what ICC method you use so you can see that  
6           the risk-standardized rate is highly  
7           correlated, the interval estimates, the  
8           uncertainty around that interval estimate,  
9           excuse me, around that risk-standardized  
10          readmission rate is also highly correlated.

11                   And any time you draw a line to  
12          move patients or hospitals into a performance  
13          category which is what the nationally reported  
14          readmission measures do. They report them as  
15          better than average, worse than average, or no  
16          different than average, or too small to  
17          quantify. You have to draw a line.

18                   And I'm happy to share this. It's  
19          also in your materials. But when you draw  
20          that line some people fall on one or the other  
21          side.

22                   But I think what's very reassuring

1 about this is that the two measures produce  
2 performance estimates for each hospital that  
3 are qualitatively highly similar.

4 Quantitatively they do miscategorize a few  
5 percentages of patients, but the specificity  
6 in the claims-based measures is close to 100  
7 percent. It's over 99 percent which I think  
8 for a high-stakes measure which readmission  
9 may be we think is the proper emphasis in  
10 terms of being conservative.

11 CO-CHAIR HALL: Okay. I'm sorry,  
12 I myself am trying to follow what you said  
13 while looking at the diagram. So I'm slightly  
14 lost on that diagram. But I know Larry has a  
15 question.

16 DR. GLANCE: So, I just wanted to  
17 comment on the validation part. And I want to  
18 preface my comments by saying I understand the  
19 need for a measure based on administrative  
20 data because some of the hospitals in the U.S.  
21 are not part of STS.

22 Having said that, you're

1 absolutely correct in that there's a very high  
2 level of agreement between your measure and  
3 the STS measure. In fact, according to your  
4 reporting there's about 97 percent agreement  
5 between the administrative data and the STS  
6 measure in terms of classification as high  
7 quality, average quality and low quality.

8           Having said that, when you look at  
9 the sensitivity of the CMS measure for  
10 identifying high-quality and low-quality  
11 hospitals it's about 40 percent and 60 percent  
12 respectively. So, I'd like you to comment on  
13 that.

14           DR. SUTER: So, I think the  
15 challenge with this validation process is in  
16 this case we were validating the risk  
17 adjustment. So we made the assumption that  
18 the registry data represents the gold  
19 standard.

20           We don't actually know what the  
21 gold standard for performance categorization  
22 is in the United States for isolated CABG

1 procedure readmission rates. So, I can't  
2 really comment on whether or not sensitivity  
3 of 40 or 60 percent is appropriate or not.

4 I think it is a challenge when you  
5 are creating measures that you want to be  
6 responsive to change and useful to hospitals,  
7 and yet they're being publicly reported and  
8 you want the estimates to be stable and  
9 reliable.

10 And in that situation we often  
11 need longer measurement periods, larger data  
12 sample sizes and we favor in the claims-based  
13 measure and the registry measure uses the same  
14 hierarchical modeling that does pull people  
15 towards a less outlier position. But I think  
16 we felt in the situation of how these measures  
17 may be used that that was a reasonable  
18 tradeoff.

19 And certainly the policy of  
20 implementation is not our decision, but we  
21 work in close concert with CMS to make sure  
22 that we're responsive to their needs.



1 CO-CHAIR KAPLAN: I'd like to just  
2 sort of clarify some issues because from a  
3 measurement person's perspective criterion  
4 validity says there is a gold standard and  
5 you're comparing a new measure to that gold  
6 standard. There is no gold standard.

7 Convergent validity says I have  
8 two sources of information and they're telling  
9 me roughly the same thing. That's confidence-  
10 inspiring from the graph I'm staring at right  
11 now. Two data sources tell you roughly the  
12 same thing.

13 Discriminate validity, however,  
14 says I can tell hospitals apart. And from  
15 that perspective not so much. So, can you  
16 help us understand sort of in those terms?

17 So, criterion validity is off the  
18 shelf. Convergent validity we're seeing  
19 evidence of. What happens to discriminate  
20 validity and can you tell hospitals apart?

21 DR. SUTER: So, we were unable to  
22 de-identify the individual hospitals that are

1 discordant. So, it's challenging to dig into  
2 the discordant hospitals to try and understand  
3 why a particular hospital might have been  
4 considered higher quality or lower quality  
5 from one data source versus another.

6 I think it is an important  
7 question. Unfortunately I can't speak to it.

8 CO-CHAIR KAPLAN: Thank you.

9 CO-CHAIR HALL: Any other  
10 comments, concerns on the topic category of  
11 validity? Wes?

12 DR. FIELDS: Yes, I just want to  
13 come at this from a different direction. So  
14 it's sort of reciprocal to my earlier comment.

15 I would assume that if you have a  
16 clinical data set as the registry does that  
17 you'd have more independent variables that  
18 help you get at the nature of quality if you  
19 will and to distinguish between facilities and  
20 programs.

21 So I just want to ask a first  
22 order question. Compared to the CMS claims

1 data set in terms of numbers of data points  
 2 how much larger is the data set the STS  
 3 registry uses compared to the number of  
 4 elements in a claim stream that CMS would  
 5 receive?

6 CO-CHAIR HALL: I want to push on  
 7 you, Wes. I can see this might shed some  
 8 light but we're only considering the measure  
 9 in front of us, right? We're not really  
 10 considering its comparison to an STS  
 11 counterpart.

12 So, if your question helps us get  
 13 to this measure I think we're okay. So, if  
 14 the developers can comment on it in that  
 15 light, in that context. Or did I  
 16 misunderstand, Wes?

17 DR. FIELDS: I thought I was  
 18 restating Sherrie's question from a different  
 19 context. I think the issue of how you define  
 20 quality is pretty interesting. And I'm  
 21 assuming that having more data elements from  
 22 a clinical registry that's larger in scope

1     than a claim stream gives you the possibility  
2     of doing that.

3                 I'm just asking them to quantify  
4     how many more variables are in the registry  
5     stream. Because -- so it's really a way of  
6     restating Sherrie's question about how you get  
7     at the nature of quality and distinguishing  
8     between facilities and programs.

9                 DR. SUTER: So I think -- thank  
10    you, Lisa Suter. The response is two that are  
11    C statistics so our discriminate ability is  
12    essentially identical.

13                And I think the other is that both  
14    measure -- I mean, certainly our -- we as the  
15    measure developer see room for both of these  
16    measures in the world of measurement. They  
17    offer unique perspectives. They were  
18    developed in an incredibly harmonized fashion  
19    and offer advantageous synergistic information  
20    about hospital performance, not necessarily  
21    replacement performance.

22                CO-CHAIR HALL: And they do

1 provide in their methodology report these  
2 insights such as you're seeing on this graph  
3 to try to help us understand whether one  
4 approach or the other approach helps  
5 discriminate the quality better.

6           The underlying notion that more  
7 variables will help you discriminate quality  
8 better may or may not be true. More variables  
9 could lead you to decide there is no  
10 difference in quality. So, the underlying  
11 construct is still ill-defined or  
12 controversial.

13           Other comments? Wes, do you have  
14 more comments? Any other comments in this  
15 category?

16           CO-CHAIR KAPLAN: I'd just add one  
17 thing. More variables usually help you  
18 improve your estimates of reliability, not  
19 necessarily your estimate of validity. So,  
20 reliability -- you ask more things, you get a  
21 tighter, more reliable response. But not  
22 necessarily a more valid response.

1 CO-CHAIR HALL: Okay, I'm not  
2 seeing any cards raised so we'll move on  
3 validity.

4 MS. SHAHAB: Voting for 2(b)  
5 validity. One is high, two moderate, three  
6 low, four insufficient and your time begins  
7 now.

8 We have all the votes for 2(b)  
9 validity. Two high, twenty moderate, zero  
10 low, zero insufficient.

11 CO-CHAIR HALL: Feasibility?  
12 Ross?

13 DR. EDMUNDSON: Feasibility, I  
14 think this is claims data. This is very  
15 feasible. We can do this.

16 CO-CHAIR HALL: Any other  
17 concerns? I don't see any raised.

18 MS. SHAHAB: Voting for criteria 3  
19 feasibility. One is high, two moderate, three  
20 low, four insufficient and your time begins  
21 now.

22 We have all the votes for

1 feasibility. Twenty voted high, two moderate,  
2 zero low and zero insufficient.

3 CO-CHAIR HALL: Usability. John?

4 DR. BULGER: So I think the  
5 usability is similar at least to the last  
6 measure. I think the question came up in our  
7 pre-work is, you know, this discrimination  
8 issue of high performers, mid performers and  
9 low performers. And if this goes like some of  
10 the other measures that have been used which  
11 are set at a midpoint really from a payment  
12 standpoint I think there was concern amongst  
13 the group how that would perform.

14 And the other concern was if it  
15 really only was able to discriminate the tails  
16 what the use to the public would be from that  
17 standpoint.

18 Otherwise, I think we were fine  
19 with what we were looking at.

20 CO-CHAIR HALL: Paul?

21 DR. HEIDENREICH: Yes, just in  
22 terms of going forward from CMS' perspective.

1 I think there's going to be 20 -- there's  
2 about 20 hospitals rated as good or better  
3 than expected. Is that about right? Which  
4 some people have said is very low.

5 I'm not sure what the right  
6 percentage we should label as outliers, but is  
7 there any plan to change that implementation  
8 when this is reported on the website? About  
9 which one -- what fraction are outliers versus  
10 what fraction are not outliers?

11 DR. SUTER: So from a measure  
12 developer standpoint -- this is Lisa Suter --  
13 that you're referring to the 2008-2010 data.  
14 I can't speak to more recent data. I don't  
15 have those estimates in front of me.  
16 Presumably more recent data would be used for  
17 reporting purposes.

18 And in terms of whether or not to  
19 use the same performance categorizations that  
20 are used in other measures I'll defer to Dr.  
21 Han.

22 DR. HAN: Hi, this is Lein Han



1 from CMS. At this moment we plan to continue  
2 the way we display the data on Hospital  
3 Compare.

4 And I believe that you all know  
5 but I just want to describe again the four  
6 categories. We have three compared to the  
7 national rate that's better, worse, or no  
8 different. And the other one is the category  
9 of small hospital that have less than 25, we  
10 put them aside. So, that would be the way  
11 this moment -- yes, that's the way we're going  
12 to plan to display the measure. Thank you.

13 DR. SUTER: And I'll just add that  
14 currently the interval estimates that were  
15 used for the graphic that was up and are used  
16 for the other measures reported on Hospital  
17 Compare uses a 95 percent interval estimate.

18 If you felt, if the nation felt  
19 that a larger number of outliers was a more  
20 revealing information you could certainly  
21 change the interval estimate for reporting  
22 purposes in order to identify more outliers.

1 DR. HAN: We welcome suggestions  
2 if you have any ideas.

3 CO-CHAIR HALL: And just to  
4 clarify it looks like in the materials  
5 submitted that there were about 1.2 percent  
6 high/good outliers and 1.5 percent low/bad  
7 outliers. So we're in the 1.2 to 1.5 percent  
8 of institutions being labeled according to the  
9 specifications you just heard.

10 DR. SUTER: And may I also add  
11 that each hospital receives a hospital-  
12 specific report for the currently publicly  
13 reported readmission measures. This is Lisa  
14 Suter.

15 And in that report they receive  
16 detailed information about all of their  
17 patients in the measures.

18 So, while there's a lot of focus  
19 on who's an outlier on Hospital Compare, there  
20 is still a tremendous amount of detailed  
21 information reported back to hospitals.

22 And I know STS I'm sure has

1 similar reporting back to their hospitals,  
2 detailed information about patients in the  
3 cohort, who was included, who was readmitted.  
4 This is information that's not available to  
5 hospitals because a large proportion of  
6 patients are readmitted to hospitals who did  
7 not perform the CABG. So this kind of  
8 information is incredibly valuable for quality  
9 improvement purposes even if there is not a  
10 distinct large number of outliers on a  
11 publicly reported website.

12 DR. HAN: Hi, this is Lein Han  
13 from CMS. I just want to add to that.

14 We also, CMS also offer the Q&A  
15 service. It's like hospital when they get the  
16 data they can call -- they can email CMS any  
17 question they have.

18 Yes, I don't know whose phone  
19 number I'll provide for who to call --

20 (Laughter)

21 DR. HAN: But we do have this  
22 service. So, hospital can contact us any time

1       they want.

2                       CO-CHAIR HALL:   Larry?

3                       DR. GLANCE:    So, I have a comment  
4       on usability.  I think we both recognize that  
5       we have two very, very high-quality measures  
6       but they're essentially looking at the same  
7       thing.

8                       And the issue that I see as a  
9       potential issue is that although all of us  
10      understand in this room that risk adjustment  
11      isn't perfect and that depending on which risk  
12      adjustment model you may end up coming to  
13      different conclusions, I'm not sure that all  
14      the consumers of this information will  
15      understand that.

16                      And I think it goes to the heart  
17      of credibility of performance measurement when  
18      you potentially release in the public domain  
19      two different report cards which significantly  
20      disagree on which hospitals are identified as  
21      high quality and which ones are identified as  
22      low quality.

1                   And I would urge caution to the  
2                   developers, CMS and STS, that when you decide  
3                   which quality measures to release to the  
4                   public that maybe you agree on releasing one  
5                   set of measures as opposed to both for the  
6                   hospitals where you have overlap.

7                   DR. HAN: Hi, this is Lein Han,  
8                   CMS. We think these CABG is a very important  
9                   area. We all recognize that. And we think  
10                  that these two models are pretty good. Two  
11                  very good measures.

12                  I think the consideration for CMS  
13                  is what is the most cost-effective and less  
14                  burdensome way for hospitals to implement the  
15                  measures. And that's really our consideration  
16                  right now.

17                  For us claims is the most cost-  
18                  effective way to implement input in measure.  
19                  So, that would be our priority to have a way  
20                  to implement most feasible to both CMS and to  
21                  hospitals.

22                  CO-CHAIR HALL: Any additional

1 concerns? Thoughts?

2 We know that the claims-based  
3 measure has been written into IPPS for 2017  
4 and the STS one has not. That's my  
5 understanding. I don't think that affects our  
6 decision about whether the measure in front of  
7 us is useful but we -- I think it does relate  
8 to Larry's comment and in fact relates to  
9 Wes's as well. Larry's and Wes's comments  
10 both related to comparison between two  
11 measurement programs that could give some  
12 different results.

13 In fact, we know the registry-  
14 based program seems to identify at least twice  
15 as many institutions on the tails as the  
16 claims-based program. So there's a danger for  
17 what Larry's concerned about.

18 But in this case the plan is to  
19 implement. We know this measure is written  
20 into IPPS for 2017 and again, that I don't  
21 think affects the overall assessment of this  
22 measure or should affect it.

1 Any other concerns or questions  
2 before we vote usability? I don't see any.

3 MS. SHAHAB: Voting for usability  
4 and use, 1 high, 2 moderate, 3 low, 4  
5 insufficient information. Your time begins  
6 now.

7 We have all the votes for  
8 usability and use. Three high, eighteen  
9 moderate, one low and zero insufficient  
10 information.

11 CO-CHAIR HALL: Okay, before we  
12 vote overall any additional concerns or  
13 comments? Summary comments? Wes, you're just  
14 smiling.

15 DR. FIELDS: Bruce, I'm just so  
16 happy to be here to participate in the  
17 process. Thank you so much.

18 (Laughter)

19 CO-CHAIR HALL: Why do I feel like  
20 Wes is coming after me. Any final comments?  
21 Not seeing any.

22 MS. SHAHAB: Voting for overall

1       suitability for endorsement, 1 yes, 2 no.

2       Time begins now.

3                       We have all the votes for overall  
4       suitability for endorsement for measure 2515  
5       Hospital 30-day All-cause Unplanned Risk-  
6       standardized Readmission Rate Following  
7       Coronary Artery Bypass Graft Surgery, 21 yes,  
8       1 no.

9                       MR. AMIN: So, before we move onto  
10       the next measure I just want to remind the  
11       committee and the developers that these  
12       recommendations for endorsement are still  
13       contingent on a conversation related to  
14       competing measures.

15                      So this measure and the STS  
16       measure will be discussed in terms of how  
17       they're, you know, whether they're competing  
18       and whether it's justified to have both  
19       measures in the portfolio.

20                      And that is in addition to this  
21       SNF measure, SNF readmission measures that we  
22       discussed yesterday. We likely won't have



1 time for that discussion during today's in-  
2 person meeting but we will have a follow-up  
3 call to discuss that.

4 CO-CHAIR HALL: I've been trying  
5 to resist going down that road but your  
6 comment makes it irresistible to ask this  
7 question though.

8 We just talked about two measures  
9 but we know one of them is written into IPPS.  
10 So does that not affect that discussion around  
11 competition between those measures?

12 DR. BURSTIN: You know, it's a  
13 great question, Bruce. I personally feel like  
14 for this committee's sake it's really about  
15 the comparability of the measures themselves  
16 and about the questions of whether you can in  
17 fact from purely a perspective of use broadly  
18 have both of those measures out there. Will  
19 it add to confusion? Can people understand  
20 the nuances? How much does the difference in  
21 data source affect the way people may use  
22 them? So I don't think it has a particular

1 issue.

2 I think it may very well come up  
3 at the MAP certainly where they are  
4 specifically charged with looking at which  
5 measures for which programs. But I don't  
6 think it should particularly have an impact on  
7 the discussion around competing -- and in this  
8 instance it's not really harmonization. They  
9 are fully harmonized except for data source.

10 I think it is still a competing  
11 issue and I think Larry's comments really  
12 raised that issue significantly in terms of  
13 understanding comparability, the comments  
14 related about the 15 percent of people who  
15 aren't in STS who are in this measure.

16 I mean there's just many issues I  
17 think you'll have a chance to chew on I assume  
18 in a separate conference call to follow.

19 CO-CHAIR HALL: We thank the  
20 developers from CMS, Yale.

21 Are the same folks going to stay  
22 at the table for the next? Or will it be a

1 different team? New crew?

2 CO-CHAIR KAPLAN: Okay, this is  
3 measure number 2513 Hospital 30-day All-cause  
4 Risk-standardized Readmission Rate Following  
5 Vascular Procedures. The developer is Yale.

6 Could you please briefly introduce  
7 yourselves and then the measure. Is anyone on  
8 the phone? No, everyone is here in the room.  
9 Excellent.

10 DR. MCNAMARA: Hi, I'm Bob  
11 McNamara. I'm a cardiologist at Yale. Jephtha  
12 Curtis is next to me, another cardiologist at  
13 Yale. Susannah Bernheim, also on the team is  
14 behind us here and we have multiple people on  
15 the phone including Lori Geary who's a part of  
16 the team.

17 I understand you have the whole  
18 measure in front of you. I just wanted to  
19 have a few -- to give a few highlights  
20 regarding this measure.

21 It's a very important measure.  
22 Vascular surgery and readmission was

1 identified in the MedPAC report as one of the  
2 seven conditions that were responsible for up  
3 to 30 percent of the preventable readmissions.  
4 The high cost, high readmission, high  
5 variation right along with the information  
6 that providers and hospitals and physicians  
7 need for quality development and patients need  
8 for choice. So that was the first one.

9 The second highlight is going into  
10 this measure we knew it was going to be very  
11 complex. We knew we would need a lot of  
12 clinical input both on our team and within our  
13 technical expert panel, the technical expert  
14 panel which was highly competent and engaged  
15 in the whole process involving multiple  
16 different specialties that are going to be  
17 affected by this measure, vascular surgeons,  
18 interventional radiologists, interventional  
19 cardiologists as well as experts in  
20 methodology, policy and patient advocate. And  
21 they were involved from the beginning for many  
22 if not all of the major decisions.

1                   A third also regards the  
2                   complexity. As opposed to some of the other  
3                   measures this is going to have many different  
4                   procedures. So, identification of the  
5                   procedures and ultimately the patients was  
6                   going to be very critical.

7                   We developed a few guiding  
8                   principles right from the beginning to  
9                   identify which procedure should be included.

10                  First, it was going to be a major  
11                  procedure that was going to be involved. We  
12                  didn't want to include venal punctures,  
13                  arterial catheterizations and things like  
14                  that.

15                  It had to be clinically coherent.  
16                  Initially MedPAC called it other vascular  
17                  meaning didn't want cardiac, didn't want  
18                  intracranial.

19                  We also made the decision not to  
20                  include hemodialysis catheter-related  
21                  thrombectomies and the like.

22                  And the third criteria was it had

1 to be central to the hospitalization. We  
2 didn't want the vascular surgery to be a  
3 suturing of an artery from another surgery.  
4 So those were some of the guiding principles.

5 Finally, another major highlight  
6 regards the risk adjustment that we used. The  
7 typical hierarchical model including both the  
8 patient characteristics as well as clustering  
9 of patients within a hospital.

10 In addition to the patient  
11 characteristics we wanted to include the  
12 different procedures. So we grouped the  
13 procedures in eight different categories.  
14 They included both anatomical location at  
15 neck, thoracic, abdominal and limb as well as  
16 an unspecified.

17 And we wanted to be inclusive as  
18 possible, include both endovascular procedures  
19 and open. So there's many other aspects of it  
20 but just wanted to give you those highlights.  
21 And open for any questions. Thank you.

22 CO-CHAIR HALL: So we apologize at

1 the table. We've been doing a little bit of  
2 whispering while Robert was talking. We  
3 apologize for that.

4 I was an expert on this measure  
5 for Yale and so I'm going to recuse myself  
6 from this discussion and that's what we've  
7 been whispering about. So I'll turn over to  
8 Sherrie.

9 CO-CHAIR KAPLAN: Okay. So, I did  
10 not review this measure and the other  
11 reviewer, Paulette, is not also with us today.  
12 So I am going to be looking at Bruce's --

13 MR. AMIN: There are a number of  
14 workgroup members --

15 CO-CHAIR KAPLAN: Who were on the  
16 workgroup.

17 MR. AMIN: Yes.

18 CO-CHAIR KAPLAN: So I'm going to  
19 look at Bruce's notes as best I can and the  
20 rely -- who was on the workgroup? Hands?  
21 Okay, so at least some people here have -- I  
22 did not review this measure so I will look at

1     Bruce's notes as best I can. And then we will  
2     count on the workgroup members to kind of  
3     pitch in here.

4                     Okay, so with respect to the  
5     evidence, comments from the workgroup?

6                     MS. KHAN: So the workgroup 1  
7     members were John Bulger, Bruce Hall, Mae  
8     Centeno, Ross, Paul, Larry, Cristie and  
9     Paulette.

10                    CO-CHAIR KAPLAN: Comments?  
11     Larry?

12                    DR. GLANCE: The evidence is very  
13     strong for this measure.

14                    CO-CHAIR KAPLAN: Other comments  
15     from anybody else on the workgroup? Okay, I  
16     guess we're ready to vote.

17                    MS. SHAHAB: Voting for 1(a)  
18     evidence. One is yes, two is no and your time  
19     starts now. We still need two more votes.

20                    We have all the votes for 1(a)  
21     evidence. Twenty yes, one no.

22                    CO-CHAIR KAPLAN: Okay.



1 Performance gap. Larry, do you want to speak  
2 to that?

3 DR. GLANCE: So there's good  
4 evidence of a performance gap. Between the  
5 10th percentile and the 90th percentile the  
6 risk-standardized readmission rates were 12.3  
7 percent versus 14.9 percent respectively. So,  
8 about an over 2.5 percent absolute difference.

9 CO-CHAIR KAPLAN: Yes, the  
10 interquartile range was 12.9 to 14.3. So, but  
11 the range looks like 10 to 18 percent from the  
12 highest to the lowest. So there appears to me  
13 as well to be compared to some of the other  
14 measures we've seen a performance gap. Paul?

15 DR. HEIDENREICH: I agree there's  
16 a gap. It doesn't seem as large to me as some  
17 of the other gaps. But that still leaves  
18 moderate.

19 CO-CHAIR KAPLAN: So I think  
20 perspective is everything. I saw one where  
21 the interquartile range was 0.9 percent. So  
22 it kind of depends. But at least it's in the

1 range I think of the ones that we've seen.  
2 Any other comments? Ready to vote performance  
3 gap?

4 MS. SHAHAB: Voting or 1(b)  
5 performance gap. One high, two moderate,  
6 three low, four insufficient. Time begins  
7 now.

8 We have all the vote for 1(b)  
9 performance gap. Four high, seventeen  
10 moderate, zero low, zero insufficient.

11 CO-CHAIR KAPLAN: Priority.  
12 Larry, do you want to -- anybody from the  
13 workgroup want to say anything?

14 DR. FIELDS: I'd just say this  
15 falls again -- this is one of MedPAC's seven  
16 conditions which account for 30 percent of all  
17 readmissions in the Medicare program. So it's  
18 a high priority.

19 CO-CHAIR KAPLAN: Thank you.  
20 Anyone else? Voting priority.

21 MS. SHAHAB: Voting for 1(c) high  
22 priority. One is high, two moderate, three

1 low, four insufficient. Time begins now. One  
2 more vote.

3 We have all the votes for 1(c)  
4 high priority. Sixteen voted high, five voted  
5 moderate, zero low and zero insufficient.

6 CO-CHAIR KAPLAN: Scientific  
7 acceptability. First up is reliability.  
8 Larry, do you have comments?

9 DR. GLANCE: So this is 30-day  
10 all-cause unplanned readmissions. This was  
11 done using hierarchical modeling as per the  
12 standard approach.

13 They adjusted for age, sex,  
14 demographics, procedures and clinical  
15 covariates using the hierarchical condition  
16 categories, a fairly standard approach.

17 In terms of reliability testing  
18 the standard approach yielded an intraclass  
19 correlation coefficient of 0.4 which is very  
20 much in the zone, maybe in the upper level of  
21 that zone.

22 CO-CHAIR KAPLAN: Thank you.

1 Others? Are we ready to vote reliability?

2 Any other comments? Okay.

3 MS. SHAHAB: Voting for 2(a)  
4 reliability. One is high, two moderate, three  
5 low, four insufficient and the time begins  
6 now.

7 We have all the votes for 2(a)  
8 reliability. Two high, nineteen moderate,  
9 zero low and zero insufficient.

10 CO-CHAIR KAPLAN: Now, validity.  
11 Larry?

12 DR. GLANCE: So, the measure  
13 developers convened a technical expert panel  
14 who expressed strong support for the face  
15 validity of this measure.

16 They validated this model in an  
17 independent data set. It had a C statistic of  
18 0.67 which is at the upper end of the zone of  
19 acceptability for these readmission measures.

20 They looked at calibrations both  
21 graphically and also using a standard  
22 methodology and the model was well calibrated,

1       showed goodness of fit.

2                   CO-CHAIR KAPLAN:   So, the  
3       discriminate validity is sort of yet to be  
4       determined.  Is that correct?  So we don't  
5       have a sense of whether this discriminates  
6       well between hospitals.

7                   DR. GLANCE:  I don't recall  
8       exactly how many hospitals were labeled as  
9       high-quality and low-quality.  Maybe the  
10      measure developers could address that?

11                  DR. MCNAMARA:  Yes, this is Bob  
12      McNamara.  We did not do that analysis feeling  
13      that this is -- to develop the measure, the  
14      implementation can be any cut point that you  
15      want.  Not to put it in more of a policy  
16      decision.

17                  We had talked about that with the  
18      prior measure.  We can address it now if the  
19      committee wants to.  I don't know if there's  
20      much more to say on that.

21                  CO-CHAIR KAPLAN:  Any other  
22      comments from the working group or the

1 steering committee? Hearing none voting  
2 validity.

3 MS. SHAHAB: Voting for 2(b)  
4 validity. One is high, two moderate, three  
5 low, four insufficient. Time begins now.

6 We have all the votes for 2(b)  
7 validity. Zero voted high, twenty voted  
8 moderate, zero low and one insufficient.

9 CO-CHAIR KAPLAN: Thank you.  
10 Feasibility?

11 DR. GLANCE: So this is a highly  
12 feasible measure. It's based on widely  
13 available administrative data.

14 CO-CHAIR KAPLAN: Any other  
15 comments or questions? Nope? Ready to vote  
16 feasibility.

17 MS. SHAHAB: Voting for  
18 feasibility. One high, two moderate, three  
19 low, four insufficient. Time begins now.

20 We have all the votes for  
21 feasibility. Seventeen voted high, four voted  
22 moderate, zero low and zero insufficient.

1 CO-CHAIR KAPLAN: Thank you.

2 Usability and use. Larry, do you have any  
3 comments?

4 DR. GLANCE: This one's a little  
5 bit more difficult to comment on. It's a new  
6 measure so we don't have too much information  
7 on the usability of this particular measure.

8 CO-CHAIR KAPLAN: Kathy?

9 DR. AUGER: I think it's a little  
10 challenging to assess usability and use if we  
11 don't know how many outlier hospitals there  
12 are. So we don't know whether it's able to  
13 really discriminate high performers from low  
14 performers. And so it just makes it  
15 challenging for me to assess.

16 CO-CHAIR KAPLAN: Taroon or Helen,  
17 you want to comment on when a measure is early  
18 on in the phase of development how that works?

19 MS. PACE: Yes. So, basically  
20 what we ask the developer to do is to do two  
21 things when it's a new measure. To write up  
22 how they think it can be used in improvement,

1     how it will be used for improvement and what  
2     are the plans for its use in accountability  
3     applications.

4                 So, we can look at that section of  
5     their form or maybe the developers just want  
6     to remind people what they indicated as far as  
7     how this measure can accommodate improvement  
8     as well as plan for accountability  
9     applications.

10                CO-CHAIR KAPLAN:  Developers?

11                DR. MCNAMARA:  This is Bob  
12     McNamara.  I think we're going to let Lein  
13     talk about that from CMS.

14                DR. HAN:  This is Lein Han from  
15     CMS.  So, I think I have to give Yale the  
16     developer, our contractor, credit.  Because  
17     for this measure to keep the integrity of the  
18     measure they actually include cases from both  
19     inpatient and outpatient settings.  Am I  
20     correct?

21                So, right now CMS is trying to  
22     figure out which program, either IQR, it means



1 inpatient quality reporting program, or  
2 outpatient quality reporting program, that  
3 this measure should be included for which  
4 program.

5 So, we are working on how to  
6 implement it. Depends on the -- our  
7 consultation with our leadership about which  
8 program it's supposed to be. But I can see  
9 that this measure could be for both programs.

10 Did I address your question about  
11 implementation?

12 CO-CHAIR KAPLAN: I remain  
13 confused. So if it's readmission to the  
14 hospital following a vascular procedure that  
15 could be done in either the outpatient or the  
16 inpatient setting what we're looking at is the  
17 readmission within 30 days of the procedure in  
18 whatever setting it's done, is that correct?

19 DR. MCNAMARA: Yes. This is Bob  
20 McNamara. I can address that. I appreciate  
21 Lein giving us credit. I think we gave her a  
22 headache with this decision.

1                   We decided that really to be  
2                   clinically coherent and to make sense for the  
3                   clinical community to include both inpatients  
4                   and outpatients many of the procedures are  
5                   done as an outpatient procedure more based on  
6                   the hospital characteristics or provider  
7                   convenience or facilities rather than on  
8                   patients.

9                   And to try to say, okay, we're  
10                  just going to do the inpatients then people  
11                  could come out of the measure just by changing  
12                  the setting, even if it's the same procedure.  
13                  So that was the logic behind it all.

14                 To talk about that is to come into  
15                 the cohort you can have an outpatient  
16                 procedure at a hospital facility. But the  
17                 readmission has to be to the hospital. So  
18                 it's not another outpatient procedure for the  
19                 outcome.

20                 CO-CHAIR KAPLAN: And for the  
21                 lumpers and splitters among us, so vascular  
22                 procedures seem like a big lumping category.

1                   And to the extent that if you find  
2                   as these things roll out that some of these  
3                   vascular procedures look and behave different  
4                   from other vascular procedures is there a plan  
5                   when you're thinking about use in trying to  
6                   categorize smaller clumps?

7                   DR. MCNAMARA: Well, I think  
8                   that's always a question of, as you said,  
9                   lumping and splitting, of how do you want to  
10                  do it.

11                  The MedPAC had lumped them  
12                  together and I think that we thought that many  
13                  of the service lines within the hospitals, how  
14                  it's set up is such that one entity could  
15                  cover them all.

16                  Certainly in the future some  
17                  people could pull out different ones but I  
18                  think the way practice is currently that it  
19                  made the most sense for us to include them  
20                  all.

21                  CO-CHAIR KAPLAN: Thank you.

22                  DR. ROBERTS: Is there a

1 difference in risk for those vascular  
2 procedures in inpatient versus outpatient?

3 DR. MCNAMARA: Yes, in a word.  
4 There's differences across which procedures  
5 you have. But the feeling was that it's not  
6 necessarily, it was, you know, the patient  
7 picking the patient's work, that lower risk  
8 that would be done as an outpatient, not  
9 necessarily that the facility as an outpatient  
10 was what was causing them lower risk. So for  
11 the patient level they were coming in as a  
12 lower risk to be done as an outpatient.

13 But if a hospital has to choose  
14 whether they do it as an outpatient or as an  
15 inpatient I wanted to include them all because  
16 it's really based upon the patient, not upon  
17 the facility or location.

18 CO-CHAIR KAPLAN: Larry?

19 DR. GLANCE: Does your risk  
20 adjustment model include an indicator for  
21 whether the procedure was performed as an  
22 inpatient versus outpatient?

1 DR. MCNAMARA: No. The way that  
2 the cohort is developed was based upon coding.  
3 And the inpatient codes are ICD-9 and the  
4 outpatient codes are CPT. So, you could  
5 develop it, you know, you could identify that  
6 from there.

7 But again, basically because of  
8 feeling that patients -- an individual patient  
9 will get their procedure, or could get a  
10 procedure as an inpatient and outpatient based  
11 upon a facility rather than based upon patient  
12 characteristics, it wouldn't be appropriate to  
13 adjust inpatient versus outpatient. You're  
14 trying to adjust it based upon the procedure  
15 being done.

16 CO-CHAIR KAPLAN: Larry, did that  
17 answer your question?

18 DR. GLANCE: Just a follow-up  
19 question. Did you look at whether or not  
20 there was a tendency for patients who were --  
21 procedures that were performed as outpatient  
22 procedures, for the same procedures to be

1 readmitted more often if they were performed  
2 as an outpatient versus an inpatient?

3 In other words, the idea being  
4 that the inpatient procedures, they're already  
5 admitted to the hospital, whereas for the  
6 outpatient procedures you're sort of -- in a  
7 way you would think that those patients are  
8 slightly more likely to be readmitted because  
9 of being sent home more quickly.

10 DR. CURTIS: So this is Jephtha  
11 Curtis. I can comment a little bit on that  
12 specifically.

13 So, the question is whether or not  
14 there's a downside to outpatient procedures.  
15 And when we say outpatient procedure we're not  
16 really talking about necessarily patients who  
17 are going home the same day. Oftentimes we're  
18 talking about procedures that are being  
19 performed on an observation stay basis as  
20 opposed to an outpatient stay. And that's  
21 pretty much the major rationalization for  
22 including them.

1           So, most of the patients who are  
2       outpatient or observation stay have the exact  
3       same hospital utilization. They're in  
4       overnight and they go home the next day. And  
5       this is almost all endovascular procedures  
6       being performed on the neck or in the legs.

7           And that's, you know, everything  
8       is the same except for whether or not the  
9       hospital administrator characterizes it as an  
10      inpatient or an observation stay basis. So  
11      there's really no other information that comes  
12      with that.

13           The lower risk of readmission  
14      associated with that observation stay  
15      population really is driven by the fact that  
16      there are low-risk populations no matter what  
17      the designation is. And that's why we adjust  
18      for the procedure, not for the setting.

19           CO-CHAIR KAPLAN: Thank you. Any  
20      other comments?

21           DR. MCNAMARA: I'm sorry, it's Bob  
22      McNamara. Just to add on that that there's

1 not a 1 to 1 correlation between the CPT codes  
2 and the ICD-9 codes. You can't exactly say.  
3 So certainly within -- there's many more CPT  
4 codes, but they can be adjusted to different  
5 ICD-9s. Or correlated.

6 CO-CHAIR KAPLAN: Thank you.  
7 Paula?

8 MS. MINTON-FOLTZ: Can you tell me  
9 if this excludes same-day transfers? So if I  
10 came in as an outpatient procedure and was  
11 immediately admitted afterwards would that  
12 count as a readmission?

13 DR. MCNAMARA: I believe it would  
14 not. We included that it was a 24-hour  
15 difference in the level -- or the date of the  
16 procedure and the admission.

17 And I think most of those within  
18 Medicare rules would be listed as an inpatient  
19 procedure, even if -- as Jephtha said, many of  
20 these are done in the same area. It could be  
21 done in the same operating suite, whether it's  
22 an inpatient or an outpatient officially.



1                   And then even if they were intake  
2                   to the surgery as an outpatient, if they  
3                   decided to change that as an inpatient from  
4                   the back end Medicare it would look like an  
5                   inpatient, not as a readmission.

6                   CO-CHAIR KAPLAN: Thank you.  
7                   Karen and then Karen.

8                   DR. MCNAMARA: That was Bob  
9                   McNamara again.

10                  MS. PACE: Right, this is Karen  
11                  Pace. I just wanted to make a comment that we  
12                  really wouldn't want to include a risk factor  
13                  related to where the procedure took place  
14                  because that may be one of the things that  
15                  might be a difference in the care provided.

16                  So it may be something that's  
17                  useful for drilldown and quality improvement  
18                  when you're looking at your data and what  
19                  patients are being readmitted. But it  
20                  generally wouldn't be something that would be  
21                  considered for a risk factor.

22                  CO-CHAIR KAPLAN: Karen?

1 DR. JOYNT: I just want to say  
2 something kind of similar which is just to  
3 commend you for going to what I'm sure was a  
4 lot of trouble to put the outpatient things  
5 in. I think that is hugely important,  
6 especially as care sort of shifts place to  
7 really think about quality spanning across  
8 different settings.

9 I just have more of a technical  
10 question maybe for NQF people which is with  
11 this measure, compared to others who really  
12 don't have a clue for how it's going to work  
13 in terms of the outliers. Is that something  
14 that we are expected to know as we think about  
15 whether or not we feel that the measure is  
16 appropriate?

17 Or do we just sort of say it  
18 doesn't matter if it identifies 4 percent or  
19 even 25 percent as outliers, that's separate  
20 from the measure itself? Any guidance would  
21 be helpful.

22 MS. PACE: So, I guess we could

1 look at the -- the information that they  
2 provided was just kind of the distribution of  
3 the scores. And we could look at that.

4 But I don't think that has to be  
5 your defining decision. You may want to not  
6 say high on usability and use because that's  
7 a question in your mind, but the real question  
8 is whether this has the potential at this  
9 point to be useful for improvement and  
10 accountability.

11 And you know, one of the things  
12 when it comes back for endorsement maintenance  
13 will be to have some real data on how that has  
14 played out. So I don't think it's an ultimate  
15 defining decision for use and usability.

16 CO-CHAIR KAPLAN: Yes. So the way  
17 I understand this process. Correct me if I'm  
18 wrong, really quickly. If we endorse this for  
19 use then it goes out and they get the  
20 information, Karen, that you would be looking  
21 for within 3 years or they don't. And when it  
22 comes back for re-approval then we reconsider

1     whether or not the information is suitable for  
2     re-endorsing this measure? Does that help?

3             DR. JOYNT: One more question.  
4     With all these measures that are again sort of  
5     a longer time frame and the information is not  
6     fed back to the hospital quite as quickly as  
7     might be optimal for quality improvement is  
8     that again something we should consider in  
9     approving a metric, or something that goes to  
10    ways that we hope that all these measures get  
11    used better in the future?

12            Because I think that's a  
13    limitation that cuts across a lot of these.  
14    It's nothing to do with the statistical power  
15    of the model, or the way that it's set up, or  
16    the way that you've chosen procedures. It's  
17    just I think it's a real problem if we're  
18    supposed to also think about the usability for  
19    improvement. So how should we think about  
20    that?

21            CO-CHAIR KAPLAN: That's also come  
22    up before. I'll let you go ahead.

1 DR. BURSTIN: This has come up in  
2 multiple discussions for us, particularly  
3 around the readmission measures and the lag  
4 time to get -- the amount of time back.

5 Again, I think it's something you  
6 could factor into usability as you're voting.  
7 I also know it's something Lein and others  
8 from CMS have pointed out as something you're  
9 actively working on, trying to -- maybe Lein  
10 wants to respond.

11 But I know there have been active  
12 efforts to see if there are more ways to get  
13 information back to hospitals more quickly.  
14 Lein?

15 DR. HAN: This is Lein Han from  
16 CMS. We got this feedback all the time from  
17 the hospitals. And it's understandable that  
18 they do need most data for quality  
19 improvement.

20 So, what we're working on is that  
21 we're not providing the risk-adjusted rate  
22 quarterly, but we would like to see if we can

1 just get the data to them. But the raw data,  
2 not really the calculated data. So when they  
3 have the raw data at least they can look at  
4 the cases.

5 So, and we plan to do this  
6 quarterly, hopefully that we can get to the  
7 hospital quarterly this type of data. But raw  
8 data like we provided in hospital-specific  
9 report, those cases. Thanks.

10 CO-CHAIR KAPLAN: Thank you.  
11 Karen, one of the issues that's come up before  
12 is that in that backwards look for three years  
13 time, for example, the tensions between  
14 getting a precise estimate and so you get more  
15 cases means that you lose on the other end in  
16 terms of usability for quality improvement  
17 issues. So there are some tensions and  
18 tradeoffs in these different kinds of calls.

19 DR. BRIGGS: So in the reporting  
20 is this going to be reported out by the  
21 anatomical buckets? Or is this going to be  
22 vascular readmissions altogether?

1 DR. MCNAMARA: As the measure  
2 specifies right now there will be an overall  
3 vascular readmission.

4 Whether in the future it can be  
5 done on a procedure level for some of the  
6 high-volume procedures or in different buckets  
7 can be done based upon how it's set up. But  
8 the measure was developed as an overall.

9 DR. CURTIS: Just to follow up on  
10 this. Jephtha Curtis. I think the way that  
11 you could use it, I think you'd report out all  
12 vascular readmission rate and that's useful  
13 for public reporting.

14 To the hospitals we could try and  
15 create buckets that make it more usable for  
16 them for actually driving quality improvement  
17 processes so they can know where they are  
18 maybe not in a risk-adjusted fashion but at  
19 least what's driving their hospital-specific  
20 readmission rates.

21 CO-CHAIR KAPLAN: Okay, we're  
22 coming up on time. I don't want to cut this

1 short. Any other comments or questions?

2 We're ready to vote on usability.

3 MS. SHAHAB: Voting for usability  
4 and use. One high, two moderate, three low,  
5 four insufficient information and the time  
6 begins now.

7 We have all the votes for  
8 usability and use. One high, eleven moderate,  
9 four low, four insufficient information.

10 CO-CHAIR KAPLAN: Thank you and I  
11 think we're ready to vote on endorsement. Any  
12 comments?

13 Okay, ready to vote.

14 MS. SHAHAB: voting for overall  
15 suitability for endorsement. One yes, two no.  
16 Time begins now. Just one more vote. Can you  
17 please just press your votes one more time?

18 We have all the votes for overall  
19 suitability for endorsement for measure 2513  
20 Hospital 30-day All-cause Risk-standardized  
21 Readmission Rate Following Vascular  
22 Procedures. The votes are 14 yes, 6 no.



1 CO-CHAIR KAPLAN: Thank you very  
2 much to the developers for coming and for CMS  
3 coming as well.

4 And we finished within three  
5 minutes which is measurement error in my view  
6 on time. So, excellent. We we have a break  
7 until 10:15. Thank you.

8 (Whereupon, the foregoing matter  
9 went off the record at 10:03 a.m. and went  
10 back on the record at 10:13 a.m.)

11 CO-CHAIR KAPLAN: Can we ask our  
12 developers to briefly introduce yourselves?  
13 And make sure when you're commenting that you  
14 state your name and briefly give us a two-  
15 minute brief discussion of the measure.

16 DR. NAKAMURA: Thank you. My name  
17 is Mari Nakamura. I'm a pediatric infectious  
18 diseases doctor and health services researcher  
19 at Boston Children's Hospital.

20 DR. ZASLAVSKY: I'm Alan  
21 Zaslavsky. I'm a statistician at Harvard  
22 Medical School.

1 DR. NAKAMURA: And as you heard  
2 joining us on the phone is our principal  
3 investigator for our center Mark Schuster  
4 who's joining us from Vancouver today.

5 Measuring and reducing  
6 readmissions has become a widespread focus in  
7 pediatrics, but to date no readmission  
8 measures developed specifically for use in  
9 children and adolescents have been publicly  
10 available.

11 We were therefore assigned to  
12 develop readmission measures by CMS and AHRQ  
13 as part of their pediatric quality measures  
14 program for which we serve as the center of  
15 excellence.

16 Hospital readmissions within 30  
17 days occur for 2 to 6 percent of children.  
18 These rates are certainly lower than the rates  
19 of about 20 percent that we often hear for  
20 Medicare beneficiaries over age 65, but  
21 overlap with rates for adults under age 65.

22 As a point of comparison pediatric

1 30-day readmission rates are equivalent to  
2 pediatric inpatient adverse drug event rates.

3 Hospitals, payers and other  
4 stakeholders are actually already actively  
5 working to reduce pediatric readmissions even  
6 in the absence of a publicly available  
7 measure.

8 Our all-condition measure  
9 evaluates readmissions following an index  
10 hospitalization for almost any condition.

11 We were encouraged by CMS to  
12 develop an all-condition measure to correspond  
13 with the adult measure that they've now rolled  
14 out. And in addition, our national  
15 stakeholder panel supported an all-condition  
16 measure because it includes the broadest range  
17 of children and hospitals.

18 Furthermore, we found that very  
19 few specific pediatric conditions are common  
20 enough to serve as a focus of a readmission  
21 measure.

22 We've prioritized harmonizing our

1 measure with the NQF-endorsed adult  
2 readmission measures while still making it  
3 appropriate for pediatric use.

4 One important way in which our  
5 measure corresponds with NQF-endorsed adult  
6 measures is that we choose to focus on  
7 evaluating unplanned readmissions. Based on  
8 our own research as well as other studies we  
9 don't think that the preventability of  
10 readmissions can be assessed using billing  
11 codes.

12 The main data set we used to  
13 develop and test the measure consisted of  
14 Medicaid claims for about 400,000  
15 hospitalizations at 2,000 hospitals in 26  
16 states.

17 We also used AHRQ HCUP all-payer  
18 data from 2 states and NACHRI case mix data  
19 from 72 children's hospitals.

20 We developed a case mix adjustment  
21 model for the measure that includes patient  
22 age, gender and chronic conditions on the

1 index hospitalization and we found that the  
2 model performed similarly to those used in  
3 other readmission measures with regard to  
4 discrimination and calibration.

5 A challenge not just for  
6 calculating pediatric readmission rates but  
7 for all pediatric quality measurement is small  
8 sample sizes at some hospitals with resulting  
9 low reliability of measure scores.

10 However, because pediatric  
11 patients are not distributed across as many  
12 hospitals as adult patients we found that the  
13 majority of pediatric hospitalizations occur  
14 at higher-volume hospitals whose readmission  
15 rates have good reliability.

16 Because the measure uses claims  
17 data that are already collected for other  
18 purposes we anticipate that implementing it  
19 will be highly feasible.

20 We believe that the measure fills  
21 an important need for publicly available  
22 readmission measures and think that it could

1     serve as a valuable tool to assess health  
2     system quality and motivate improvements in  
3     pediatric care delivery. Thank you.

4                   CO-CHAIR KAPLAN: Thank you very  
5     much. Kathy?

6                   DR. AUGER: So, to speak to  
7     evidence. Certainly there isn't as much  
8     evidence around pediatric readmission as there  
9     is in the adult world.

10                   However, certainly it meets the  
11     overall construct that this could be an  
12     important measure. So I think it's high in  
13     that sense.

14                   CO-CHAIR KAPLAN: Karen, do you  
15     have anything to add? Are we ready to vote  
16     evidence? Any other discussion? Go.

17                   MS. SHAHAB: Voting for 1(a)  
18     evidence. One is yes, two is no. And time  
19     begins now. We need one more vote, please.

20                   We have all the votes for  
21     evidence. Twenty-one yes, one no.

22                   CO-CHAIR KAPLAN: Thank you.

1 Performance gap. Kathy?

2 DR. AUGER: So, as the developers  
3 note the prevalence of pediatric readmission  
4 rate is between 2 and 6 percent.

5 What I was just looking for and  
6 couldn't find is what the range in  
7 interquartile ranges for the risk-standardized  
8 rate. Do you guys have that available?

9 DR. NAKAMURA: This is Mari  
10 Nakamura again. To give you a sense for an  
11 all-condition measure based on the variance  
12 component of the hospital random effect in our  
13 mix model a hospital that's two standard  
14 deviations below the mean would have a  
15 readmission rate of 2.4 percent whereas one  
16 that's two standard deviations above would  
17 have a readmission rate of 10.3 percent. So  
18 about 4 times greater.

19 CO-CHAIR KAPLAN: Karen?

20 DR. JOYNT: We're actually looking  
21 for this information together. And I think  
22 that there's actually impressive performance

1 gap when looked at that way.

2 The graph -- I didn't find a  
3 distribution on this. The distribution in the  
4 Berry paper from last year suggests that most  
5 hospitals actually don't fall that far outside  
6 the mean. So do you know the 25th and 75th  
7 percentiles?

8 DR. NAKAMURA: I don't have that  
9 with me, no.

10 DR. JOYNT: In that one it looked  
11 like there were really very few that were past  
12 about between 5 and 7. But that may be  
13 because it was the NACHRI hospitals.

14 DR. NAKAMURA: This is Mari  
15 Nakamura again. So, it's a good point that in  
16 that study it was a quite homogenous set of  
17 hospitals. And so you might expect that there  
18 wouldn't be as much difference among them in  
19 terms of the range of readmission rates.

20 CO-CHAIR KAPLAN: I might point  
21 out that the magnitude of the difference is  
22 about in the range of other measures that



1 we've looked at before. In fact, it seems to  
2 be somewhat broader than some of them that we  
3 looked at.

4 Other comments? Ready to vote  
5 performance gap?

6 MS. SHAHAB: Voting for 1(b)  
7 performance gap. One is high, two moderate,  
8 three low, four insufficient and the time  
9 begins now. One more vote, please.

10 We have all the votes for 1(b)  
11 performance gap. One high, twenty moderate,  
12 one low, zero insufficient.

13 CO-CHAIR KAPLAN: Great.  
14 Priority?

15 DR. AUGER: So, the developers  
16 mentioned cost of readmissions at six months  
17 which is certainly a longer window than the  
18 measure in front of us which was \$136 million.

19 So, of course pediatric costs are  
20 not anything what adult costs are. Having  
21 said that, they do also present data on  
22 disparities that exist in pediatric

1 readmission, including race/ethnicities  
2 disparities and payer disparities. So that  
3 goes certainly to priority.

4 And then also of course as they  
5 mentioned this would be the first pediatric  
6 metric. So that again speaks to priority.

7 CO-CHAIR KAPLAN: Karen? Other  
8 comments? Ready to vote?

9 MS. SHAHAB: 1(c) high priority.  
10 One high, two moderate, three low, four  
11 insufficient. Time begins now. One more.

12 We have all the votes for 1(c)  
13 high priority. Seven high, thirteen moderate,  
14 two low, zero insufficient.

15 CO-CHAIR KAPLAN: Thank you.  
16 Scientific acceptability. We'll talk about  
17 reliability first. Kathy?

18 DR. AUGER: Sure. So, as the  
19 measure development experts had mentioned  
20 previously they used ICC to assess  
21 reliability. And it's very much dependent on  
22 the volume of cases seen at hospitals.

1                   So, with the reliability of 0.5  
2                   there were only 607 out of the 2,011 hospitals  
3                   that had an ICC greater than that but that did  
4                   a count for 88 percent of the index  
5                   hospitalizations. So the majority of the  
6                   hospitalizations are at higher-volume  
7                   hospitals which had the higher reliability  
8                   with the low-volume hospitals are the issue.

9                   CO-CHAIR KAPLAN: Karen? Other  
10                  comments? Ready to vote reliability?

11                  MS. SHAHAB: Voting for 2(a)  
12                  reliability. One is high, two moderate, three  
13                  low, four insufficient and the time begins  
14                  now. One more.

15                  We have all the votes for 2(a)  
16                  reliability. Three high, seventeen moderate,  
17                  two low and zero insufficient.

18                  CO-CHAIR KAPLAN: Thank you.  
19                  Validity. Kathy?

20                  DR. AUGER: So, this is an  
21                  examination of unplanned hospitalization or  
22                  readmissions. So the developers have a

1 somewhat novel way of determining planned or  
2 unplanned which is worth mentioning.

3 The way that they did that was  
4 through expert opinion panels of which codes  
5 could be consistent with a planned procedure.  
6 So they also went through some validation of  
7 that algorithm in and of itself using chart  
8 review at Boston Children's which seemed  
9 reasonable.

10 Then in terms of the risk  
11 adjustment validity they use the number -- age  
12 and the number of chronic conditions as well  
13 as gender.

14 There was some concern in the  
15 public reporting comments that they hadn't  
16 used primary diagnosis so that might be  
17 something worth just asking about.

18 And then in terms of how the model  
19 performed the C statistic was 0.69. In terms  
20 of calibration there was good observed-to-  
21 expected graphs.

22 And then the other question I had

1 was again about how many hospitals or  
2 outliers, whether or not they have done that  
3 assessment.

4 And finally, other threats to  
5 validity would just be in terms of missing  
6 data because of the MAX chart. The MAX data  
7 system in and of itself has a lot of issues  
8 with handling admission data.

9 CO-CHAIR KAPLAN: Karen, I'm going  
10 to ask you to hold on a second and let the  
11 measure developers respond.

12 DR. NAKAMURA: Thank you.  
13 Regarding the question of --

14 CO-CHAIR KAPLAN: State your name,  
15 please.

16 DR. NAKAMURA: Sorry. Mari  
17 Nakamura. Regarding the question of including  
18 the reason for admission, the primary  
19 diagnosis, this was something that we thought  
20 a great deal about and had done some  
21 exploratory analysis of and ultimately  
22 concluded didn't make sense to include.

1           One reason is that we found that  
2           actually performance in a given hospital  
3           tended to track across different types of  
4           diagnoses so that it does make sense to be  
5           able to aggregate all of the patients into a  
6           single measure.

7           We also found that there's a  
8           challenge in using pediatric diagnosis codes  
9           with a good grouping system. We even  
10          experimented with trying to devise one of our  
11          own.

12          Because patients don't have just a  
13          sort of few common diagnoses but really in  
14          pediatrics diagnoses are quite variable we  
15          found that for any given category that for  
16          some hospitals there were problems with cell  
17          sizes.

18          I don't know if Alan has anything  
19          further he might want to say? No? Okay.

20          Regarding the question of outliers  
21          what we had provided in our submission was one  
22          way of looking at outliers which is to use the

1 method that's currently used for the adult  
2 measure pay-for-performance program.

3 And using those methods we found  
4 that for the all-condition readmission measure  
5 that about 47 percent of hospitals have a  
6 higher than expected readmission rate. So  
7 their predicted readmissions exceed their  
8 expected.

9 And that the median readmission  
10 rate for those hospitals that were above 1 in  
11 their ratio was 1.15 suggesting that they have  
12 about 15 percent in excess in terms of the  
13 median readmissions.

14 We haven't looked at the question  
15 in terms of outliers using confidence  
16 intervals, but recognize that there are  
17 different ways that one could apply the  
18 measure and choose to identify outliers.

19 And then I think your last  
20 question was about missing data in MAX. So we  
21 definitely acknowledge that MAX is a very  
22 messy data set as we learned once we delved

1       into it.

2                       For those of you who may not be as  
3       familiar it's assembled by collecting Medicaid  
4       claims from all of the 50 states and the  
5       District of Columbia and then trying to make  
6       them into a uniform data set for researchers  
7       to use.

8                       And as you might imagine that  
9       process is a difficult one. It seems to be  
10      definitely improving over time. But that is  
11      one reason, for example, that in our MAX data  
12      set we felt that not all states had good  
13      enough data quality for key variables such as  
14      hospital identifiers to be able to include  
15      them.

16                      So all that said while our test  
17      data set was the MAX data and we were actually  
18      pleasantly surprised that the percentage of  
19      records that had to be dropped based on data  
20      quality or completeness issues was actually 10  
21      percent.

22                      That doesn't necessarily mean that



1 the real data sets that would be used, meaning  
2 the actual claims data available to, for  
3 example, state Medicaid agencies would have as  
4 many issues with missing data as the MAX data.

5 CO-CHAIR KAPLAN: Thank you.

6 We're going to go Karen and then Frank.

7 DR. JOYNT: Yes, just had a few  
8 additional questions to the ones that were  
9 brought up before.

10 I think one of the threats to  
11 validity is just that there aren't other  
12 pediatric measures with which to compare this  
13 one. And so it's a little bit difficult to  
14 know exactly what we're measuring.

15 Certainly hospitals can differ on  
16 things like socioeconomic status and access to  
17 care for kids. And that may be the difference  
18 that we're seeing driving this. It's hard  
19 without having anything else that we would  
20 sort of consider to be "quality" to compare  
21 this to to know exactly what we're measuring  
22 here.

1 I think that's probably the case  
2 with most of the readmission metrics to some  
3 degree but it's particularly problematic if we  
4 don't have comparisons. This is not the  
5 developer's fault and kudos to you for trying  
6 to develop a quality metric in what is often  
7 a very data-free zone. But I think it is an  
8 important threat to validity.

9 The two other -- well, I guess the  
10 one other question is really if you could just  
11 explain this a little bit, how this model is  
12 similar or different to the ones that we're  
13 used to hearing for the adult metrics. Just  
14 so that we are clear on whether or not this is  
15 the same method as is being used for the other  
16 measures or if it's different and in what ways  
17 it differs beyond the exclusion of procedures.  
18 Or, sorry, planned admissions.

19 DR. NAKAMURA: Thank you. This is  
20 Mari Nakamura again. Karen is absolutely  
21 right that a challenge we faced in trying to  
22 assess the validity of our measures is the

1 fact that there are not other pediatric  
2 inpatient measures we could use, or widely  
3 available data sources for which we would be  
4 able to even evaluate such measures.

5 We agree that this is a really  
6 important question and one that we think will  
7 need to be evaluated as more measures are  
8 developed. We felt like it was good to start  
9 somewhere and acknowledged that this is a  
10 limitation currently in our field in pediatric  
11 measurement.

12 Regarding the question of how our  
13 measure compares to the adult measures in  
14 terms of our statistical approach. Overall  
15 the approaches are really similar in that we  
16 use hierarchical modeling.

17 We do as a result have the  
18 shrinkage effect that I've heard discussed  
19 quite a bit here. And we've talked about both  
20 the advantages of that.

21 It is relevant to pediatrics  
22 because of course we do have many small-volume

1 hospitals in terms of pediatric volume.

2 One difference with the all-  
3 condition measure is that the all-condition  
4 measure for the adult Yale measure uses five  
5 different service line models and then  
6 combines the outputs of that to end up with a  
7 single readmission rate.

8 We considered such an approach but  
9 our worry was that at many hospitals given  
10 that pediatric volumes overall are low that we  
11 would then have trouble with the sample sizes  
12 for splitting our sample among different  
13 models.

14 Another difference which Alan may  
15 want to speak a little bit more to in terms of  
16 the statistical implications is that we use  
17 direct rather than indirect standardization.

18 Meaning that in our approach of  
19 standardizing we hypothesize what the rate  
20 would be at a given hospital assuming that the  
21 entire cohort of reference data set was cared  
22 for at that hospital. In the indirect method

1     instead it's this approach of using predicted  
2     to expected readmissions.

3             But the end result again is that  
4     it tends to pull the small-volume hospitals  
5     closer to the mean. So in that way the  
6     outputs are similar.

7             DR. ZASLAVSKY: Alan Zaslavsky. I  
8     would just add that while the direct and  
9     indirect standardization look on the face of  
10    it pretty different the underlying models  
11    actually work out to be pretty similar.

12            The direct standardization we're  
13    doing uses the logistic model. Indirect uses  
14    usually a ratio of observed to expected which  
15    implies a multiplicative or log linear model.  
16    But in the range we're talking about the two  
17    models are pretty close to each other. So,  
18    that doesn't make a big difference.

19            And the shrinkage effects as Mari  
20    said are handled in pretty similar ways. The  
21    sufficient statistic for the performance of a  
22    particular hospital is essentially the total

1 number of readmissions. And that's the same  
2 in both models. So the two should give pretty  
3 similar results.

4 We're another group. We set  
5 things up a little differently in a way that  
6 we found to be a little bit more direct, not  
7 just because it's direct standardization but  
8 because it's all done on one model. But I  
9 think the two are similar enough that we  
10 wouldn't have found anything terribly  
11 different if we'd done it exactly the way Yale  
12 did it.

13 CO-CHAIR KAPLAN: Thank you. Any  
14 other comments? Frank, and then Leslie, and  
15 then Tony.

16 DR. BRIGGS: So, two quick  
17 questions. First just being a definition.  
18 You said you excluded specialty hospitals. I  
19 was wondering if that was the same cancer  
20 hospitals that you see in the adult realm.

21 And then the other was hospitals,  
22 if the readmission was in the discharge was

1 readmitted to an area out of the state because  
2 of limitations on the data set. Although you  
3 might have some data I was wondering how often  
4 that happened, especially for border states  
5 and rural care and things of that nature.

6 DR. NAKAMURA: So for the question  
7 about specialty hospitals, in pediatrics that  
8 designation tends to capture, for example,  
9 hospitals that do deal with specific  
10 conditions. Cancer hospitals are one.  
11 Another would orthopedic hospitals.

12 The other sort of major category  
13 is more -- and another category, excuse me, is  
14 the Shriner's hospitals that deal with burns  
15 and trauma.

16 And then another sort of group of  
17 hospitals that we excluded is hospitals that  
18 don't provide acute care, that are more long-  
19 term care such as for rehabilitation.

20 For the question about what  
21 percentage of readmissions are to an out-of-  
22 state hospital, so the good thing is that

1     because Medicaid claims go back to the state  
2     of residence of the patient there's actually  
3     complete data for the patients who are in a  
4     given state about where they were readmitted.

5                 Where there is a challenge is for  
6     the states that weren't in our data set.

7     Because for those we have probably a minority  
8     of information. We would only know about the  
9     claims that happen to come through the  
10    particular states that were in our data set.

11                And so that's why we exclude the  
12    hospitals that are outside of the states that  
13    we include in our data set. But for those  
14    that are in the data set we would be able to  
15    tell if patients are admitted outside of their  
16    home state.

17                CO-CHAIR KAPLAN: Thank you.

18    Leslie?

19                MS. HALL: So, I have a question.  
20    Where you might have two hospitals in the same  
21    community, one hospital is known as a brand  
22    for children's hospital. It's not a



1 children's hospital, it's just where most  
2 children go.

3 Both hospitals would be very high-  
4 volume community hospitals. But one would  
5 display as a low-volume hospital even though  
6 it wasn't in this case. Does this create any  
7 challenges where we might have the same sort  
8 of problem we've mentioned over and over again  
9 about low-volume hospital size and low-volume  
10 overall when we just simply have a patient mix  
11 that's very different in an otherwise high-  
12 volume hospital?

13 DR. NAKAMURA: This is Mari  
14 Nakamura. I want to make sure I understand  
15 your question.

16 So you're wondering about the  
17 issue of community hospital that has done  
18 pediatric patients but overall not a very high  
19 volume of pediatric patients compared to  
20 another hospital?

21 MS. HALL: That's correct.

22 DR. NAKAMURA: So, this is

1 certainly a challenge about trying to measure  
2 pediatric readmission rates or any sort of  
3 hospital-based quality measure. You're right  
4 that there are big differences in the types of  
5 hospitals that care for children.

6           What we've found is that children  
7 tend to be really concentrated at relatively  
8 small numbers of hospitals. So they tend to  
9 be high-volume, they tend to provide a full  
10 range of care. And then the community  
11 hospitals tend to provide care for relatively  
12 small numbers of children.

13           To give you a sense, children's  
14 hospitals make up about 5 percent of all of  
15 the 4,000 hospitals in the country but  
16 actually care for about one-third of pediatric  
17 inpatients.

18           And so I think where this is a  
19 challenge is that as we've alluded to for  
20 these community hospitals on the one hand we  
21 didn't want to ignore them. But we also  
22 acknowledge that the reliability of their

1 readmission rates is limited because of the  
2 low volume.

3 And so one way that we think these  
4 hospitals could still be included is of course  
5 to be very responsible about explaining the  
6 limits and what we actually know about them.  
7 And also perhaps to compare like hospitals  
8 with like.

9 CO-CHAIR KAPLAN: Thank you.  
10 Tony?

11 DR. GRIGONIS: Yes, I just have a  
12 quick question about your databases from you  
13 said 26 states I believe. Were they  
14 consistent in terms of the state populations?  
15 That's the first question.

16 The second follow-up would be did  
17 you see any differences in states that have  
18 higher populations.

19 DR. NAKAMURA: So to answer --  
20 this is Mari Nakamura again -- to answer the  
21 question about population, the states actually  
22 varied quite a bit in population. Because we

1 found that the states with the best data  
2 quality fortunately were geographically  
3 distributed. And so some of them were lower  
4 population states and other high.

5 We didn't actually do an analysis  
6 to evaluate how the volume of the state  
7 related to readmission rates. That's  
8 something we certainly would be able to do.

9 CO-CHAIR KAPLAN: Thank you very  
10 much. Other comments?

11 I would remind the group that as  
12 with the previous measure on all-cause  
13 readmissions following vascular procedures  
14 this would be a new measure. So if endorsed  
15 the 3-year period would ask that the  
16 developers generate some of the data that have  
17 been raised and issues of concern and so on.

18 So if approved it would be a new  
19 measure that we would ask the developers to  
20 consider some of these -- response to some of  
21 these kinds of issues.

22 Are we ready to vote validity?

1 MS. SHAHAB: Voting for 2(b)  
2 validity. One is high, two moderate, three  
3 low, four insufficient. Time begins now.

4 We have all the votes for 2(b)  
5 validity. Zero voted high, nineteen voted  
6 moderate, three low and zero insufficient.

7 CO-CHAIR KAPLAN: Thank you.  
8 Feasibility. Kathy?

9 DR. AUGER: Certainly these are  
10 claims data so potentially feasible.

11 I think it is worth mentioning, as  
12 Mari already did, that what's in Medicaid  
13 claims does vary from state to state. So  
14 that's a little bit of an issue.

15 Having said that they did test the  
16 measure on the New York database and were able  
17 to see a little bit of model fitting issues  
18 with rare values. But then they were able to  
19 offer some troubleshooting to address any  
20 issues of feasibility. So I think that's a  
21 strength.

22 CO-CHAIR KAPLAN: Karen?

1 DR. JOYNT: Yes, I think  
2 feasibility is a real concern here because  
3 kids, unlike adults over 65, are covered by a  
4 whole bunch of different insurance plans.

5 So yes, there's a chunk in  
6 Medicaid but they certainly don't represent a  
7 randomly selected group of kids. And so  
8 understanding how this measure might act in  
9 all-payer claims databases versus a Medicaid  
10 database versus Aetna or something like that  
11 I think is something that would really need to  
12 be thought through as this is rolled out.

13 Are we trying to build a Medicaid  
14 quality metric? Are we trying to build a  
15 pediatric quality metric? And I think those  
16 two things are probably different. And so I  
17 think the model and the measure would probably  
18 have to take that into account given the  
19 limitations of the pediatric data and the ways  
20 in which the populations that underlie those  
21 data might actually differ quite a bit.

22 CO-CHAIR KAPLAN: Other comments

1 or thoughts?

2 DR. NAKAMURA: Thank you. This is  
3 Mari Nakamura again.

4 The issue about the variation in  
5 Medicaid claims from state to state is  
6 certainly a true one. We anticipate that one  
7 of the likely uses for the measure will be by  
8 Medicaid programs. We know that's something  
9 that CMS is interested in.

10 And at least initially it seems  
11 that what would be most feasible is to  
12 evaluate readmission rates within a state  
13 rather than trying to compare across states.

14 That said it may be that as more  
15 measures come out for pediatrics that this  
16 will perhaps drive the creation of a national  
17 data set that's available in a more timely way  
18 than the MAX data set.

19 We also note that there are  
20 several states that are developing or already  
21 have all-payer claims data sets that could be  
22 useful for this measure.

1           Again, that wouldn't necessarily  
2           allow national comparisons but at least  
3           within-state comparisons.

4           One thing that we tried to do with  
5           our measure and have provided the SAS program  
6           for is we've provided a way for a given state  
7           Medicaid program to be able to calculate  
8           nationally comparable rates using our MAX data  
9           set as a reference data set.

10          And so this is something that if a  
11          state Medicaid program really wanted to have  
12          a sense of how they compared to another state  
13          that they would have the option to use.

14          Regarding Karen's point about the  
15          fact that there are different insurers for  
16          children and that unlike the adult over-65  
17          program there's not a Medicare for children.  
18          This is very true.

19          Medicaid covers about one-third of  
20          hospitalized children. So it is a sizeable  
21          portion. But she's absolutely right that  
22          those children are not necessarily directly



1 comparable to children covered by other  
2 insurance plans.

3 We've looked at insurance  
4 disparities and found in fact that Medicaid-  
5 insured children do have a higher risk of  
6 readmission.

7 We know that there has been a lot  
8 of discussion about including such sort of  
9 sociodemographic factors. And if there was  
10 interest in including something like insurance  
11 status for pediatrics we would be very  
12 interested in discussing that further.

13 CO-CHAIR KAPLAN: Thank you. I'm  
14 going to -- we're shading into usability here  
15 so I'm going to ask Tom and then Larry.

16 DR. SMITH: Well, that was my  
17 question. Is this a feasibility issue or a  
18 usability issue? Are all your data from MAX  
19 data? And are you putting this out there as  
20 a Medicaid performance measure or a children's  
21 performance measure?

22 DR. NAKAMURA: This is Mari

1 Nakamura again. As a pediatric performance  
2 measure but recognizing that one probably  
3 common use will be as a Medicaid performance  
4 measure. We were aiming to be as inclusive as  
5 we could.

6 An example of another data set  
7 that could be used with our measure would be  
8 an all-payer claims data set at a state level.  
9 And so as part of our measure testing we did  
10 work with the State of New York as Kathy  
11 mentioned to test the measures on their all-  
12 payer data set as well.

13 CO-CHAIR KAPLAN: Again, this is a  
14 usability issue. We're still on feasibility.

15 DR. SMITH: Well, I was going to  
16 say I now agree with Karen that there's a  
17 significant feasibility issue here based upon  
18 your response.

19 CO-CHAIR KAPLAN: So feasibility  
20 for application across all -- I'm concerned  
21 about your issue. Let me have you guys re-  
22 frame that as what is the actual nature of the

1 concern about feasibility?

2 DR. SMITH: I'll defer to Karen.

3 DR. JOYNT: Well, I just -- I  
4 think it depends what you're trying to define  
5 it as. As a Medicaid measure it is feasible  
6 for states to use because it's based on claims  
7 data.

8 CO-CHAIR KAPLAN: So is your  
9 concern the target of inference here?

10 DR. JOYNT: As a pediatric measure  
11 it's not super feasible because there are  
12 entire swaths of the population that are in no  
13 claims data set. Which makes it very  
14 difficult to apply a claims-based metric to  
15 them. So I think it depends a little bit on  
16 the population that we're trying to assess  
17 whether or not it is actually feasible to do.

18 If you had a kid in, I don't know,  
19 Kansas -- I don't know if Kansas is an all-  
20 payer claims data set -- covered by Aetna I'm  
21 not sure that you actually could include that  
22 child in a metric. But for Medicaid it's

1 highly feasible because it's a claims base.

2 So it just depends on the group.

3 CO-CHAIR KAPLAN: Larry? Taroon?

4 MR. AMIN: It's an interesting  
5 sort of characterization of the feasibility  
6 question.

7 The way that we generally think  
8 about it is so if a state had an all-payer  
9 claims database, let's say California for  
10 instance, and they wanted to be able to run  
11 this measure for their pediatric patients in  
12 their state, would they be able to do that?  
13 I think that's generally the way that we would  
14 look at it. So if they had the data can they  
15 take these specifications and run them?

16 And so I'll just open that. And  
17 if they can I think that makes it a very  
18 feasible measure. I mean, if there's no -- if  
19 a user doesn't even have the data that's not  
20 necessarily a feasibility question for the  
21 measure developer.

22 So, maybe I'll just -- with that

1 framing maybe the measure developer can  
2 respond.

3 DR. NAKAMURA: Yes, thank you.  
4 This is Mari Nakamura.

5 So with that framing we certainly  
6 think that the measure is highly feasible,  
7 that it's actually quite easy to implement.  
8 We have very detailed specifications and we've  
9 also provided or can provide programs to  
10 actually be able to do a lot of the data  
11 preparation and running of the model.

12 So in our experience working with  
13 New York and in working with the programs  
14 ourselves we feel like if you have the data  
15 that it's highly feasible.

16 CO-CHAIR KAPLAN: Thank you.  
17 Larry?

18 DR. GLANCE: A quick comment  
19 though. Was the model validated in all-payer  
20 data? And if not, although it may be feasible  
21 to use with all-payer data it probably would  
22 not be a very appropriate use if it has not

1       been validated using all-payer data.

2                   DR. NAKAMURA:  It's true that our  
3       primary data set for development was Medicaid  
4       claims data.  And so we've done the most  
5       testing absolutely in that data set.

6                   We did also, however, use a couple  
7       of states, HCUP state inpatient database data  
8       to test the measures as well.  And to be able  
9       to also in the case of New York to compare our  
10      findings with their findings on their all-  
11      payer claims data set.

12                  CO-CHAIR KAPLAN:  So now I would  
13      like to ask NQF to comment on how we frame  
14      this.  Because the issue has become the target  
15      of inference here.

16                  And if we're trying to infer what  
17      the all-cause readmission rates for pediatrics  
18      are using the Medicaid database that's a  
19      different issue -- I'm hearing that's a  
20      different issue than if you're trying to  
21      extrapolate to the entire pediatric  
22      population.

1                   MR. AMIN: Well, I'll answer but  
2                   with a question I guess. I mean, in some ways  
3                   when we look at -- I mean, not to draw  
4                   comparisons with other measures, but you know,  
5                   the Yale CMS measures that are -- the all-  
6                   cause hospital readmission measure, has been  
7                   developed using Medicare claims data, then  
8                   tested with California all-payer claims  
9                   database. So, and it's specified as 18 and  
10                  older. So the unit of inference could be any  
11                  group of people that are over that population.  
12                  In this case it seems very similar to me.

13                 So I would say that -- I mean, I'm  
14                  not judging this but I think you should keep  
15                  that in mind as you make your decision about  
16                  the feasibility of this measure.

17                 CO-CHAIR KAPLAN: Leslie?

18                 MS. HALL: So, just a  
19                  clarification though. Didn't you already  
20                  state that the research showed that there  
21                  actually was a difference with the current  
22                  Medicaid covered population, and that you saw

1 right away that there was a difference in that  
2 insured population versus the other insured  
3 population?

4 So therefore we're starting to  
5 game with a difference in class of service I  
6 guess based upon the insurance. And so do we  
7 have mixed messages?

8 DR. NAKAMURA: Thank you. This is  
9 Mari Nakamura. So yes, you're correct that  
10 Medicaid-insured children have a higher  
11 readmission risk than privately insured  
12 children, for example.

13 This would be one argument for why  
14 it might be important to eventually adjust for  
15 insurance status as part of the case mix  
16 adjustment.

17 At the same time, to go back to  
18 the analogy that Taroon made, we know that  
19 Medicare-insured adults over age 65 are at a  
20 higher risk of readmission than other adults.

21 And so I think as you're pointing  
22 out very well the population that you're



1 evaluating is a really important question.

2 And it's important to be careful to consider  
3 who you compare.

4 But we don't feel that that limits  
5 the ability to use a measure either in a  
6 specific payer population or more broadly by  
7 taking into account the fact that there are  
8 differences among different payers.

9 CO-CHAIR KAPLAN: Okay, so I'm  
10 hearing some confusion about -- that I think  
11 probably although it does touch on feasibility  
12 for certainly the data you've run, you've run  
13 it. So you can get access to that data.

14 And I think the issue now is  
15 shading over into usability and that's causing  
16 a little bit of concern around here, although  
17 the feasibility issue -- does anybody else  
18 want to make a comment on feasibility? Are we  
19 ready to vote? All right, let's vote.

20 MS. SHAHAB: Voting for  
21 feasibility. One high, two moderate, three  
22 low, four insufficient. Time begins now.

1                   We have all the votes for  
2                   feasibility. Three voted high, eighteen  
3                   moderate, one low and zero insufficient.

4                   CO-CHAIR KAPLAN: Thank you. Now  
5                   we're into usability. And does anybody have  
6                   further comments on the potential usability of  
7                   this issue? Kathy, you want to go first?

8                   DR. AUGER: I think it's just  
9                   worth noting the potential differences between  
10                  what is an unplanned readmission, an actual  
11                  preventable readmission.

12                  I think there's a decent amount of  
13                  angst in the pediatric hospital medicine  
14                  community that there may not be a lot we can  
15                  do broadly to prevent readmission.

16                  Although I would personally  
17                  comment it's still early in the game. It's  
18                  still a little hard to actually come down on  
19                  whether or not that's true or not.

20                  There's certainly large groups  
21                  trying to reduce readmission rates nationally.  
22                  And frankly, the studies that they have done

1 haven't yet been published so I think it's  
 2 still just -- it's just early to assess. But  
 3 I think it's a consideration is whether or not  
 4 how much this is actually preventable versus  
 5 planned. Unplanned, sorry.

6 CO-CHAIR KAPLAN: Paul?

7 DR. HEIDENREICH: Along similar  
 8 lines I do have significant concerns that  
 9 there's not a credible rationale for  
 10 improvement. I know looking through the  
 11 background that there have been almost no  
 12 studies of interventions but it doesn't seem  
 13 like there's either been -- or maybe you can  
 14 tell me if there are some studies that at  
 15 least correlating certain hospital practices  
 16 with better readmission rates even though  
 17 there wasn't an obvious randomization or  
 18 experimental design.

19 And without that it seems -- and  
 20 given that pediatrics I think is significantly  
 21 different from adult with multiple chronic  
 22 diseases, a large number of medications, it

1 would seem that your interventions you would  
2 do would be different.

3 And so I'm very concerned that  
4 it's not clear how hospitals will be able to  
5 use the information once it's released.

6 CO-CHAIR KAPLAN: Developers want  
7 to comment?

8 DR. NAKAMURA: Yes, Your Honor.  
9 This is Mari Nakamura.

10 To start with Kathy's point about  
11 preventability versus unplanned readmissions.  
12 We agree that ideally it would be desirable to  
13 be able to assess preventable readmissions  
14 rather than unplanned readmissions.

15 We just don't think that that's  
16 possible using claims data, using the data  
17 that we currently have widely available to us.  
18 And so we took the approach in harmony with  
19 what has been done in adult measures to  
20 instead focus on unplanned readmissions.

21 That said, research that we're  
22 currently working on as well as conducted at

1 other institutions has indicated that a  
2 sizeable proportion of unplanned readmissions  
3 actually are potentially preventable.

4 Of course, how preventability is  
5 determined is highly controversial. It's  
6 something that I think will probably always be  
7 a subject of debate because it's so  
8 subjective.

9 We have a study that's still  
10 currently underway in which we've talked with  
11 patients, families, nurses, outpatient  
12 doctors, inpatient doctors to try to get a  
13 sense from all of them of how preventable they  
14 thought readmissions were.

15 What we found is the more  
16 information you get the better sense you get  
17 that it's a very complicated question. And so  
18 knowing that we are using claims data for this  
19 measure we're choosing to focus on unplanned  
20 readmissions.

21 Regarding the rationale for  
22 whether readmission rates can be improved in

1       pediatrics it is indeed true that there are  
2       far fewer studies in pediatrics than adults  
3       looking at interventions for readmission.

4               There are a handful that have  
5       focused on pediatric patients or that have  
6       included pediatric patients and evaluated them  
7       as a subset that have found, for example,  
8       better adherence to practice guidelines has  
9       been associated with reduced readmissions or  
10      improvements in criteria for discharge.

11             All that said we acknowledge that  
12      in this space for pediatric measures that more  
13      likely what we're dealing with is a rationale  
14      that makes sense rather than a lot of evidence  
15      already in the literature.

16             And we believe that given that  
17      processes such as discharge preparation and  
18      education, making sure that there are good  
19      transitions to the community are felt to be  
20      equally important in pediatrics that  
21      improvements in those processes could also  
22      lead to improvements in readmission rates.

1           The point that there are not as  
2           many very chronically ill complex patients  
3           among pediatric patients as adults is true.

4           That said, one of my colleagues at  
5           our center conducted a study a couple of years  
6           ago examining specifically the population of  
7           patients with chronic complex conditions who  
8           are frequently readmitted and found that while  
9           they're a small percentage of all patients  
10          they account for a high percentage of  
11          readmissions in cost.

12          And so in terms of a population  
13          that could be a focus for readmission  
14          improvement that seems like a natural one.  
15          Thank you.

16                 CO-CHAIR KAPLAN: Thank you.  
17          Taroon, do you have something specific to  
18          this? Then let's go Leslie, Karen and Taroon.

19                 MS. HALL: So, this is an  
20          interesting area in usability and maybe should  
21          be questioned or comments aimed towards  
22          implementation.

1 But communication and education  
2 around this measure could not be stressed  
3 more. Because readmission is something that  
4 is known in the public I guess consciousness.  
5 And now we apply the highly emotional area of  
6 pediatrics. And without good explanation and  
7 the fact that we have data sources coming from  
8 Medicaid patients that were already felt that  
9 are disenfranchised by other payer groups we  
10 have the potential to have a good deal of  
11 angst associated with this measure release.

12 And so I would just caution and  
13 encourage that along with the implementation  
14 guide we include communication plans and  
15 education to the public.

16 CO-CHAIR KAPLAN: Certainly this  
17 is one of those ones that if approved that MAP  
18 is going to have something to say a lot about.  
19 So, Karen?

20 DR. JOYNT: I just have two  
21 additional thoughts about the usability. Both  
22 again perhaps not things that would keep the



1     measure from going forward but things that I  
2     think would be particularly essential in this  
3     population to consider.

4             And one is socioeconomic status.  
5     I don't think you can get away from that in  
6     this population. And especially because  
7     you've shown data that shows us that there's  
8     a big difference there. Not necessary to  
9     adjust for it but it's got to be part of the  
10    discussion about how we think about this and  
11    how it sort of rolls out. Because if we're  
12    just identifying hospitals that differ by  
13    socioeconomic status I don't think we're doing  
14    anyone a favor.

15            And the second is administration  
16    rates. We've talked about this with the adult  
17    measures as well. If a community works to  
18    reduce their admission rates for asthma they  
19    could potentially increase their readmission  
20    rates. And I think that would be equally true  
21    for the complex chronic condition patients.  
22    If you put a good intervention in place to

1     improve their care as outpatients they might  
2     not go into the hospital as much.

3             And I would hate to see hospitals  
4     look worse on readmissions because they have  
5     done such a good job of providing good  
6     outpatient care for their patients.

7             I just don't think the long-term  
8     quality here is just about readmission. It's  
9     also got to be about admission. That's where  
10    this stuff is moving. And I would really  
11    encourage as we think about usability think  
12    about some sort of companion way to examine  
13    that piece.

14            CO-CHAIR KAPLAN: Thank you.  
15    Taroon?

16            MR. AMIN: Just to follow up on  
17    the question of the all-payer claims and the  
18    MAX data.

19            I just wanted to clarify from the  
20    developer is the information that's provided  
21    in the testing form, that's a testing from the  
22    MAX data set, right?

1 DR. NAKAMURA: This is Mari  
2 Nakamura. Yes, that's right.

3 MR. AMIN: Is there information  
4 that you can share with the committee around  
5 the testing from the New York State all-payer  
6 claims database that you've done?

7 DR. NAKAMURA: What we would be  
8 able to provide is a sense of what the  
9 readmission rates look like, how they compared  
10 to the Medicaid readmission rates.

11 We also specifically used our all-  
12 payer data sets to be able to evaluate some  
13 questions that we couldn't in MAX. So,  
14 specifically insurance status. And also the  
15 relationship between insurance status and  
16 race/ethnicity and risk factors for  
17 readmission.

18 That said, we did not do all of  
19 the testing in the all-payer data set that we  
20 did with the MAX data set in part because we  
21 were limited in the all-payer data set to not  
22 as many states and we felt that the MAX data

1 set was actually far larger. And although it  
2 was limited to Medicaid patients based on the  
3 power that we had the more desirable data set  
4 to use as our primary development data set.

5 CO-CHAIR KAPLAN: Thank you.  
6 We're over time for this measure by a  
7 considerable amount.

8 On the other hand, since this is  
9 the first of its kind I feel like this was a  
10 very good discussion of the kinds of issues  
11 that are problematic.

12 With respect to Medicaid status  
13 and Karen's issue about socioeconomic status,  
14 if you use it as an adjuster you're adjusting  
15 away the thing you're trying to explain.

16 So it's one of these problematic  
17 areas that once again we are faced with here's  
18 new ground and we're faced with the measure we  
19 have in front of us, not the one we would like  
20 to develop 5-10 years hence. So, staring at  
21 the thing you're staring at, this issue we're  
22 now preparing to vote for. Any other

1       comments?

2                       CO-CHAIR HALL:  I do.  I'm not an  
3       expert in gates data and I'm still not sure  
4       what I've heard.  So a couple of the experts  
5       maybe could comment.

6                       The extrapolatability from  
7       Medicaid to the general population sounded  
8       like there were concerns about the -- resolved  
9       in my head.

10                      Those still exist.  Anybody want  
11       to?

12                      DR. FIELDS:  Yes, I think the  
13       tough thing about this, I'm just trying to  
14       summarize what I've heard and what I know is  
15       that ideally the first measure for pediatric  
16       care would probably be more related to access  
17       to care and especially primary care and  
18       surveillance.  It wouldn't be about hospital  
19       services.  Children have the lowest overall  
20       admission rate of any cohort seen in the  
21       emergency department, for example, in terms of  
22       unscheduled admissions or readmissions.

1                   So, in a perfect policy  
2       development world you wouldn't start with the  
3       hospital piece. You'd probably end with it.

4                   The other fundamental problem  
5       which we touched on yesterday is that the  
6       place you need to move the rock with the most  
7       urgency are the very states where you're going  
8       to have the poorest Medicaid data and the  
9       smallest number of children who should be  
10      getting better primary care eligible for  
11      Medicaid services.

12                  So it's a fundamental conundrum.  
13      Because as with other applications of  
14      administrative data this is an easy place to  
15      start. It may be the only place to start, but  
16      it's not the best place to start.

17                  CO-CHAIR KAPLAN: Thanks. Kathy?

18                  DR. AUGER: I would comment that I  
19      agree with you that certainly some aspects of  
20      pediatric readmission are -- hinge upon things  
21      like access to care although I don't think  
22      that that's all of it.

1                   And certainly I think in terms of  
2       -- I think it's a real question of whether or  
3       not hospitals can truly move this metric  
4       although it seems like with the new metric the  
5       standard is to reassess in three years and see  
6       whether or not -- if there was any change in  
7       time.

8                   But then I would just also -- I  
9       think to me the bigger question is what Bruce  
10      raised. It's primarily based on Medicaid data  
11      and how it extracts beyond Medicaid is still  
12      a little bit of a question mark in my mind.

13                  CO-CHAIR KAPLAN: I would just add  
14      from a non-physician, non-provider standpoint  
15      it isn't a good idea if children are  
16      readmitted to the hospital. So the idea that  
17      readmission to the hospital is a quality  
18      measure is not a stretch for me.

19                  I mean, the question is rather as  
20      Bruce alluded to who are we extrapolating to  
21      from who are we actually able to measure this  
22      on. And that remains a difficulty.

1                   On the other hand we are again,  
2                   right Taroon? Stuck with -- we're not stuck  
3                   with --

4                   (Laughter)

5                   CO-CHAIR KAPLAN: -- we have what  
6                   exactly we have in front of us and that's what  
7                   we're considering.

8                   CO-CHAIR HALL: We're looking  
9                   where the light is. Leslie.

10                  MS. HALL: I guess my concern  
11                  about the Medicaid data is somewhat helped by  
12                  the thought that if we help the poor we help  
13                  everyone.

14                  CO-CHAIR KAPLAN: Okay. Go ahead.

15                  MS. TRAVIS: I guess -- this is  
16                  just a clarification because I might have  
17                  gotten confused along the way.

18                         If this measure is fully tested in  
19                         the Medicaid population with the validity  
20                         testing and not fully tested in the all-payer  
21                         or in other settings, when we approve it it  
22                         will say it was tested in the Medicaid



1     population how does that affect how it is used  
2     out of the portfolio?

3             Because usually if I remember  
4     correctly we've always said that it's endorsed  
5     based on how it's specified and how it's  
6     tested I think was the second part of that.  
7     So I'm just trying to ask for clarification on  
8     that.

9             CO-CHAIR HALL:  It's not specified  
10    to be exclusively used in Medicaid.  It is --  
11    the details reveal that it was tested on  
12    Medicaid so my interpretation is that it would  
13    not be limited to application in Medicaid.  
14    But then in follow-up somebody would see how  
15    it performs.  Taroon, do you want to add to  
16    that?

17            MR. AMIN:  Yes, and I think that  
18    seems to be the conundrum that you've raised  
19    which started this conversation which is that  
20    it's not specified -- the testing doesn't  
21    match completely the specifications.

22            So if it were to be used outside

1 of Medicaid, you know, it's specified to be  
2 able to do that. Although the testing doesn't  
3 demonstrate how it would perform outside of  
4 Medicaid.

5 CO-CHAIR KAPLAN: So, are we close  
6 to ready? It's my understanding that if you  
7 did nothing else you would overestimate the  
8 amount of -- the readmission rates by  
9 hospital. And then the question is whether or  
10 not that overestimation would compromise its  
11 usability for when measures got less and less  
12 stable because the numbers got smaller and  
13 smaller for readmission rates. So, that could  
14 be addressed in a use if approved.

15 DR. NAKAMURA: Thank you. This is  
16 Mari Nakamura. You're correct that  
17 readmission rates will tend to be higher in a  
18 Medicaid-only population we found than in an  
19 all-payer population.

20 There's some different sort of  
21 considerations that work in going from a  
22 Medicaid-only to an all-payer data set.

1                   So, for example, we would  
2           anticipate that for many hospitals the sample  
3           sizes used would actually get better because  
4           while Medicaid is a sizable portion of all  
5           hospitalizations it's only about one-third.  
6           And of course that will differ depending on  
7           the proportion of Medicaid at a given  
8           hospital.

9                   But if anything we would expect  
10          that reliability would improve and that the  
11          position of rates would actually get better.

12                   CO-CHAIR KAPLAN: Gotcha. The  
13          numerator would -- okay.

14                   CO-CHAIR HALL: I think the  
15          numerator would get better but fundamentally  
16          you are -- you're drawing coefficients out of  
17          a higher-risk population which means you're  
18          less likely to hold a hospital accountable  
19          that has a lower risk population.

20                   DR. NAKAMURA: This is Mari  
21          Nakamura. Thank you for that question because  
22          I hadn't realized -- I apologize -- part of

1 the concern here.

2 So the way that our measure is run  
3 is that actually we don't provide the beta  
4 coefficients as set numbers to be used in the  
5 model. Instead the model is actually run on  
6 the data set to which it's being applied and  
7 new coefficients for that particular  
8 population are generated.

9 So I agree that the choice of  
10 covariates we made certainly was based  
11 primarily on the Medicaid data set. We did  
12 test the very same model on our all-payer data  
13 set and we believe that in terms of the  
14 relationships between things like age and  
15 gender and chronic conditions that one can  
16 generalize from the Medicaid population to an  
17 all-payer data set in terms of those fixed  
18 effects relationships while recognizing that  
19 at the same time having Medicaid insurance as  
20 a child is, it appears, an additional risk  
21 factor on top of those patient  
22 characteristics.

1 CO-CHAIR HALL: Thank you.

2 CO-CHAIR KAPLAN: Fair enough.

3 Kathy.

4 DR. AUGER: Do you have a sense of  
5 what the C statistic was in the all-payer  
6 model? Is it the same?

7 DR. NAKAMURA: This is Mari  
8 Nakamura. No, I'm sorry, I don't have that  
9 although we would be able to easily determine  
10 that.

11 CO-CHAIR KAPLAN: Okay. I think  
12 we are ready to vote on the issue of, where  
13 are we, usability? Usability.

14 MS. SHAHAB: Voting for usability  
15 and use. One is high, two moderate, three  
16 low, four insufficient information and time  
17 starts now.

18 We have all the votes for  
19 usability and use. Zero high, fourteen  
20 moderate, eight low, zero insufficient  
21 information.

22 CO-CHAIR KAPLAN: Thank you. And

1 drum roll, drum roll, we are now to  
2 endorsement. Any more further thoughts?  
3 Okay.

4 MS. SHAHAB: Voting for overall  
5 suitability for endorsement. One is yes, two  
6 no. Time begins now.

7 We have all the votes for overall  
8 suitability for endorsement. Measure 2393  
9 Pediatric All-Condition Readmission Measure,  
10 the votes are 17 yes, 5 no.

11 CO-CHAIR KAPLAN: Thank you very  
12 much and thank you to the developers. Now we  
13 are 20 minutes behind. And so we are going to  
14 have to sort of make tracks.

15 I assume much of the discussion  
16 will now sharpen up and condense itself around  
17 many of either not similar issues but possibly  
18 easier to deal with issues.

19 So, would you reintroduce  
20 yourselves for the record and then describe  
21 the measure.

22 DR. NAKAMURA: Thank you. This is

1 Mari Nakamura from Boston Children's Hospital.

2 DR. ZASLAVSKY: Alan Zaslavsky  
3 from Harvard Medical School.

4 DR. NAKAMURA: And we have Mark  
5 Schuster on the phone. I will keep my  
6 introduction brief because by design these two  
7 measures are very similar and so for the most  
8 part the same considerations apply.

9 Our pediatric lower respiratory  
10 infection measure evaluates readmissions  
11 following an index hospitalization for  
12 bronchiolitis, influenza, or community-  
13 acquired pneumonia.

14 We decided on a measure focusing  
15 on lower respiratory infections because  
16 they're among the most common reasons for  
17 hospitalization in children.

18 In addition, they're among the  
19 diagnoses with the most prevalent  
20 readmissions. We found an overall 30-day  
21 readmission rate of 5.6 percent which  
22 corresponds with the large absolute number of

1 readmissions given the high number of initial  
2 hospitalizations for lower respiratory  
3 infection.

4 We prioritize harmonizing this  
5 measure with NQF-endorsed adult readmission  
6 measures as well as with our all-condition  
7 measure. And as a result the approaches we  
8 used in developing the measure are very  
9 similar.

10 We used the same case mix  
11 adjustment model because we found that it  
12 performs very well for LRI readmissions with  
13 regard to discrimination and calibration.

14 The issue of limited reliability  
15 due to small sample sizes is even more of an  
16 issue for any condition-specific rate -- and  
17 this is true for LRI -- than for all condition  
18 rates. But again we found that a majority of  
19 children were cared for at higher-volume  
20 hospitals than as a result were at hospitals  
21 with good reliability.

22 The New York Office of Safety and



1     Quality also tested this measure on its  
2     Medicaid and all-payer databases and noted  
3     that having implemented one measure it  
4     required minimal effort to be able to  
5     implement the other.

6                     And so we do think that this  
7     measure could be a useful tool to evaluate  
8     quality and encourage improvements in care for  
9     an important pediatric condition. Thank you.

10                    CO-CHAIR KAPLAN: Thank you. I  
11     think Mari is the only person in the room that  
12     talks faster than I do so thank you very much  
13     for that quick summary.

14                    Jo Ann, do you want to talk to us  
15     about evidence?

16                    DR. BROOKS: I'll go ahead and get  
17     started with this.

18                    As was said this is a companion  
19     measure to the one we just discussed. And  
20     looking at lower respiratory infections,  
21     accounting for a large number of the  
22     readmissions we see it is an important area.

1                   And there's good support here on  
2                   how these readmissions, we may be able to look  
3                   at things to improve the readmissions, looking  
4                   at our key processes, our discharge planning,  
5                   care transitions, appropriate follow-up, et  
6                   cetera.

7                   And disparities exist for many of  
8                   these differences we see in patients being  
9                   readmitted for lower respiratory infection.

10                  CO-CHAIR KAPLAN: Thank you.  
11                  Kathy, nothing to add? Others? Vote  
12                  evidence.

13                  MS. SHAHAB: Voting for 1(a)  
14                  evidence, one yes, two no. Time begins now.

15                  We have all the votes for 1(a)  
16                  evidence. Nineteen voted yes, two voted no.

17                  CO-CHAIR KAPLAN: Performance gap.  
18                  Jo Ann?

19                  DR. BROOKS: There exists a  
20                  performance gap for this. This is also a  
21                  newly commissioned measure by CMS and AHRQ.  
22                  There's disparities in care across populations

1 in many different ways and there are strong  
2 data to support that there is a quality gap  
3 and a need for this measure.

4 There is support in the  
5 application talking about some of the  
6 pediatric data that's out there although it is  
7 not as rich as the adult data. But the  
8 appropriate rationale is there.

9 CO-CHAIR KAPLAN: Kathy?

10 DR. AUGER: I'd just comment  
11 though that the readmission rate for the lower  
12 respiratory tract infections is actually lower  
13 than the all-cause.

14 And so it's hard to know what the  
15 -- like how much of a range we're actually  
16 dealing with at the different hospitals, like  
17 what the interquartile range would be for the  
18 risk-standardized rate and whether or not  
19 that's significant.

20 CO-CHAIR KAPLAN: Do the  
21 developers have any information for us?

22 DR. NAKAMURA: This is Mari

1 Nakamura. I guess -- thank you.

2 So, for our lower respiratory  
3 infection measure to give you analogous  
4 numbers to what I provided for all-condition,  
5 a hospital that's two standard deviations  
6 below the mean would have a readmission rate  
7 of 1.7 percent.

8 A hospital two standard deviations  
9 above would have a readmission rate of 12.6  
10 percent. So, there's actually a wider range  
11 for lower respiratory infection.

12 CO-CHAIR KAPLAN: Thank you for  
13 that. Others? Okay, ready to vote?  
14 Performance gap.

15 MS. SHAHAB: Voting for 1(b)  
16 performance gap. One high, two moderate,  
17 three low, four insufficient. And the time  
18 begins now.

19 We have all the votes for  
20 performance gap. Three voted high, eighteen  
21 moderate, zero low and zero insufficient.

22 CO-CHAIR KAPLAN: Thank you.

1 Priority. Jo Ann?

2 DR. BROOKS: And this continues to  
3 be a high-priority measure as it was  
4 commissioned by AHRQ and CMS. Also because it  
5 relates and impacts a large number of  
6 pediatric patients and accounts for a large  
7 number of the readmissions in hospitals.

8 CO-CHAIR KAPLAN: Thank you.  
9 Kathy?

10 DR. AUGER: Yes, just lower  
11 respiratory tract infections are one of the  
12 most common indications for hospitalization in  
13 pediatrics so to me it's high priority.

14 CO-CHAIR KAPLAN: Others? Ready  
15 to vote?

16 MS. SHAHAB: Voting for 1(c) high  
17 priority. One high, two moderate, three low,  
18 four insufficient. Time begins now. Just one  
19 more vote.

20 We have all the votes for 1(c)  
21 high priority. Twelve voted high, eight  
22 moderate, one low and zero insufficient.

1 CO-CHAIR KAPLAN: Thank you very  
2 much. Scientific acceptability. Start with  
3 reliability. Jo Ann?

4 DR. BROOKS: Yes, this measure was  
5 tested the exact same way as the previous  
6 measure using the MAX data. And when we  
7 looked at reliability it ranged between 0.5 to  
8 0.77.

9 The measure was also found to be  
10 highly reliable at hospitals with an adequate  
11 sample size, but obviously it did not perform  
12 as well in those with lower sample size.

13 And one of the questions was will  
14 exclusions make the reliability across time  
15 and place an issue for this measure. Because  
16 there's a large number of exclusions in this  
17 measure.

18 DR. NAKAMURA: This is Mari  
19 Nakamura. Regarding exclusions the -- one  
20 difference with our all-condition measure is  
21 the case definition requirement for the index  
22 hospitalizations.

1                   So, speaking more generally about  
2 both measures I think that we've created an  
3 appearance of maybe more exclusions than  
4 typical because we listed everything in terms  
5 of being exclusion rather than some as  
6 inclusions.

7                   So, some of these are, for  
8 example, based on limiting to the pediatric  
9 age range. Some other common exclusions that  
10 we saw have been used quite uniformly in adult  
11 measures such as excluding patients who leave  
12 AMA or certainly patients who die in the  
13 hospital.

14                  Our other set for the exclusions  
15 that are quite similar to the adult  
16 readmission measures are certain data quality  
17 exclusions for key variables with missing or  
18 what looked like poor quality data. For  
19 example, a discharge date that occurs before  
20 a date of birth.

21                  The main clinical exclusions that  
22 we apply for both measures are, first of all,

1 patients who are receiving obstetric care with  
2 the rationale that these patients are  
3 typically not under the purview of pediatrics  
4 even if they fall in the pediatric age range.  
5 And so we felt would most likely be better  
6 included in obstetric measures rather than a  
7 pediatric measure.

8 We also exclude patients with a  
9 primary mental health diagnosis. That is  
10 consistent with other measures but in our own  
11 testing as well we felt it was justified  
12 because we found that readmission people for  
13 a given hospital does not track for mental  
14 health conditions as compared with other  
15 conditions.

16 And then finally we exclude  
17 newborns who are in the hospital for their  
18 birth admission. The clinical rationale for  
19 that is that they are among all patients in  
20 the hospital not actually there because  
21 they're ill, but rather for another life  
22 event. And so we felt that it made sense not



1 to include them in a readmission rate.

2 CO-CHAIR KAPLAN: Thank you. I'm  
3 going to ask the committee to hold that  
4 consideration for the validity discussion as  
5 opposed to -- unless those exclusions change  
6 the reliability we need to keep focused on  
7 reliability. Kathy?

8 DR. AUGER: I would just comment  
9 as Mari already acknowledged the reliability  
10 in this metric is not quite as good as the  
11 previous measure in that only 229 of the 1,743  
12 hospitals actually had a readmission rate  
13 reliability of greater than 0.5.

14 But that again these hospitals  
15 accounted for 62 percent of the lower  
16 respiratory tract infection hospitalizations.  
17 So it's still -- even though it's a smaller  
18 number of hospitals it's still a majority of  
19 the hospitalizations.

20 CO-CHAIR KAPLAN: The precision of  
21 those estimates once again sort of tracks with  
22 everything else we're seeing. In fact, it

1 lands a little bit on the higher side compared  
2 to other reliability estimates we've been  
3 seeing in some of these other measures.  
4 Anybody else? Vote reliability.

5 MS. SHAHAB: Voting for 2(a)  
6 reliability. One is high, two moderate, three  
7 low, four insufficient. Time begins now.  
8 We're still waiting on two more votes. One  
9 more.

10 All votes are in for 2(a)  
11 reliability. The results are 1 high, 18  
12 moderate, 2 low and zero insufficient.

13 CO-CHAIR KAPLAN: Thank you.  
14 Validity. And I'll ask you to keep in mind  
15 the exclusion discussion we just had.

16 DR. BROOKS: On the validity, the  
17 construct validity was demonstrated as  
18 associated with the literature and the quality  
19 of care. The processes related to reductions  
20 and readmissions that we're all aware of.

21 Criterion validity was shown using  
22 a data set from Boston Children's Hospital

1 over a 1-year period. And the sensitivity and  
2 the specificity were 87.0 and 99.7 percent  
3 respectively.

4 They also did face validity on the  
5 planned procedure algorithm that was completed  
6 and also received public comments from the  
7 Federal Register. And they then took those  
8 comments and put those into the methodology to  
9 improve it.

10 And those would be my comments.

11 DR. AUGER: So, very similar  
12 issues with validity in terms of identifying  
13 unplanned readmissions as appropriate.

14 The couple of questions -- well,  
15 so I'd say that the model calibration is good  
16 and the C statistic for predictive ability was  
17 0.71 so that's in a reasonable range.

18 The one question that we were just  
19 talking about is how CF exacerbations come  
20 into play here, whether or not the model would  
21 adequately account for CF as well.

22 DR. NAKAMURA: This is Mari

1 Nakamura.

2 So, cystic fibrosis in particular  
3 would end up being included in the model as  
4 one of the chronic condition indicator  
5 variables for chronic respiratory infections.

6 But this is also an opportunity --  
7 I'll keep it very brief -- to mention that we  
8 thought about whether we needed to have more  
9 symptom variables for chronic conditions for  
10 the LRI measure versus the all-condition.

11 And in reflecting decided not to  
12 because it's actually a wide range of  
13 conditions that place patients at higher risk  
14 of severe lower respiratory infections.  
15 They're not just respiratory, but for example,  
16 cardiac, neurological. And so we felt that it  
17 made sense to keep all of the chronic  
18 condition indicators and found indeed that the  
19 model actually performs very well.

20 CO-CHAIR KAPLAN: Thank you. I  
21 want to ask for a point of clarification about  
22 criterion validity because that implies a gold

1 standard. You weren't using Boston Children's  
2 as the criterion. Did I misunderstand that?  
3 How is what you did criterion validity?

4 DR. NAKAMURA: This is Mari  
5 Nakamura.

6 So we were using the electronic  
7 health record data as our gold standard based  
8 on having performed detailed chart reviews of  
9 the cases that we evaluated with the idea that  
10 such a chart review is at least a better  
11 standard than what can be found from claims  
12 data in terms of being able to assess both  
13 whether readmission occurred as well as  
14 whether it met our definition for an eligible  
15 readmission meaning that it wasn't for a  
16 planned procedure or chemotherapy.

17 CO-CHAIR KAPLAN: Thank you. Some  
18 of us would call that convergent validity  
19 because it converges with a different data  
20 source as opposed to criterion validity. But  
21 that's okay.

22 DR. NAKAMURA: Thank you.

1 CO-CHAIR KAPLAN: Other comments  
2 on validity? Let's vote.

3 MS. SHAHAB: 2(b) validity. One  
4 is high, two moderate, three low, four  
5 insufficient. Time begins now. One more  
6 vote.

7 All votes are in for 2(b)  
8 validity. Zero voted high, twenty moderate,  
9 one low and zero insufficient.

10 CO-CHAIR KAPLAN: Thank you.  
11 Feasibility?

12 DR. BROOKS: And on feasibility I  
13 would say that since it's claims data it's  
14 easily feasible for us to get these data.

15 The one question -- some of the  
16 concerns we've already had is it's based on  
17 Medicaid data. But is it feasible as claims  
18 data.

19 CO-CHAIR KAPLAN: Others? So  
20 we're burned out on feasibility.

21 (Laughter)

22 CO-CHAIR KAPLAN: Ready to vote.

1 MS. SHAHAB: Voting on  
2 feasibility. One high, two moderate, three  
3 low, four insufficient. Time begins now.  
4 Still waiting on two more votes.

5 All votes are in for feasibility.  
6 The results are 3 high, 17 moderate, 1 low and  
7 zero insufficient.

8 CO-CHAIR KAPLAN: Thank you. Onto  
9 usability.

10 DR. BROOKS: Usability, since this  
11 measure is really a subset of the previous  
12 measure all the issues we've discussed with  
13 usability in the previous discussion are the  
14 same here.

15 CO-CHAIR KAPLAN: Kathy?

16 DR. AUGER: So yes, again, just  
17 the whole issue of preventability versus  
18 unplanned is a consideration. But that's the  
19 same as the other metric.

20 The one thing that I would comment  
21 might be different for this metric compared to  
22 the other metric is this is -- lower

1     respiratory infection is a very seasonal  
2     illness. And so therefore as it's written I  
3     think it's not an issue because it's an annual  
4     evaluation.

5                 But it's something that it would  
6     not be appropriate for it to be used as a  
7     quarterly evaluation because of the seasonal  
8     variability in this. But I see it as written  
9     as fine.

10                CO-CHAIR KAPLAN: Want to respond  
11     to that?

12                DR. NAKAMURA: Thank you. This is  
13     Mari Nakamura. Kathy is correct that if we  
14     were to try to report these results as  
15     quarterly that season would be a really  
16     important consideration.

17                We chose to make it annual, taking  
18     care of that fact but also recognizing that  
19     quarterly rates would be an even greater  
20     challenge with regard to sample size.

21                CO-CHAIR KAPLAN: Thank you.  
22     Other comments? Ready to vote.



1 MS. SHAHAB: Voting on usability  
2 and use. One high, two moderate, three low,  
3 four insufficient in. The time begins now.

4 All votes are in for usability and  
5 use. The results are zero high, 17 moderate,  
6 4 low and zero insufficient information.

7 CO-CHAIR KAPLAN: Are we ready to  
8 vote on endorsement? Any discussion?

9 DR. BROOKS: My only comment is  
10 that I think this one is very specific to  
11 sociodemographic data as well and we need to  
12 consider that as we move forward with this  
13 down the road.

14 CO-CHAIR KAPLAN: Yes, the issue  
15 of sociodemographic data as we've discussed  
16 yesterday and today is going to be, you know,  
17 one of these things that is going to be guided  
18 by a committee that hasn't yet kind of given  
19 its guidance to us. So we are going to either  
20 endorse or not endorse the -- right.

21 CO-CHAIR HALL: Understanding that  
22 we can all as a group express that we want our

1 NQF colleagues to capture that for these two  
2 measures the group in particular felt very  
3 strongly that this question needs to be  
4 addressed in the future.

5 Do people feel that's a relative  
6 consensus? Anyone would object to attaching  
7 that comment?

8 CO-CHAIR KAPLAN: No, but and the  
9 issue of Medicaid and SES adjustment is one of  
10 these things that's also going to present a  
11 rather dodgy problem. Because socioeconomic  
12 status and some of the adult measures actually  
13 use Medicaid status as a proxy for  
14 socioeconomic status. So it's going to be a  
15 more complex issue with some of these  
16 measures.

17 CO-CHAIR HALL: All I'm suggesting  
18 is we create a bit of a flag for our NQF  
19 colleagues that if someday comes where the  
20 white paper recommendations have changed on  
21 this that this is an easy flag to spot.

22 CO-CHAIR KAPLAN: So flaggage

1 approved and associate recommendations.

2 (Laughter)

3 CO-CHAIR KAPLAN: Are we ready?

4 Any other comments before we vote for

5 endorsement or non-endorsement?

6 MS. SHAHAB: Voting for overall

7 suitability for endorsement. One yes, two no.

8 Time starts now.

9 All votes are in for overall

10 suitability for endorsement for measure 2414

11 Pediatric Lower Respiratory Infection

12 Readmission Measure. The results are 18 yes

13 and 3 no.

14 CO-CHAIR KAPLAN: Thank you very

15 much. And now we are ready for NQF member and

16 public comment. And we will invite public

17 comment. Thank you to the developers for a

18 nice summary and discussion.

19 We're onto the NQF member and

20 public comment. I'm going to turn over to

21 Adeela.

22 MS. KHAN: Kathy, can we compile

1 the list, please?

2 OPERATOR: Yes, ma'am. If you  
3 would like to make a public comment please  
4 press \* then the number 1. No, no public  
5 comments at this time.

6 MS. KHAN: Do we have any public  
7 comment in the room?

8 DR. SCHWALENSTOCKER: Good  
9 afternoon -- or I guess it's good morning.  
10 And I realize I'm standing between you and  
11 lunch.

12 My name is Ellen Schwalenstocker.  
13 I'm with the Children's Hospital Association.

14 And I just wanted to highlight  
15 some of the discussion among the committee  
16 that I just think is really important some of  
17 which is outside your purview.

18 But we've been saying for a long  
19 time that it's really important to develop  
20 good pediatric measures. And I want to thank  
21 the Center of Excellence at Boston Children's  
22 Hospital for their work in developing these

1 measures.

2 I'm not sure, and this may be a  
3 question for you, what the 3-year experience  
4 sort of guidelines are. I do strongly agree  
5 with the recommendation on should the NQF  
6 change its policy on adjustment for SES and  
7 other factors, that it would be really  
8 important to look at these measures as well as  
9 adult readmissions measures in that light.

10 I also think because of the lack  
11 of a large set of good pediatric measures it  
12 will really be important to have other  
13 measures available before these kinds of  
14 measures are used for, say, accountability  
15 purposes or pay-for-performance.

16 And so I'm wondering if that's  
17 sort of part of the 3-year process to give us  
18 more chance for validation of measures against  
19 other measures? I guess that's convergent  
20 validity.

21 And I know there are some other  
22 measures that will be coming forward from the

1 CHIPRA Centers of Excellence which we just  
2 think is a really important program and are  
3 glad to see the measures coming to NQF.

4 MR. AMIN: So, I can address that,  
5 Ellen, right now.

6 So, the NQF reevaluates all of its  
7 measures that are recommended for endorsement  
8 in a 3-year maintenance cycle.

9 In that 3-year maintenance cycle  
10 we look for experience on the measure. In  
11 particular in the importance to measure  
12 criteria we're looking for some actual, at the  
13 measure performance gap information we're not  
14 just looking conceptually whether there's a  
15 measure performance gap, we want to see the  
16 performance gap in the measure itself and to  
17 see the distribution and if there's any  
18 overall gap in performance or overall less  
19 than optimal performance.

20 And then also in the use and  
21 usability criteria we want to see if the  
22 measure has been implemented for use in

1     quality improvement applications and then a  
2     further time line is ready for accountability  
3     applications which we include public reporting  
4     in that domain.

5                 So the purpose there is that we  
6     have measures that are actually picked up by  
7     the field and we can demonstrate that they're  
8     actually being used for the purposes of  
9     quality improvement and reporting the  
10    information to the public.

11                DR. BURSTIN: I'm just wanting to  
12    add again if this measure is endorsed and goes  
13    through the entire process, again, the SES  
14    issue I think outstanding. We don't know how  
15    that's all going to play out.

16                But I think certainly we'll have  
17    to make a decision with our CSAC and our board  
18    depending on how that lands in terms of  
19    whether we'll bring measures back sooner than  
20    the 3-year time frame for maintenance if in  
21    fact there are additional issues to address.

22                But you know, a very important

1 piece of this. As these measures are going  
2 out there NQF endorsement does imply they are  
3 appropriate for any accountability application  
4 and could get picked up for any of those  
5 certainly by CMS or others.

6 We would really encourage the  
7 field to be really vigilant about keeping  
8 track of measures that are really helping to  
9 drive improvement, measures for which there  
10 may be unintended consequences and bring that  
11 forward, that information, in realtime rather  
12 than just waiting for the 3-year limit.

13 MR. AMIN: Are there any other  
14 public comments?

15 OPERATOR: Once again to make a  
16 public comment please press \*1. You have a  
17 comment from John Muldoon with 3M Health  
18 Information Systems.

19 MR. MULDOON: Are you able to hear  
20 me?

21 MS. KHAN: Yes, we can hear you.

22 MR. MULDOON: Several comments.



1 And I submitted a lengthy quite detailed set  
2 of comments about a month ago.

3 But in terms of the concept of  
4 readmissions, the risk adjustment and the  
5 testing and the evaluation work. And just  
6 highlights some concerns that we had  
7 identified. And some of these came up during  
8 discussion as well.

9 The approach focuses on unplanned  
10 readmissions as opposed to trying to identify  
11 potentially preventable. And realize that  
12 that's a tough challenge to identify.

13 But there's a number of  
14 consequences. Because there are a number of  
15 very low preventability readmissions such as  
16 malignancy-related admissions, neutropenia,  
17 classic anemia, just an easy one to highlight.  
18 And those kinds of kids are treated at certain  
19 centers. So it creates numbers that may not  
20 be that real in terms of preventability and  
21 distortions in terms of comparisons across  
22 different settings.

1                   Also, when you go out to 30 days  
2                   and the number of unrelated and low  
3                   preventability readmissions increases. So  
4                   that compounds the concern and the approach to  
5                   readmissions.

6                   On the risk adjustment concern  
7                   that often the principal diagnosis and the  
8                   acuity of the admission and really complex  
9                   prior conditions that have a very big impact  
10                  on admission rates and readmission rates.

11                  And that's not very specifically  
12                  addressed. It's more of a generic approach to  
13                  any chronic condition from a list of about  
14                  4,500, mild, moderate and severe, many of  
15                  which have very little influence over  
16                  admissions and readmissions.

17                  So, we're concerned that that's  
18                  not picking up the readmission factors very  
19                  well.

20                  And in terms of testing and  
21                  evaluation I don't think we really saw it  
22                  tested across different subgroups of pediatric

1 patients and across different hospitals who  
2 serve different populations.

3 So I think there's a lot that we  
4 don't know and need to be concerned about as  
5 it gets rolled out if it's endorsed.

6 And just to illustrate, for lower  
7 respiratory infections for the pediatric  
8 population those with major chronic  
9 conditions.

10 We've done a lot of research and  
11 analysis on this such as cystic fibrosis as  
12 the committee discussed, bronchopulmonary  
13 dysplasia, ventilator-dependent patients,  
14 chronic respiratory failure. They tend to  
15 have readmission rates in the 10 to 15 percent  
16 range compared to otherwise healthy children  
17 in the 3 to 5 percent range.

18 And we just don't see how that can  
19 be teased out with the more generic risk  
20 adjustment methods. So those are the thoughts  
21 that we'd like to share.

22 And if the committee does endorse

1 I think there's a lot of cautions to go  
2 forward. Thank you.

3 MR. AMIN: Thank you. Is there  
4 any other comments on the phone?

5 OPERATOR: At this time there are  
6 no public comments on the phone line.

7 MR. AMIN: There are no other  
8 public comments in the room.

9 CO-CHAIR HALL: I think we can  
10 break for lunch then. Just a quick note for  
11 those who weren't here yesterday. We would  
12 ask the audience members to wait for the  
13 committee members to grab their lunch first  
14 before helping yourself.

15 CO-CHAIR KAPLAN: So we'll  
16 reconvene at 12:15.

17 (Whereupon, the foregoing matter  
18 went off the record at 11:41 a.m. and went  
19 back on the record at 12:13 p.m.)

20 CO-CHAIR HALL: We have three  
21 measures left this afternoon, one from the  
22 American College of Cardiology and two from

1 Yale CMS.

2 And then we have a very important  
3 brief update on measure 1789. So we're hoping  
4 we'll still have faces around the table when  
5 we get to that point.

6 We'll ask the American College of  
7 Cardiology representatives to introduce  
8 themselves and briefly introduce their  
9 measure, please.

10 DR. CURTIS: Hi, this is Jephtha  
11 Curtis from Yale also representing the ACC  
12 today.

13 CO-CHAIR HALL: Hang on, I'm not  
14 sure we heard that.

15 DR. CURTIS: Sorry. Jephtha Curtis  
16 from Yale representing the ACC today.

17 MS. SLATTERY: So Dr. Curtis will  
18 be speaking primarily to the measure  
19 methodology but I'm Lara Slattery, ACC senior  
20 director for scientific reporting and I can  
21 address any questions related to  
22 implementation.

1 DR. CURTIS: So, for endorsement  
2 maintenance today under review is the Hospital  
3 30-day Risk-standardized Readmission Rates  
4 Following Percutaneous Coronary Intervention.

5 It is a measure that was endorsed  
6 I believe 3 or 4 years ago. And identifies  
7 unplanned readmission rates for hospitals that  
8 perform percutaneous coronary interventions on  
9 Medicare fee-for-service patients greater than  
10 65 years old.

11 As I mentioned this is unplanned  
12 readmissions and we updated the measure from  
13 the initial endorsement to include a modified  
14 version of the hospital-wide readmission  
15 algorithm that identifies unplanned  
16 readmissions. Basically including a larger  
17 number or considering a larger number of  
18 readmissions planned.

19 In addition, we've updated the  
20 measure to include the use of direct as  
21 opposed to indirect identifiers to match the  
22 CathPCI registry data with CMS information

1 about readmission which is used to identify  
2 the risk-standardized rates.

3 And has also in the interim  
4 actually gone into implementation. And last  
5 March the hospitals received their reports as  
6 to their risk-standardized readmission rates.  
7 And then there was a voluntary public  
8 reporting of those rates on Hospital Compare  
9 as well as the ACC's internal websites.

10 So that this information has -- or  
11 this measure has progressed from development  
12 to approval to implementation in a relatively  
13 short time frame. And I think it's open for  
14 questions.

15 CO-CHAIR HALL: Thank you very  
16 much. We will start with the category of  
17 evidence and our lead discussants are Mae and  
18 Larry. So I invite them to kick it off.

19 DR. GLANCE: I'll go ahead and  
20 start. In terms of evidence to support the  
21 measure focus the measure developers present  
22 evidence that there is a high level of

1 variation across hospitals which to me  
2 represents strong evidence.

3 When you have variation in  
4 outcomes that means that there's the potential  
5 to improve your outcomes assuming that you  
6 have properly adjusted for differences in case  
7 mix. So I think the evidence is strong.

8 CO-CHAIR HALL: Mae said she  
9 agreed but I didn't -- is your mike working?

10 MS. CENTENO: I agree.

11 (Laughter)

12 CO-CHAIR HALL: Okay, great. Any  
13 other comments on evidence? Okay, we'll move  
14 to vote.

15 MS. SHAHAB: Voting for 1(a)  
16 evidence. One is yes, two is no and the time  
17 begins now.

18 Twenty yes and zero no.

19 CO-CHAIR HALL: Moving into  
20 performance gap, opportunity.

21 DR. GLANCE: In terms of the  
22 performance gap without risk adjustment the



1 difference between the lowest decile and the  
2 highest decile was zero percent readmission  
3 rates versus 28 percent readmission.

4 After risk adjustment the  
5 difference between the 10th percentile and  
6 90th percentile was 13.5 versus 10.1 percent.  
7 So again, evidence of a significant  
8 performance gap.

9 CO-CHAIR HALL: Additional  
10 comments? Okay.

11 MS. SHAHAB: Voting for 1(b)  
12 performance gap. One high, two moderate,  
13 three low, four insufficient and your time  
14 starts now.

15 All votes are in for performance  
16 gap. Seventeen high, four moderate, zero low  
17 and zero insufficient.

18 CO-CHAIR HALL: Priority.

19 DR. GLANCE: In terms of priority  
20 this is one of the conditions that was  
21 identified as a high-priority condition by  
22 MedPAC.

1                   The overall incidence of  
2                   readmissions within 15 days was 10 percent  
3                   which represents roughly about 44,000  
4                   readmissions in 2005 at a cost of \$360 million  
5                   annually. So, I would suggest that this is a  
6                   high-priority condition.

7                   CO-CHAIR HALL: Additional  
8                   comments? Seeing none.

9                   MS. SHAHAB: Voting for 1(c) high  
10                  priority. One is high, two moderate, three  
11                  low, four insufficient and time begins now.  
12                  Three more votes.

13                  All votes are in for 1(c) high  
14                  priority. Eighteen high, three moderate, zero  
15                  low, zero insufficient.

16                  CO-CHAIR HALL: Scientific now.  
17                  Reliability and validity.

18                  DR. GLANCE: In terms of  
19                  reliability -- data reliability. This is  
20                  based on clinical data which is audited using  
21                  annual onsite chart reviews and data  
22                  abstraction.

1                   In terms of model reliability the  
2                   intraclass correlation coefficient was 0.37  
3                   which is indicative of fair agreement and very  
4                   much in the zone of the other measures that we  
5                   have looked at over the past two days.

6                   CO-CHAIR HALL: Additional  
7                   comments? Seeing none.

8                   MS. SHAHAB: Voting for 2(a)  
9                   reliability. One high, two moderate, three  
10                  low, four insufficient and the time starts  
11                  now. One more vote.

12                  All votes are in for 2(a)  
13                  reliability. Five high, sixteen moderate,  
14                  zero low and zero insufficient.

15                  CO-CHAIR HALL: Validity.

16                  DR. GLANCE: In terms of validity  
17                  testing, in terms of looking at the  
18                  statistical performance of the model the  
19                  discriminate ability, the C statistic was  
20                  0.66, actually 0.67 in the validity data set  
21                  which is very good for this kind of a model.

22                  Model calibration was also very

1 good. They looked at this using both  
2 graphical techniques and other approaches as  
3 well.

4 In terms of threats to validity 29  
5 percent of the observations were missing data  
6 on ejection fraction. Ejection fraction is  
7 considered to be a very important clinical  
8 risk factor for these types of models.

9 They imputed the missing data but  
10 they used a very rough approach I guess for  
11 imputation. And I quote, "We stratified by  
12 gender and imputed the missing values to the  
13 median of the corresponding groups."

14 So state of the art for imputation  
15 is to use multiple imputation. I was a little  
16 surprised that this approach was used. And I  
17 was wondering if the measure developers could  
18 maybe comment on this.

19 DR. CURTIS: Yes. I mentioned  
20 we've been on this journey for 5 or 6 years so  
21 sometimes it's a little hard to reconstruct  
22 exactly what the logic was from that long ago.

1                   Nevertheless there are two aspects  
2     to, first, why EF is missing so frequently and  
3     second, our approach to accounting for the  
4     information that's conveyed by the missing  
5     data.

6                   So first off, the LVF is specified  
7     to be an ejection fraction that -- an  
8     information by the ejection fraction that is  
9     available prior to the performance of the PCI.  
10    So we obviously don't want to -- if a PCI goes  
11    wrong and the patient has a large MI, has a  
12    low EF we don't want to account for that in  
13    the model. So it has to be LVF prior to the  
14    PCI.

15                  The patients who don't have  
16    information about an ejection fraction before  
17    the PCI typically are those that are being  
18    done on an urgent or emergent basis. So, it  
19    is very much colinear with patients who have  
20    an ST elevation MI, patients with cardiogenic  
21    shock or other highly morbid conditions. And  
22    for that reason it's certainly not missing at

1 random.

2 To account for that, in addition  
3 to imputation we actually also have a dummy  
4 variable in the model for missing LVEF. So  
5 that aggregates both as patients in whom it's  
6 missing at random as well as those in whom it  
7 is missing not at random, i.e., that they had  
8 an emergent procedure.

9 But it does account for the  
10 information that runs or is colinear with  
11 missingness. And so we don't ignore the  
12 information that's conveyed by that.

13 In terms of the single versus  
14 multiple imputation, that's something I think  
15 -- a decision that we made a long time ago  
16 that was consistent with the inpatient  
17 mortality model for ACC. And so for that  
18 reason I think we were trying to be harmonized  
19 in terms of our approach.

20 It's something that we could re-  
21 look at or modify going forward. There's no  
22 reason that we couldn't do it from a

1 statistical standpoint.

2 DR. GLANCE: So, in my mind this  
3 remains a bit of a threat to validity. Some  
4 people would contest that if you're missing  
5 this much data on a particular covariate that  
6 it shouldn't even be included in the model.

7 And usually people typically, if  
8 you're missing more than about 10 percent,  
9 maybe 20 percent of the data that's grounds  
10 for sometimes not including it in the model.

11 The reference was made as to  
12 whether it's missing at random or missing not  
13 at random. Without getting into a lot of the  
14 technical details what lots of folks will do  
15 in this particular setting is they will create  
16 a regression model based on all the other  
17 available risk factors to predict the missing  
18 values for patients who have missing values.

19 If you can do this, if you can  
20 predict a missing value using available  
21 covariates then it is missing at random. And  
22 I would suggest that probably in many of these

1 cases you could do that, that the data  
2 actually is missing at random as opposed to  
3 not missing at random. And I do think that is  
4 a bit of a threat to validity.

5 Missing completely at random would  
6 be if it was just -- well, I don't want to get  
7 into too much of the details on this. But I  
8 think it is an issue.

9 CO-CHAIR HALL: Jephtha, you  
10 indicated that it was -- or did I  
11 misunderstand that you said it was somewhat  
12 colinear with emergency status.

13 DR. CURTIS: Right. I mean, it's  
14 been a long time since we did those analyses,  
15 but the patients in whom LVEF is not  
16 available, it's not really necessarily missing  
17 but it's not -- the test of ejection fraction  
18 has not been performed, that is typically  
19 those patients in whom you're under the gun to  
20 perform a primary angioplasty.

21 So the STEMI patients for whom  
22 we're trying to do a door to balloon time in



1 less than 90 minutes oftentimes we'll forego  
2 doing an ejection fraction before the  
3 procedure. So from that standpoint it is  
4 colinear with the urgency or emergency  
5 procedures.

6 And that it sort of fits in that  
7 it's missing in about I'd say 10 to 20 percent  
8 which is -- I'm sorry, I can't remember the  
9 exact number. But that's the lion's share of  
10 what's missing.

11 It's not necessarily missing the  
12 information was available and just not  
13 captured. I don't think that's what we're  
14 looking at here.

15 DR. GLANCE: So by imputing it to  
16 essentially a normal value which I believe is  
17 what you're doing you are to some extent  
18 disadvantaging hospitals that are taking care  
19 of more emergencies compared to fewer  
20 emergencies.

21 DR. CURTIS: Because we have a  
22 dummy variable for missing information my

1       understanding -- I said that before, yes.

2                       We have a category for LVF of --  
3       and I miss the actual specifications, but it's  
4       low EF, moderately low EF, normal EF, and  
5       missing EF. I think there are four or five  
6       categories for EF in the model. So missing  
7       information is not ignored.

8                       CO-CHAIR HALL: So the continuous  
9       variable is moved to median and there's an  
10      indicator as well. And we think it's probably  
11      redundant information somewhat with at least  
12      one other variable as well.

13                      So, although it may not be perfect  
14      it's probably less of a threat than it might  
15      at first sound like it is.

16                      DR. GLANCE: I will take back my  
17      original comment. I did not realize, or I  
18      didn't hear you when you said that you had an  
19      indicator variable for missing. So I would no  
20      longer qualify that as a significant threat to  
21      validity.

22                      CO-CHAIR HALL: Paul.

1 DR. HEIDENREICH: I'd also say  
2 that we have all this clinical data here that  
3 we have in a couple of other measures. But  
4 most of the measures you've been talking about  
5 have claims data. And we're talking about  
6 potentially even better risk prediction. So  
7 I think in the big scheme of things any  
8 threats to validity are probably pretty small.

9 CO-CHAIR HALL: I'm not seeing any  
10 other cards raised so I would just like to  
11 highlight if for my own understanding to make  
12 sure.

13 The real significant updates to  
14 the measure are that there were some changes  
15 in the CathPCI registry variables which  
16 warranted remodeling.

17 There's an improved strategy for  
18 linkage, so that should again improve. I'm  
19 just thinking in terms of overall validity.  
20 The first issue, the update to Cath registry  
21 data fields you would expect to improve the  
22 validity overall as Paul just hinted at.

1           The improved linkage we would  
2       expect to be an improvement overall.

3           The planned readmission algorithm  
4       is an interesting aspect. You updated and  
5       more or less expanded the planned readmission  
6       algorithm such that at least in summary the  
7       end result was that the overall crude planned  
8       rate fell from 12.3 in the percent according  
9       to the prior algorithm to 11.8 percent  
10      according to the new algorithm.

11           In other words, you're giving more  
12      institutions and providers more credit for  
13      readmissions being planned. And so we're  
14      minimizing -- hopefully we're minimizing or  
15      reducing the chance of falsely throwing a flag  
16      at them. Perhaps at some cost but that's what  
17      we're doing.

18           The ICD crosswalk, not really an  
19      issue yet.

20           And then updating your cohort code  
21      again appears to be an improvement to the  
22      overall validity of the measure.

1 Any other -- yes, Sherrie.

2 CO-CHAIR KAPLAN: So, you're not  
3 opposed to doing multiple imputation if we  
4 suggested that that might be an enhancement to  
5 the missing data problem?

6 DR. CURTIS: I don't see it as  
7 being a major barrier. I think that the vast  
8 majority of the information that's conveyed by  
9 missing LVEF is captured in that categorical  
10 variable of missing EF. It is one of the more  
11 powerful coefficients in the model. But yes,  
12 we could certainly do that.

13 CO-CHAIR HALL: Well, I think as a  
14 small ask maybe you could show in the future  
15 what some of the modeling looks like with and  
16 without in order to make the case of whether  
17 it's really worth the effort.

18 Paul?

19 DR. HEIDENREICH: It just seems  
20 like that would be an NQF sort of policy if  
21 they want to make that, that one does multiple  
22 imputation whenever you're doing imputation.

1           I would not recommend that but it  
2       seemed like rather than have the different  
3       groups suggest it here and there that should  
4       be a standard policy.

5           CO-CHAIR HALL: I understand that  
6       comment. I think NQF has shied away from  
7       saying that models have to be performed in a  
8       particular specific way as we've seen. We've  
9       seen modeling done in a number of different  
10      ways already.

11           So I understand your comment but I  
12      would hazard a guess that it will remain the  
13      judgment of the group as to whether a model is  
14      appropriately specified. Larry?

15           DR. GLANCE: I think the issue  
16      really isn't single imputation versus multiple  
17      imputation. I think they're both fairly  
18      straightforward to carry out. There's not a  
19      huge difference in terms of doing that  
20      mechanistically.

21           I think the issue is whether or  
22      not you should use an indicator approach

1       versus an imputation-based approach. And I  
2       think there's a lot of literature which will  
3       show that estimates based on multiple  
4       imputation are less biased than are based on  
5       the indicator variable approach.

6               CO-CHAIR HALL: At the same time,  
7       Larry, with all due respect that might be true  
8       of the imputed variable itself. But in this  
9       case, the variable probably is as part of a  
10      large number of variables in this model the  
11      information value may be redundant. And in  
12      fact, there could be no value to multiply  
13      imputing versus the current approach.

14             DR. GLANCE: So, agreed. We've  
15      actually done some of that research and have  
16      shown that there is a significant difference,  
17      at least in the population that we looked at.  
18      Whether or not that's generalizable to this  
19      population I don't know. It's an empirical  
20      question.

21             CO-CHAIR HALL: Agreed. We've  
22      done the same thing in NSQIP so it's a common

1       topic that people spend money on beer on.

2                   I think that, correct me if I'm  
3       wrong, so far what we've stated is that the  
4       current implementation seems to be a minimal  
5       threat.

6                   Other concerns or comments in this  
7       category of validity? Not seeing any.

8                   MS. SHAHAB: Voting for 2(b)  
9       validity. One is high, two moderate, three  
10      low, four insufficient and your time starts  
11      now.

12                   We have all the votes for 2(b)  
13      validity. Two high, eighteen moderate, zero  
14      low and zero insufficient.

15                   CO-CHAIR HALL: Feasibility.

16                   DR. GLANCE: So this measure is  
17      based on a hybrid of clinical data and  
18      administrative data. The administrative data  
19      is just to identify which patients were  
20      readmitted.

21                   The clinical data is based on the  
22      CathPCI registry. I would ask the measure



1 developers to tell us what percentage of U.S.  
2 hospitals that are currently performing PCIs  
3 are in this particular registry.

4 MS. SLATTERY: So it's hard for us  
5 to get to an exact number but based on what we  
6 --

7 CO-CHAIR KAPLAN: Could you state  
8 your name, please?

9 MS. SLATTERY: Sorry. Lara  
10 Slattery. Based on what we -- when we look at  
11 our participating facilities against American  
12 Hospital Association we estimate about 85  
13 percent of current PCI hospitals are  
14 participating in the registry, but that it  
15 probably represents more about 90 percent of  
16 the patients because it tends to be smaller  
17 facilities, and usually smaller facilities  
18 where they have a state reporting requirement  
19 and no other incentive for them to join our  
20 registry that are the facilities that are not  
21 participating in.

22 DR. GLANCE: It's in line with the

1       STS measure that we looked at previously.

2                   CO-CHAIR HALL:  I don't know  
3       whether feasibility is the right category, but  
4       could the developers comment on improvements  
5       over time?  This has been in play now for at  
6       least 3 years, isn't that right?

7                   DR. CURTIS:  It's really only been  
8       publicly reported last year.  And so we don't  
9       really have good information about  
10      improvements over time.

11                   And in fact, as we've made these  
12      improvements to the model moving to direct  
13      identifiers there's been enough changes that  
14      I don't know if we have a good way of  
15      surveillance as to what's been going on even  
16      prior to public reporting.  So it's probably  
17      still a little bit early for us to comment.

18                   CO-CHAIR HALL:  Fair enough.  But  
19      there's a very clear implementation plan,  
20      ongoing implementation.  So it seems  
21      acceptable from that perspective.

22                   Other comments on feasibility from

1 other group members? I don't see any.

2 MS. SHAHAB: Voting for 3  
3 feasibility. One is high, two moderate, three  
4 low, four insufficient and your time starts  
5 now.

6 We have all votes for feasibility.  
7 Six high, thirteen moderate, one low and zero  
8 insufficient.

9 CO-CHAIR HALL: Usability.

10 DR. GLANCE: So, I ask the measure  
11 developers to provide us with information on  
12 how this information is reported to  
13 participating hospitals.

14 Do you report it both as a  
15 continuous measure and also as a categorical  
16 measure, meaning high-quality, low-quality and  
17 average quality?

18 And if so in the most current  
19 reporting period what proportion of the  
20 hospitals were reported as being quality  
21 outliers?

22 DR. CURTIS: So in the hospital-

1 specific reports and actually in the public  
2 reporting it's put both in buckets as well as  
3 the overall adjusted risk-standardized rate.  
4 So they receive that information.

5 In addition, in the hospital-  
6 specific reports they receive information  
7 about what hospital -- to what hospital the  
8 patient was readmitted, the principal  
9 diagnosis for that readmission and the time  
10 frame of the dates of it.

11 So we're trying to encourage  
12 through this hospital-specific report sort of  
13 cross-fertilization and crosstalk across  
14 hospitals so that they can try to work and  
15 improve these rates.

16 In terms of the buckets, the  
17 calculation of the outliers was done  
18 completely in line with what's been done with  
19 the other CMS measures. And I believe it was  
20 about 2 percent of hospitals that were either  
21 high or low outliers.

22 So relatively small number in part

1     because the data that we had available for the  
2     measure with the Social Security numbers in it  
3     that we needed to identify we only had 2 years  
4     of data. So it was a little bit of probably  
5     a challenge in terms of having enough  
6     hospitals with enough volume that we could get  
7     really good discrimination as to put them into  
8     categories, but not that far out of line for  
9     other publicly reported measures.

10                 CO-CHAIR HALL: Was that 2 percent  
11     at each tail, or 2 percent total?

12                 DR. CURTIS: I think it was 2  
13     percent total.

14                 MS. SLATTERY: Lara Slattery. I  
15     just wanted to clarify. Hospitals received  
16     the feedback report by virtue of participating  
17     in the registry regardless of whether they  
18     opted in for the public reporting component.  
19     So they all received the feedback reports.

20                 And the hospitals for which we had  
21     no data still received a benchmarking report  
22     just for information purposes only.

1 CO-CHAIR HALL: Additional  
2 comments or concerns on usability? Karen?

3 DR. JOYNT: I know someone just  
4 said this, but is there any way to -- or  
5 should we be thinking about ways to update the  
6 measure such that more than 2 percent can be  
7 identified as something? Or do you feel that  
8 the value is not about the identification as  
9 an outlier but about the benchmarking?

10 DR. CURTIS: I think we've had  
11 this discussion in different forms all  
12 morning.

13 DR. JOYNT: Do you know what  
14 happened to those that were identified? Like  
15 can you look over the last 3 years and see  
16 what prior to the reporting or identification  
17 as outliers, sort of how your measure helps  
18 people move? Do you have the information on  
19 that?

20 DR. CURTIS: Again, we've only had  
21 one year of public reporting which is last  
22 March. And so we have not seen what's

1       happened over time.

2                   And I think your work and others  
3       has questioned whether or not it does make a  
4       dramatic change as opposed to incremental  
5       change.

6                   And I think the jury's still out  
7       on how any of these measures can be used to  
8       change national performance. I think we are  
9       seeing encouraging trends but nothing definite  
10      yet.

11                   But I think of it as an  
12      implementation question as to where do you  
13      draw the buckets and where do you draw the  
14      line. Are you very restrictive or are you  
15      more permissive in terms of categorizing  
16      hospitals as better than or worse than.

17                   And again, we in this case tried  
18      to be as consistent as possible with other CMS  
19      measures.

20                   CO-CHAIR HALL: Could the  
21      developers comment briefly on the unintended  
22      negative consequences remarks in the measure

1 materials?

2 DR. CURTIS: I think as we've  
3 discussed for other measures there's always  
4 the possibility of unintended consequences  
5 where you could have at worst case aversion on  
6 the basis of readmission rates. And that's  
7 really nothing that you can necessarily  
8 prophylaxe against.

9 I think it's probably lower stakes  
10 for readmissions in procedures than it is  
11 perhaps for mortality. Just that would be my  
12 initial impression. But I think it's  
13 something that has to be monitored and can be  
14 monitored.

15 And we've looked at for other,  
16 specifically for mortality we've been looking  
17 at whether or not expected case mix and  
18 predicted risk has changed over time in states  
19 that publicly report PCI mortality and have  
20 not seen dramatic changes in sort of -- I'm  
21 sorry, not the predicted but the expected  
22 mortality at the states that do have public



1 reporting.

2 CO-CHAIR HALL: Other thoughts or  
3 concerns on usability? Seeing none.

4 MS. SHAHAB: Voting for usability  
5 and use. One high, two moderate, three low,  
6 four insufficient information and the time  
7 starts now. Three more votes.

8 CO-CHAIR HALL: Can everybody do  
9 it one more time? Sorry.

10 MS. SHAHAB: We have all the votes  
11 for usability and use. Three high, fourteen  
12 moderate, three low and zero insufficient  
13 information.

14 CO-CHAIR HALL: Any comments in  
15 summary before an overall vote? I see Karen.

16 DR. JOYNT: I just have another  
17 clarifying question. You can tell I've not  
18 been on this committee before.

19 This came up with another measure  
20 yesterday that we were re-approving or  
21 whatever. Is the burden of proof that it has  
22 been implemented, or that it has made X amount

1 of change? Or what is the sort of -- what is  
2 our responsibility in terms of looking at its  
3 longitudinal performance in continuing it  
4 forward?

5 CO-CHAIR HALL: I'll give my  
6 opinion on that but I'll be corrected if I'm  
7 wrong.

8 I think when there's a clear plan  
9 for ongoing implementation that's kind of set  
10 one. And if that plan has been and is being  
11 carried out in good faith but may not have  
12 results yet I think that should meet our  
13 adequacy threshold. That's my opinion.

14 DR. BURSTIN: Just to add to that,  
15 last year -- Karen had to leave, but she led  
16 an effort with a task force to update our use  
17 and usability criterion.

18 It used to just be usability which  
19 basically was it in use. And I think what we  
20 really heard from the community, that's not  
21 enough.

22 So in use is really important.

1 And by the 3-year window we want to see that  
2 it's being used in an accountability  
3 application within two of those cycles. We  
4 want to see evidence of public reporting.

5 But I think increasingly what  
6 we're trying to see is in addition to that,  
7 and this is not a must-pass like evidence and  
8 scientific acceptability, but we want to in  
9 fact be able to see over time that measures in  
10 use have helped to move the needle hopefully  
11 positively.

12 We also want to be cautious as  
13 we've talked a lot about over the last couple  
14 of days that we also haven't seen any  
15 unintended consequences as a result of that  
16 use.

17 So it's something we'd love your  
18 input on. This is really just I think the  
19 first year that we've actually implemented the  
20 broader lens on use and usability. Bruce got  
21 it right.

22 DR. CURTIS: Can I just follow up?

1 I mean, I think there are different ways that  
2 you can measure impact.

3 I think when we developed this  
4 measure nobody was talking or thinking about  
5 readmissions after PCI. And certainly the  
6 whole healthcare system has really evolved in  
7 their consideration of the importance of this  
8 particular aspect for pros and cons and  
9 differences of opinions. It's out there.

10 I can say that over the past 5  
11 years since we published our first paper in  
12 JACC just describing the readmission rates  
13 there has been an abundance of literature  
14 coming out examining the issue.

15 So I think we have moved the  
16 conversation on this. The next will be to see  
17 can we move the actual rates.

18 CO-CHAIR HALL: The notion that  
19 you're only calling out -- going back to one  
20 of Karen's earlier remarks, that you're only  
21 calling out a percent or so at each tail. Do  
22 you have any internal plans or deliberations

1     around changing that as potentially a way to  
2     drive change faster?

3             DR. CURTIS:   So let me throw that  
4     out.   I think we are going to be cautious as  
5     an organization in terms of how we call out  
6     hospitals.

7             And I think that the real value  
8     for me is in reporting this information back  
9     to hospitals, that they get their risk-  
10    standardized rates, that they have -- that  
11    they're valid, that they're believable and  
12    that they are usable.

13            And the usable is I think what  
14    needs to evolve most rapidly.   I have spent  
15    the last four years of my life as opposed to  
16    -- sorry, in addition to working on this  
17    measure working on developing the evidence  
18    that will support reducing these readmission  
19    rates.

20            And we're in the last stages of a  
21    mixed method study understanding both the  
22    qualitative and quantitative strategies

1 associated with lower readmission rates.

2 So I think what the ACC and what  
3 we're talking about, and I'm not going to  
4 guarantee that this will be done because I  
5 don't speak for them in that regard, but we're  
6 trying to create an environment where we will  
7 take that evidence, combine it with this  
8 information and create a campaign or an effort  
9 to try and systematically reduce these rates  
10 at hospitals.

11 And I think much more so than  
12 identifying high and low outliers that's the  
13 way we're going to push things forward. You  
14 have to develop the evidence. You have to  
15 package it up in a toolkit or some other  
16 change -- some process that promotes change in  
17 a positive force much more so than putting it  
18 in buckets.

19 MS. SLATTERY: And so if I can  
20 just add to Dr. Curtis' remarks which are  
21 totally in line and I agree with.

22 This is our first foray out with a

1     measure that the hospitals were offered the  
2     opportunity to publicly report on.

3             The College has a larger portfolio  
4     within PCI but also this year we will be  
5     implementing it in the ICD implantable  
6     cardiodefibrillator. We do have plans to  
7     expand public reporting opportunities for all  
8     hospitals across our registry initiatives.

9             So, once we start to look at that  
10    contextually we want to ensure consistency in  
11    how we report the information out. So we  
12    actually -- it's a separate workgroup that is  
13    taking that on and will be working through  
14    those approaches. And we will likely evolve  
15    it over time.

16            But I agree, it's meant to drive  
17    quality improvement and be engaging a dialogue  
18    and useful for consumers. So it's hard to  
19    balance out all of those.

20            CO-CHAIR HALL: Thank you. Larry?

21            DR. GLANCE: I'd just like to add  
22    my thoughts on this discussion.

1 I think that the burden on showing  
2 that there is an improvement in population  
3 outcomes with a quality measure should not  
4 rest primarily with the measure developer.

5 I think that as long as the  
6 quality of the information that's being  
7 provided in a quality metric is deemed to be  
8 acceptable or high then it really is up to the  
9 end user to make those -- to use that  
10 information and improve population outcomes.

11 So I think we should be hesitant  
12 about looking for improvement in population  
13 outcomes as a determining factor in whether or  
14 not a quality metric is usable or not usable.

15 CO-CHAIR HALL: Cristie.

16 MS. TRAVIS: Just a clarifying  
17 question on the public reporting because you  
18 said it just a couple of times. Is this a  
19 voluntary public reporting on behalf of the  
20 hospitals? And if so, about what percentage  
21 of those who are reporting are actually being  
22 willing to be voluntarily reported publicly?



1 DR. CURTIS: That's a great  
2 question. Yes, it is a completely voluntary  
3 public reporting. And if hospitals opted out  
4 there was no indication that they had opted  
5 out. So it was simply those hospitals that  
6 opted in, at least on Hospital Compare.

7 Of the I think 1,200 hospitals  
8 that had met our reporting thresholds 350  
9 roughly decided to participate. I will say  
10 personally that was about 320 more than I  
11 thought were going to be willing to do it. So  
12 I thought for an initial year's effort for  
13 voluntary public reporting it was very  
14 successful.

15 MS. SLATTERY: I'll also -- just  
16 since we talked a little bit about  
17 implementation and you want to understand  
18 where we're going with it.

19 I think that that's incredibly  
20 admirable, the hospitals that opted in.  
21 Because one of the things for you to  
22 understand is we went from providing the

1 reports to the hospitals to giving them a  
2 window of about 6 to 8 weeks to make a  
3 decision to voluntarily report.

4 The lion's share of those 300 and  
5 some odd hospitals opted in at that point.  
6 There was only one other opportunity for those  
7 hospitals to opt in to have it publicly  
8 reported and that's why the number is stable.

9 Dr. Curtis also referenced the  
10 fact that if you chose not to report there's  
11 nothing reflected on Hospital Compare.

12 Moving forward the ACC has made  
13 the decision that we will be making it more  
14 obvious to consumers if a hospital is  
15 participating in our registries and had the  
16 opportunity to be able to report that and  
17 elected not to. And then differentiating some  
18 of the categories of decision-making in  
19 displaying that information out. So moving  
20 forward there will be more.

21 And moving forward we will  
22 continue to partner with CMS on reporting this

1 data on Hospital Compare because we think that  
2 that is a very valuable resource for  
3 consumers.

4 We also will have a complementary  
5 effort within our organization. And the  
6 reason for doing that is it allows for a  
7 mechanism for more rapid dissemination of  
8 information.

9 So, right now data gets reported  
10 to Hospital Compare on a quarterly basis. The  
11 infrastructure we will put in place on our  
12 website will allow that as soon as a hospital  
13 makes the decision to publicly report it will  
14 be made available to the public. And we can  
15 control the infrastructure better to be able  
16 to do that.

17 CO-CHAIR HALL: Do you know if the  
18 performance distribution in the reporting  
19 group is different than in the overall group?

20 DR. CURTIS: Yes.

21 CO-CHAIR HALL: Is there a concern  
22 that the public is getting the wrong

1 impression?

2 (Laughter)

3 MS. SLATTERY: So we did have some  
4 of the low-performing hospitals opt in for  
5 voluntarily publicly reporting.

6 I mean, again, I do think that in  
7 fairness to them the window of opportunity for  
8 which to make a decision was incredibly tight.

9  
10 So, even for the second sweep they  
11 at best had about 12 weeks to make a decision,  
12 get leadership buy-in within their  
13 organization, get legal counsel to review it,  
14 and get the paperwork back to us for it to  
15 appear.

16 So we think that moving forward  
17 over time it will be easier for hospitals to  
18 get on board with this.

19 CO-CHAIR HALL: Thank you.

20 Sherrie?

21 CO-CHAIR KAPLAN: To follow on to  
22 Larry's comment. And that is sensitivity to

1 change is one of these awkward things where  
2 you don't know what actually manipulations  
3 were going on that your measure should be  
4 responsive to. So, the attribution to  
5 sensitivity to change implies efforts to  
6 quality improve where you don't know what  
7 those are. And especially at the tails where  
8 we are the worst at estimating where a  
9 hospital actually might be.

10 Regression to mean pops to mind.

11 And you think the trouble around the tails  
12 without actually having a response to chase.

13 So, is there -- is there any  
14 effort -- and distributional scoring will  
15 always have this property. Somebody always  
16 loses. So is there any push towards trying to  
17 find the mutable point beyond which a  
18 threshold one would declare a hospital as  
19 either better or worse or whatever?

20 Or is there any effort along those  
21 lines to shift away from distributional  
22 scoring?

1 DR. CURTIS: I think it's a great  
2 question and something that the field as a  
3 whole I think continues to struggle with. And  
4 I think we always default to the  
5 distributional because it's comfortable and  
6 familiar.

7 I think for readmissions  
8 specifically we don't know what the floor is.  
9 And I think until we kind of know and they  
10 start bunching up on the lower side I think  
11 it's reasonable to use the distributional but  
12 be attuned to the fact that since we know that  
13 there are unplanned readmissions that are not  
14 preventable that the goal is not to go to  
15 zero.

16 CO-CHAIR HALL: Larry?

17 DR. GLANCE: One last comment.  
18 Since our discussion now is about endorsement  
19 I'd like to point out that this like many of  
20 the other measures that we have looked at over  
21 the last two days is I believe a very robust  
22 measure methodologically speaking.

1                   What differentiates this measure  
2                   from many of the other measures that we've  
3                   looked at is that this particular measure is  
4                   largely based on clinical as opposed to  
5                   administrative data.

6                   And I think that's really a very,  
7                   very important qualifier because clinical data  
8                   is believed by most to be much more accurate  
9                   and therefore have much greater face validity  
10                  compared to administrative data.

11                  CO-CHAIR HALL: Thank you. Same  
12                  comments we had about the STS discussion  
13                  earlier on. Jephtha?

14                  DR. CURTIS: Not to shoot chart-  
15                  based measures in the foot, but I do think  
16                  it's important to recognize that they have  
17                  different strengths.

18                  And I think that, yes, we're  
19                  really good at knowing whether or not a  
20                  patient has diabetes or what the creatinine  
21                  was and things like that. And that is  
22                  important in terms of risk adjustment.

1                   We're not as good as an  
2           administrative model I don't think at  
3           measuring frailty and accounting for frailty  
4           in a robust fashion. So, I think it's -- I  
5           appreciate the support and I hope that it's  
6           taken into account but I think there are two  
7           different schools of thought and there are  
8           competing strengths.

9                   CO-CHAIR HALL: Thank you. I see  
10          no cards up so let's move to vote overall.

11                  MS. SHAHAB: Voting for overall  
12          suitability for endorsement. One yes, two no  
13          and time starts now. Two more votes. One  
14          more.

15                  CO-CHAIR HALL: There's some empty  
16          chairs down at the end of the table.

17                  MS. SHAHAB: All votes are in.  
18          For overall suitability for endorsement for  
19          measure 0695 Hospital 30-day Risk-standardized  
20          Readmission Rates Following Percutaneous  
21          Coronary Intervention, 20 yes, zero no.

22                  CO-CHAIR HALL: We thank the



1 developers and we'll ask the Yale CMS teams to  
2 come back to the table for the next measure.

3 CO-CHAIR KAPLAN: Okay, welcome to  
4 the developer. I'd ask you to do what we've  
5 been doing which is briefly introduce  
6 yourself.

7 And also as soon as you speak  
8 remind you please say again your names because  
9 the recorder back in the corner can't see you.  
10 And then briefly introduce your measure.

11 DR. BERNHEIM: Hi, this is  
12 Susannah Bernheim. I'm a director of quality  
13 measurement for the Yale Core Team many of  
14 whom you have met today.

15 Nihar, do you want to introduce  
16 yourself?

17 DR. DESAI: My name's Nihar Desai.  
18 I'm a cardiologist at Yale and an investigator  
19 at the Center for Outcomes, Research and  
20 Evaluation.

21 MR. AMIN: Do you have anyone on  
22 the phone?

1 DR. BERNHEIM: I don't know that  
2 we have anyone on the phone. Do we have  
3 anyone on the phone?

4 (Laughter)

5 DR. BERNHEIM: We have some  
6 support in the back and CMS here.

7 MR. AMIN: Okay.

8 DR. BERNHEIM: But I don't believe  
9 that there's anybody on the phone for this  
10 measure.

11 Okay, so I will just say a couple  
12 of words about this measure. This is a 30-day  
13 all-cause unplanned readmissions for  
14 hospitalizations -- following hospitalizations  
15 with an acute myocardial infarction.

16 This measure originally came to  
17 NQF in 2008 and this is its first time back  
18 for full re-endorsement which is a little  
19 longer than usual just because of the cycles  
20 of projects.

21 It has been in public reporting  
22 through the inpatient quality reporting

1 program since 2009 and last year was included  
2 in the first year of the hospital readmission  
3 reduction program.

4 It is designed much like our other  
5 measures where you look at a cohort of AMI  
6 patients. We look at readmissions 30 days  
7 later. I will talk a little bit about the  
8 planned readmission algorithm in a moment to  
9 identify unplanned readmissions. It uses the  
10 same hierarchical modeling approach as our  
11 other measures and it is a claims-based  
12 measure.

13 There have been a number of  
14 changes over the years that are detailed in  
15 your -- in the application. I'll just  
16 highlight the important ones.

17 When it first was reported we  
18 moved from a one-year measure to a three-year  
19 measure because many hospitals do not have a  
20 huge volume of AMI cases and that allowed us  
21 to report on a greater number of hospitals.

22 Other key changes. Early on we

1 excluded patients who were discharged against  
2 medical advice. That's true now with all of  
3 the readmission measures.

4 In reporting I believe two years  
5 ago this measure was expanded to include data  
6 from VA hospitals. So in the publicly  
7 reported measure it's now all CMS hospitals  
8 and patients hospitalized originally with  
9 their AMI at a VA hospital. So that was a  
10 neat collaboration between CMS and the VA  
11 which took a fair amount of work.

12 And then the one other big change  
13 has been that as part of the development of  
14 our hospital-wide readmission measure which  
15 this committee is going to be talking about  
16 later we created an algorithm that used claims  
17 codes to try to define readmissions that were  
18 planned or likely to be scheduled in advance,  
19 largely procedural readmissions that were not  
20 associated with an acute diagnosis code. And  
21 there's a long algorithm that does that.

22 And we developed that first in a

1 hospital-wide cohort and then we carefully  
2 checked it against the condition-specific  
3 cohorts.

4 And last year NQF held an ad hoc  
5 review of our condition-specific measures  
6 including this measure just to look more  
7 closely at this planned readmission algorithm.  
8 So that piece of this measure has come before  
9 committee at NQF previously, but the whole  
10 measure hadn't come back at that point for re-  
11 endorsement.

12 I think an interesting case was  
13 made earlier that improvement doesn't prove  
14 that the measure works or not. But I will say  
15 because we're really excited about it that in  
16 the 3-year cycle that was reported last  
17 December we are seeing for the first time  
18 declining national AMI readmission rates. And  
19 that's in the context of also decreasing  
20 admissions for AMI and potentially higher  
21 severity admissions. And big declines in  
22 mortality.

1                   And so I think we're very  
2                   reassured around questions of unintended  
3                   consequences that the decline in readmissions  
4                   is happening in the context of other  
5                   improvements around AMI.

6                   I think that that's probably  
7                   enough of a quick overview of who know this  
8                   measure well. But obviously we'll answer  
9                   questions.

10                  CO-CHAIR KAPLAN: Thank you very  
11                  much. Paul, do you want to go first on the  
12                  evidence?

13                  DR. HEIDENREICH: Yes. I think  
14                  there is -- we don't necessarily have a lot of  
15                  evidence to know exactly how hospitals are  
16                  improving. Clearly in 2012 there was a sudden  
17                  drop in readmissions for MI as well as all.  
18                  It seems to be most hospitalizations for  
19                  Medicare patients. So I think there's clearly  
20                  a strong rationale that one could make  
21                  improvements.

22                  CO-CHAIR KAPLAN: Larry? Nothing

1 to add? Other comments? Ready to vote?

2 MS. SHAHAB: Voting for 1(a)  
3 evidence. One is yes, two is no and your time  
4 begins now.

5 All votes are in for 1(a)  
6 evidence. Nineteen yes, zero no.

7 CO-CHAIR KAPLAN: Great.  
8 Performance gap. Paul?

9 DR. HEIDENREICH: So that has  
10 narrowed but I think still remains important.  
11 I think the 10 percent/90 percent went from  
12 17.9 to 19.4 several years ago and it looks  
13 like with the last drop was down to 17.3 and  
14 18.3. So the higher end clearly dropped  
15 although still a reasonable difference between  
16 the groups. And the overall rate some might  
17 argue is still too high. So I'd say there is  
18 a significant evidence performance gap.

19 CO-CHAIR KAPLAN: Larry? Other  
20 comments? Ready to vote?

21 MS. SHAHAB: Voting for 1(b)  
22 performance gap. One is high, two moderate,

1 three low, four insufficient. And the time  
2 begins now. Just one more vote.

3 All votes are in for 1(b)  
4 performance gap. Nine high, ten moderate,  
5 zero low and zero insufficient.

6 CO-CHAIR KAPLAN: Thank you very  
7 much. Priority?

8 DR. HEIDENREICH: It has been, I  
9 think probably still remains a priority for  
10 the government, for CMS to improve readmission  
11 rates for MI.

12 CO-CHAIR KAPLAN: Larry? Other  
13 comments? Ready to vote?

14 MS. SHAHAB: Voting for 1(c) high  
15 priority. One is high, two moderate, three  
16 low, four insufficient. And the time begins  
17 now.

18 All votes are in for 1(c) high  
19 priority. Fourteen high, five moderate, zero  
20 low and zero insufficient.

21 CO-CHAIR KAPLAN: Thank you.  
22 Scientific acceptability, reliability. Paul.



1 DR. HEIDENREICH: So, I think this  
2 has been felt to be moderate. I think they  
3 used a test/retest with a random sample and I  
4 see a reported ICC of 0.38 which is, you know,  
5 I think relatively common for this type of  
6 data.

7 CO-CHAIR KAPLAN: Larry? Other  
8 comments? Ready to vote? Oh, you have a  
9 comment.

10 DR. BERNHEIM: I just wanted to  
11 clarify it was brought up in the CABG just  
12 because people had taken some interest in  
13 this. We did do some work because when we  
14 create these ICCs we're not using six years of  
15 data to get a three-year sample size. So Lisa  
16 explained earlier we put together a correction  
17 factor. And we can share those details.

18 And when you do that for this  
19 measure it goes up to 0.48 just so people  
20 know. It's stronger. Our best estimate of  
21 what it would be with a full three-year sample  
22 size.

1 CO-CHAIR KAPLAN: Certainly well  
2 within what we've been seeing. So it's not  
3 exactly like this is a huge departure but  
4 thank you for that clarification.

5 Other comments? Ready to vote?

6 MS. SHAHAB: Voting for 2(a)  
7 reliability. One is high, two moderate, three  
8 low and four insufficient. And the time  
9 starts now.

10 All votes are in for 2(a)  
11 reliability. Three voted high, sixteen  
12 moderate, zero low and zero insufficient.

13 CO-CHAIR KAPLAN: Thank you.  
14 Validity, Paul?

15 DR. HEIDENREICH: Yes, there's  
16 been -- I think with the original submission  
17 I'm not sure if things were updated but the  
18 model, the overall model's discrimination had  
19 C statistics close to 0.6 and slightly under.

20 It sounds like interestingly it  
21 was -- I think when it was tested in the CCP  
22 project which had actual chart review it

1       sounded like there was a very similar C  
2       statistic. So it didn't seem like you were  
3       losing a whole lot from using, or if any at  
4       all of using administrative data.

5               So that seems to be I think very  
6       reasonable for this type of data. I think the  
7       exclusions as described are reasonable. I  
8       don't think there's been -- if anything the  
9       slight changes over time have improved --  
10      improved the model since it was last approved.

11             I didn't feel there were any  
12      significant issues with missing data but we'll  
13      see if anyone else has concerns.

14             CO-CHAIR KAPLAN: Larry? Can you  
15      clarify the C statistic for us? Because I  
16      want to make sure everybody understands. What  
17      the magnitude of it.

18             DR. BERNHEIM: Sure. So you were  
19      right. When it was first developed, the  
20      technical report from development I think it  
21      was 0.58. In the most recent year of data --  
22      we look at it each time it gets run. The most

1 recent three years it was 0.64.

2 DR. HEIDENREICH: Oh, I actually  
3 remember I did have one question. The -- I  
4 know it's been then tested in California data  
5 so now you can have an 18 and over measure.  
6 But I didn't -- it wasn't clear to me if there  
7 was a significant improvement or decrease in  
8 the model's performance.

9 DR. BERNHEIM: So that's a great  
10 question that I don't remember the answer to.  
11 In general our measures often do slightly  
12 better in the all-payer data sets. We think  
13 that's because the comorbidities are even more  
14 powerful predictors in younger populations  
15 that have fewer of them.

16 And I can quickly find you the  
17 answer to this for this particular one. So  
18 0.67 was the discrimination for the 18 and  
19 over measure. And the correlation between the  
20 two was 0.998.

21 CO-CHAIR KAPLAN: Larry?

22 DR. GLANCE: So, just as a quick

1 point of clarification. As was alluded it's  
2 very common to see a model perform differently  
3 in data sets.

4 And specifically if you're going  
5 to use an all-payer data set you expect to see  
6 more heterogeneity in the patient population  
7 and therefore as a result of that you'll see  
8 better discriminatory power.

9 CO-CHAIR KAPLAN: Thank you.

10 Other comments? Frank.

11 DR. BRIGGS: What was the impact  
12 of expanding the planned readmission  
13 algorithm?

14 DR. BERNHEIM: Great question.  
15 Again, numbers I don't have at the tip of my  
16 tongue.

17 It reduces the overall readmission  
18 rate very slightly. Although for this  
19 measure, let's see if I can find it rapidly  
20 for you.

21 CO-CHAIR KAPLAN: So refreshing to  
22 see people throwing pages as opposed to

1 scroll.

2 (Laughter)

3 DR. BERNHEIM: Exactly, not be on  
4 a screen. Okay. Planned readmission  
5 algorithm I don't see here.

6 If somebody on the phone from our  
7 team has this handy please speak up. And I  
8 will otherwise find it quickly but it'll take  
9 me just a minute.

10 Can the operator open the lines  
11 and make sure that somebody on our team is  
12 available to answer this question quickly?  
13 Because they have it at their fingertips  
14 quicker than I do.

15 MS. KHAN: What are their names?  
16 The people that are on the phone.

17 DR. BERNHEIM: Chanch Nabat, are  
18 you there?

19 OPERATOR: All lines are open.

20 DR. BERNHEIM: Okay, great.

21 Anybody on the Yale team have this number  
22 handy quickly so I don't have to make this

1 poor, tired committee wait while I flip pages?

2 MS. GEARY: Hi, this is Lori Geary  
3 at Yale. Can you hear me?

4 DR. BERNHEIM: Yes.

5 MS. GEARY: We are pulling that up  
6 now. Bear with us one minute.

7 DR. BERNHEIM: The easiest place  
8 may be the NQF application where we brought it  
9 back last year.

10 MS. GEARY: Okay. From version 1  
11 to version 2 it went from 19.7 to 19.0. I'm  
12 sorry, 18.7.

13 DR. BERNHEIM: Okay, so a  
14 percentage point. We should have gone with my  
15 guess, I was right. Thank you, Lori.

16 MS. GEARY: Okay.

17 CO-CHAIR KAPLAN: Thanks for that  
18 clarification. Any other comments? Ready to  
19 vote?

20 MS. SHAHAB: Voting for 2(b)  
21 validity. One is high, two moderate, three  
22 low, four insufficient and your time begins

1 now.

2 All votes are in for 2(b)  
3 validity. Four high, fifteen moderate, zero  
4 low and zero insufficient.

5 CO-CHAIR KAPLAN: Thank you.  
6 Feasibility?

7 DR. HEIDENREICH: Based on claims  
8 data, highly feasible.

9 CO-CHAIR KAPLAN: Larry? Other  
10 comments? Ready to vote?

11 MS. SHAHAB: Voting for  
12 feasibility. One high, two moderate, three  
13 low, four insufficient. Time starts now.

14 All votes are in for feasibility.  
15 Eighteen high, one moderate, zero low, zero  
16 insufficient.

17 CO-CHAIR KAPLAN: Thank you.  
18 Usability and use. Paul?

19 DR. HEIDENREICH: Well, it already  
20 is being used. And you know, one could argue  
21 it's been successful given that it's been used  
22 both I think for public reporting as well as



1       for payment.

2                   And we've seen the expected  
3       changes at least within 2012.

4                   CO-CHAIR KAPLAN: I have one quick  
5       question. If it were possible, would it be  
6       possible to investigate actually the  
7       sensitivity to places where you actually knew  
8       there were efforts underway to improve this?  
9       And so responsiveness to change could actually  
10      be estimated.

11                  DR. BERNHEIM: So I think what  
12      you're asking is could we focus in on places  
13      that we know are making a big effort around  
14      this and show that those efforts are playing  
15      out. I mean I think that's a great research  
16      question. It's not something we've done on  
17      our team, but I think it is an important link  
18      that the research is slowly building to show.  
19      And there are some trials out there that have  
20      shown particular interventions work AMI  
21      patients.

22                  CO-CHAIR KAPLAN: Thank you. That

1 raises the specter of the R word so we're  
2 moving on really quickly. So, for usability  
3 and use are there any other -- sorry, Karen?

4 DR. JOYNT: I think this is a  
5 great example of ways in which the same  
6 measure can be used a lot of different ways.

7 In the way that it's used in  
8 public reporting the -- of the 4,464 hospitals  
9 in the U.S. 23 are identified as being better  
10 than average, 2,327 are no different, 29 are  
11 worse and 2,085 are number of cases too small.

12 That's a lot of effort for  
13 hospitals to make for this amount of  
14 discrimination. And I know they get more  
15 information than this.

16 On the completely opposite side as  
17 the weight of the readmissions penalty is  
18 calculated in which there's no uncertainty  
19 built into the model if you're 0.001 percent  
20 worse than predicted on dollars, not even on  
21 rates, that you will in theory get a penalty.

22 And I don't know that there's any

1 way in this committee to address the different  
2 ways in which something can be used, but it  
3 certainly points out that the statistical  
4 arguments that we have about the way that this  
5 thing is done can go any number of different  
6 ways when things are put forward.

7 And to me the way that things are  
8 used actually is really important to how the  
9 measure is going to work. And I might  
10 personally choose different ways of  
11 calculating this based on whether it was going  
12 to be used for public reporting or for pay-  
13 for-performance or whatever this is going to  
14 be.

15 So I just have concerns about this  
16 sort of blanket blessing of measures when they  
17 can be used in such vastly different ways.  
18 That may be a bigger problem in this  
19 particular measure but I think I'd be  
20 interested in hearing from the developers sort  
21 of how we should think about what your model  
22 can do.

1           The data to suggest exactly what  
2       you're saying which is what we know can and  
3       can't work to improve readmissions is not  
4       great. And I'd be interested in knowing from  
5       your work are the people that are identified  
6       as outliers doing something differently.

7           What's happening as a result of  
8       the way that this metric is being used?

9           CO-CHAIR KAPLAN: Hold on a  
10       second.

11          CO-CHAIR HALL: A couple of  
12       things. Karen, your sentiment is a  
13       longstanding one. It's been heard in many,  
14       many NQF forums over the years. And in fact  
15       I think -- I won't jump the gun, but in the  
16       upcoming white paper coming out from NQF there  
17       may be some commentary about NQF increasing  
18       its guidance around recommended uses or uses  
19       where a particular measure seems most  
20       appropriate. So we won't change that aspect  
21       of it today but your sentiment has been heard  
22       many, many times.

1                   If there's --

2                   DR. JOYNT: And if this needs to  
3 be tabled I'm totally fine with that. I'm  
4 struggling a little bit with sort of the  
5 questions around usability for us to sort of  
6 say as it's being used what are the negative  
7 consequences, what's happened. And we don't  
8 really get that data --

9                   CO-CHAIR HALL: Absolutely. And  
10 that's been -- I think we all sympathize.  
11 That's absolutely been the case.

12                  But so if there is something you  
13 would like our developers to state please  
14 rephrase that. I didn't want to cut you off,  
15 but I do want you to know that that is a  
16 longstanding concern and there may be some  
17 change in the air around that concern. But it  
18 won't happen today.

19                  Is there anything you do want the  
20 developers to state? Okay. Any other  
21 comments or concerns then?

22                  CO-CHAIR KAPLAN: Just to say that

1     some of us share your pain. And the hopefully  
2     MAP group will begin to address these kinds of  
3     issues.

4                     So there's a safety clause built  
5     in but it's not sufficient for some of us to  
6     kind of feel cozy about these decisions.

7                     Okay, Susannah.

8                     DR. BERNHEIM: I will decline from  
9     commenting on the pieces that you guys want  
10    not commented on. I just wanted to make sure  
11    that people know that a part of the work that  
12    we do with CMS is explicitly monitoring for  
13    unintended consequences. And we do some  
14    surveillance work. And there is a constant  
15    measure or maintenance process. So just in  
16    terms of the unintended consequences piece  
17    that is a part of the expectation as part of  
18    the measure life cycle.

19                    CO-CHAIR KAPLAN: Thanks for that  
20    clarification. Any other comments? Are we  
21    ready to vote usability and use? Okay.

22                    MS. SHAHAB: Voting for usability

1 and use. One high, two moderate, three low,  
2 four insufficient information and the time  
3 starts now.

4 All votes are in for usability and  
5 use. Four high, fourteen moderate, zero low  
6 and one insufficient information.

7 CO-CHAIR KAPLAN: Thank you very  
8 much. Moving onto suitability for  
9 endorsement. Paul?

10 DR. HEIDENREICH: I think no  
11 additional comments. I'd say it meets  
12 endorsement in my opinion.

13 CO-CHAIR KAPLAN: Larry?

14 DR. GLANCE: I think this measure  
15 is also very typical of most of the CMS  
16 measures that we've heard in other measures.  
17 It's very robust in terms of the methodology  
18 and I would also vote for endorsement.

19 CO-CHAIR KAPLAN: This is  
20 Washington so I won't say "robustitude" in  
21 this audience but it does -- so we are voting  
22 on its suitability for endorsement. Ready to

1 vote?

2 MS. SHAHAB: Voting on overall  
3 suitability for endorsement. One yes, two no.  
4 Time starts now.

5 All votes are in for overall  
6 suitability for endorsement for measure 0505  
7 Hospital 30-day All-cause Risk-standardized  
8 Readmission Rate Following Acute Myocardial  
9 Infarction Hospitalization. The results are  
10 17 yes, 2 no.

11 DR. BERNHEIM: Thank you.

12 CO-CHAIR KAPLAN: Thank you to the  
13 Yale group.

14 CO-CHAIR HALL: We'll invite the  
15 next Yale group to the table.

16 (Laughter)

17 CO-CHAIR HALL: We'll be  
18 discussing 2539 Seven-day Risk-standardized  
19 Hospital Visit Rate after Outpatient  
20 Colonoscopy. I think in some sense there's a  
21 little bit of a twist compared to some other  
22 topics we've discussed. So we'll wait for our



1 developers.

2 No, that was not a pun.

3 (Laughter)

4 CO-CHAIR HALL: So we have 18  
5 people in the room. No one's permitted to  
6 leave because we lose our quorum. So raise  
7 your hand if you have to do a number one.

8 (Laughter)

9 MS. KHAN: We should be done by 2  
10 I think.

11 CO-CHAIR HALL: We'll continue to  
12 push on. Our colleagues from Yale, please  
13 introduce yourselves and your measure.

14 DR. DRYE: Hi, I'm Elizabeth Drye  
15 from Yale.

16 DR. RANASINGHE: My name's Isuru  
17 Ranasinghe from Yale.

18 DR. DRYE: I was just going to say  
19 following up on Bruce's point that this is a  
20 little bit of a twist. This is the first  
21 measure we're bringing to NQF that is for  
22 outcome of ambulatory care. So we're really

1 excited about it. It is new terrain. And  
2 Isuru led the work and he's going to walk us  
3 through.

4 DR. RANASINGHE: Okay. So it's  
5 Isuru here again.

6 I'll start off by doing a quick  
7 summary of the measure and the rationale for  
8 the measure.

9 So the measure is a measure of  
10 unplanned hospital visits following outpatient  
11 colonoscopy. And that is colonoscopies  
12 performed in hospital outpatient department  
13 ambulatory pre-surgical centers and physician  
14 office settings.

15 The denominator for this measure  
16 is low or moderate risk colonoscopy  
17 procedures. And based on our inclusion and  
18 exclusion criteria we actually capture about  
19 94 percent of all outpatient colonoscopies  
20 performed.

21 The numerator for this measure is  
22 unplanned hospital visits within 7 days of the

1 procedure. And hospital visits include ED  
2 admissions, observation stays and inpatient  
3 admissions.

4 Now, that's a very broad patient-  
5 centered outcome that captures adverse events  
6 that are related to the bowel prep, the  
7 anesthesia itself and the procedure.

8 Now, this measure is really  
9 important because of four critical reasons and  
10 I'll outline them.

11 First is that colonoscopy is  
12 incredibly common. So this is the most common  
13 procedure performed in the outpatient setting.  
14 We see an outcome rate of about 16.2 per 1,000  
15 procedures in the Medicare data and we see  
16 significant variation between 8 to 20 per  
17 1,000 between providers. So there is a  
18 facility-level variation in quality.

19 And if you extrapolate that to  
20 national data that's about 27,000 hospital  
21 visits following colonoscopy procedure  
22 nationally.

1                   And that's really important  
2           because most of these procedures, we know two-  
3           thirds to three quarters are screening  
4           colonoscopies. So by definition these are  
5           procedures occurring in relatively healthy  
6           people who don't have signs or symptoms of a  
7           disease. And ensuring monitoring quality in  
8           that group is -- there's a strong mandate for  
9           measuring quality.

10                   We also know when we look at the  
11           top diagnosis that many of these patients come  
12           back in with serious and very mild things, and  
13           potentially preventable things. Things like  
14           abdominal pain, nausea, bloating, bleeding,  
15           perforation, syncope, aspiration because of  
16           the anesthesia. So we think these are really  
17           important things to measure and potentially  
18           preventable.

19                   The key thing with this is many of  
20           these providers in the outpatient setting are  
21           completely unaware of these events. They're  
22           simply invisible.

1                   So for example, there's a study  
2                   from Boston that suggests that about 80  
3                   percent of these visits the providers are  
4                   actually unaware of. And you can understand  
5                   that. So if you're an ASC, ambulatory  
6                   surgical center, you're legally not allowed to  
7                   provide follow-up care. You can understand  
8                   why patients would present to a different  
9                   provider in the event of an adverse event. So  
10                  we think this measure is really important for  
11                  illuminating quality.

12                 And if I can finish by very  
13                 quickly saying that this measure was developed  
14                 with input from working group that -- we had  
15                 input from Dr. Ron Bender and John Allen who  
16                 are heads of the American Gastroenterology  
17                 Association and the American College of  
18                 Gastroenterology.

19                 We were extremely fortunate to  
20                 have them and they had a huge input into  
21                 shaping this measure.

22                 We were also very lucky to have

1 the highly qualified technical expert panel  
2 which provide us great insights into this  
3 measure. And a period of public comment which  
4 we addressed many of the issues that came up.

5 And I must say overwhelmingly this  
6 measure has been supported by that group. So  
7 we think that provides a lot of rationale.

8 This measure uses Medicaid data so  
9 it's eminently feasible. It's risk-adjusted.  
10 It uses a hierarchical model. We can  
11 statistically determine the outliers.

12 And just lastly, we submitted this  
13 measure for approval to MAP during the  
14 development process and we have received  
15 conditional approval from them.

16 CO-CHAIR HALL: And just  
17 immediately clarifying, the accountable entity  
18 is the outpatient department or the ambulatory  
19 surgery center?

20 DR. RANASINGHE: That's right.

21 CO-CHAIR HALL: All right. So,  
22 thank you for that introduction to the

1     measure.  We're in the category of evidence.  
2     We'll ask Ross and/or Cristie if they would  
3     like to open the discussion.

4                   DR. EDMUNDSON:  Sure, I can start  
5     here if that's okay with you, Cristie?

6                   MS. TRAVIS:  Please.

7                   DR. EDMUNDSON:  Okay.  On  
8     evidence, so you've already alluded to some of  
9     the evidence.  But there's not a lot.  This is  
10    a new measure.

11                   I think -- you mentioned four  
12    reasons why this is important.  I'd add a  
13    fifth one.  When I need my colonoscopy I don't  
14    want a complication.  And that's important to  
15    everybody because this is our general  
16    population.  If you live long enough you  
17    should have one of these.

18                   So the evidence that is literally  
19    reviewed shows complication rates from 20 to  
20    34 percent.  And then you did have on HCUP  
21    data unplanned hospital visits ranging from  
22    8.2 to 20.1 per 1,000 colonoscopies.

1 DR. RANASINGHE: That's right.

2 DR. EDMUNDSON: And I think that -  
3 - so there's some evidence out there although  
4 it's light at this point in time for the  
5 evidence.

6 Cristie?

7 MS. TRAVIS: No, just that you all  
8 did document at least some of the  
9 interventions that you thought would be  
10 possible to actually improve upon the measure.  
11 So from my perspective it meets the evidence  
12 for health outcome.

13 CO-CHAIR HALL: Any other comments  
14 or concerns? We'll consider this an  
15 intermediate outcome for now. No other  
16 comments. No cards. Let's vote on evidence.

17 MS. SHAHAB: Voting for 1(a)  
18 evidence. One is yes, two no. Time starts  
19 now. One more vote.

20 All votes are in for 1(a)  
21 evidence. Fourteen yes, four no.

22 CO-CHAIR HALL: Performance gap



1 opportunity.

2 MS. TRAVIS: There does appear to  
3 be variability in performance. The  
4 standardized range was from 8.3 to 20.1. So  
5 there seems to be quite an opportunity for  
6 improvement.

7 CO-CHAIR HALL: Additional  
8 comments?

9 DR. EDMUNDSON: I agree. No other  
10 comment.

11 CO-CHAIR HALL: Let's move to  
12 vote.

13 MS. SHAHAB: Voting for 1(b)  
14 performance gap. One high, two moderate,  
15 three low, four insufficient. Time starts  
16 now.

17 CO-CHAIR HALL: Let's try again.

18 MS. SHAHAB: All votes are in for  
19 1(b) performance gap. Seven high, eleven  
20 moderate, zero low, zero insufficient.

21 CO-CHAIR HALL: Priority.

22 MS. TRAVIS: This is a U.S.

1 Preventive Services Task Force recommendation  
2 as was talked about since we're recommending  
3 that people go get this as a screening test  
4 that we have an obligation to be sure they're  
5 getting a high-quality. I think I was  
6 impressed by the 14 million colonoscopies that  
7 were done back in 2004 alone. So a very high-  
8 frequency procedure that needs to have the  
9 quality measured.

10 CO-CHAIR HALL: Additional  
11 comments? No additional comments.

12 MS. SHAHAB: Voting for 1(c) high  
13 priority. One high, two moderate, three low,  
14 four insufficient. And your time begins now.

15 All votes are in for 1(c) high  
16 priority. The results are 12 high, 6  
17 moderate, zero low, zero insufficient.

18 CO-CHAIR HALL: Thank you. Moving  
19 into scientific acceptability, reliability.

20 DR. EDMUNDSON: The reliability  
21 was on a 2010 split population arm. Large  
22 numbers of colonoscopies.

1                   And I believe your -- the ICC on  
2                   that was 0.335 judged as fair. And I think  
3                   that's the information provided. Is that  
4                   correct?

5                   DR. DRYE: Correct. We did, as  
6                   you heard on our other measures, we have  
7                   recalculated that with the Spearman-Brown  
8                   prophecy formula. It's an interesting name.  
9                   And it's at 0.43. That gives us a better  
10                  estimate if we had a full data set.

11                  I would just note I think as  
12                  you're all aware the outcome rates for this  
13                  measure are lower than they are for, for  
14                  example, AMI readmission. And so we have to  
15                  get a bigger sample size to get reliable  
16                  measure score results.

17                  And we're happy with what we're  
18                  seeing here but this is an inherent challenge  
19                  in a healthier population with a high volume  
20                  of procedures but a lower outcome rate.

21                  CO-CHAIR HALL: Any additional  
22                  comments or concerns on reliability? Seeing

1 none.

2 MS. SHAHAB: Voting for 2(a)  
3 reliability. One high, two moderate, three  
4 low, four insufficient and the time starts  
5 now. We need one more vote, please.

6 All votes are in for 2(a)  
7 reliability. The results are 1 high, 17  
8 moderate, zero low, zero insufficient.

9 CO-CHAIR HALL: Moving into  
10 validity. Opening remarks.

11 DR. EDMUNDSON: Okay, on validity  
12 you had your technical expert panel that drove  
13 a lot of I think the validity questions as I  
14 read through your information.

15 In addition, you had split sample  
16 two years of data. And on that C statistics  
17 of 0.67. And your conclusions were that this  
18 is good model discrimination.

19 The other piece of information  
20 that you provided that I'd like to have you  
21 comment on is the Charleston model. Better  
22 than Charlson model in that I believe this is

1     your risk stratification tool. And the  
2     Elixhauser model of your C statistics actually  
3     being better than those as a risk model.  
4     Would you comment, please?

5                 DR. RANASINGHE: So, this is  
6     Ranasinghe here again.

7                 So, we did two things. One was  
8     that we compared the C statistics between  
9     development and the validation sample, and  
10    then again in using data. So we developed our  
11    data using the 2010 sample and then we  
12    validated it again in the 2011 sample.

13                The other validation step we did  
14    was to construct the risk adjustment model  
15    using -- we constructed a risk adjustment  
16    model based on our conceptual and statistical  
17    understanding of what we total predict  
18    hospital visits in this population.

19                But we wanted to benchmark against  
20    a risk model that's already being used. And  
21    one option was to use the Charlson and the  
22    Elixhauser models which are widely accepted.

1                   Please keep in mind Charlson and  
2                   Elixhauser are unknown to gastroenterologists,  
3                   specifically -- not colonoscopy-specific. In  
4                   fact, the Elixhauser model was to predict  
5                   mortality from what I understand.

6                   But this would give us a good idea  
7                   of where our model sits and our C statistics.  
8                   And the model characteristics actually ended  
9                   up being better than both those models.

10                  DR. DRYE: This is Elizabeth Drye.  
11                  I would just add that, again, we're in a novel  
12                  data environment in a novel setting. We don't  
13                  have other, you know, there are not like 5 or  
14                  10 other readmission measures, similar  
15                  measures we can compare it to.

16                  So even though we were hoping with  
17                  thoughtful variable selection with a lot of  
18                  clinical input that we would do better than  
19                  these indices we felt we should at least use  
20                  some other approach to make sure we were  
21                  getting what we thought we should be getting.

22                  CO-CHAIR HALL: Karen?

1 DR. JOYNT: I just have a few  
2 additional questions. One is I know there's  
3 not a lot of other quality measures in this  
4 group. But is there anything else you can  
5 compare this to? Do we know if procedure  
6 volume matters for colonoscopy? The rate of  
7 detection of abnormalities I know has been  
8 proposed as a quality. Is there anywhere else  
9 to sort of externally validate whether or not  
10 the rates that you're seeing are indicative of  
11 bad procedure as opposed to sick patient?

12 DR. RANASINGHE: It's Isuru here  
13 again. It's a great question and one that we  
14 find really challenging because really there  
15 is no outcome measures full stop for any of  
16 the ambulatory measures. And we didn't really  
17 know what to compare against.

18 And in fact we -- our conclusion  
19 we reached was that there is no measure that  
20 we could adequately compare against.

21 The only sort of measure that  
22 comes close is the NQF measure that -- NQF-

1 approved measure for ambulatory surgical  
2 centers which does an immediate transfer  
3 following the procedure. But at the time we  
4 didn't have the actual reports of those  
5 values. Individual hospital-level values were  
6 not reported for that measure for us to  
7 compare against.

8 DR. DRYE: I would just add also  
9 that -- Elizabeth Drye again -- we relied  
10 heavily on looking at the reasons for the ED  
11 visits, observation stays and readmission and  
12 just thinking clinically, you know, are these  
13 likely to be just sick patients, or are they,  
14 you know, did they look like they're related.

15 And also we know we're dealing  
16 with a patient group and a procedure that  
17 typically would not be done in an outpatient  
18 setting on patients who were acutely ill for  
19 other reasons.

20 We did pull out of the measure  
21 those patients who we felt might end up in the  
22 hospital for the reason for which they were



1     having the colonoscopy. So, IBD, inflammatory  
2     bowel disease patients, patients with history  
3     of diverticulitis are pulled out of the  
4     measure. We had a lot of discussion around  
5     that and comment on that issue.

6             We also pull out of the outcome  
7     admissions for planned care like colorectal  
8     resection. And that's one-third of all  
9     hospital admissions that we see following  
10    colonoscopy. So we tried to triangulate or  
11    whatever, get at that concern in a number of  
12    different ways.

13            We also looked at the baseline  
14    admission rates and we looked at the falloff  
15    in the first few days to try to pick the  
16    outcome time frame. And we're confident that  
17    we are zeroing in on hospital visits that are  
18    really related to the procedure versus patient  
19    factors that we're not adjusting for. But it  
20    took a lot of different strategies.

21            CO-CHAIR HALL: Sherrie?

22            CO-CHAIR KAPLAN: I was just going

1 to sort of notice, and this is not for slowing  
2 the conversation down or anything, but  
3 different from the dialysis measure where the  
4 attribution was back to the hospital, right,  
5 for readmission to the hospital.

6 CO-CHAIR HALL: No, it was to the  
7 dialysis.

8 CO-CHAIR KAPLAN: It was to the  
9 dialysis center. So then it does follow the  
10 same issue.

11 So the skill in that case of the  
12 colonoscopist so confounded with center. At  
13 that time there was some discussion about the  
14 interest of the physician-level stuff and the  
15 potential for estimating things, or  
16 attributing things to the outpatient center  
17 versus the providers.

18 And there was some conversation  
19 around that. And I didn't want to -- I don't  
20 want to cause a -- stir up a storm here, but  
21 I did want to kind of for fairness of  
22 comparison raise that issue.

1 CO-CHAIR HALL: Actually in a  
2 similar place because we're assuming that the  
3 facility has some impact on quality and it's  
4 not just the operator's skill and proficiency.

5 DR. DRYE: That's a great issue.  
6 I think it's come up before.

7 The reason that we put the measure  
8 at the facility level, there's a couple of  
9 reasons.

10 One, there is a component of  
11 facility care that we think contributes to the  
12 outcome. There's the anesthesia care, there's  
13 the post-op care, there's decision about when  
14 a patient is ready to go home.

15 These facilities, a lot of them,  
16 particularly ambulatory surgery centers are  
17 physician-owned and they tend to specialize  
18 and they may have a couple of physicians who  
19 regularly work there.

20 But in general the physicians do  
21 colonoscopies in multiple settings too. So if  
22 you wanted to look at volume at the facility

1 related to outcome you might not necessarily  
2 be getting at the volume that you were trying  
3 to capture which would be the per-physician,  
4 at least for the physician component.

5 We're confident given the nature  
6 of things that we see people go back to the  
7 hospital for that there is a facility  
8 component. And we expect that there's a  
9 consistency at which physicians are doing the  
10 care.

11 Also, as I mentioned before we  
12 need to get a certain volume of patients and  
13 outcomes to be able to get a reliable  
14 estimate. So for all those reasons we housed  
15 it at the facility level.

16 Like the other measures -- this  
17 measure would be, if it's implemented by CMS  
18 would be implemented in the hospital  
19 outpatient department. I mean, sorry, the  
20 hospital outpatient prospective -- OPPOS system  
21 as well as under the ambulatory surgery center  
22 program.

1           So, they have not had this type of  
2           measure as far as I know implemented there.

3           And we have encouraged CMS to follow the  
4           approach that is taken for the hospital-based  
5           measures in which facilities get patient-level  
6           data, they can see which patients are in the  
7           measure and where they ended up which are  
8           things they won't otherwise see. And we think  
9           that's going to be really critical.

10           And they won't be able to see in  
11           there who the physician was, who the  
12           anesthesiologist was, et cetera.

13           CO-CHAIR HALL: Paula.

14           MS. MINTON-FOLTZ: Does this  
15           include immediate admission to either obs? Or  
16           is there is a 24-hour lag?

17           DR. RANASINGHE: So this includes  
18           sort of direct admissions from ASCs or from  
19           HOPDs. Hospital outpatient departments.

20           And the rationale was that this is  
21           -- colonoscopy procedures should be  
22           straightforward procedures, range from 30

1 minutes to an hour. There's really no reason  
2 for the patient to stay for an extended length  
3 of time unless some sort of adverse event  
4 occurs.

5 MS. MINTON-FOLTZ: Well, there are  
6 those patients who have no ride even. We've  
7 seen those. But it's not a large percent.

8 CO-CHAIR HALL: Frank?

9 DR. BRIGGS: I was wondering if  
10 you had data in regards to the how did you  
11 come up with the seven days, seven days for  
12 this type of procedure. And the side effects  
13 that you're describing trying to capture seven  
14 days actually seems a little bit long. And  
15 you're thinking the first day, two days, maybe  
16 three days. Out seven days you're probably  
17 looking at continuation of symptoms and things  
18 like that. So I was wondering if you had data  
19 specifically to support your cutoff of seven.

20 DR. RANASINGHE: So that's a great  
21 question. So there's a range of side effects  
22 that could occur after a colonoscopy. And

1     they range from within a few days for things  
2     like perforation but up to 30 days for things  
3     like bleeding, GI bleeding. And so there's a  
4     definite phenomenon of delayed GI bleeding.

5                 We know from the literature that a  
6     vast majority of those complications or  
7     adverse events occur within the first seven  
8     days.

9                 And we can empirically test that  
10    by looking at the number of hospital visit per  
11    each day post procedure. And what we see is  
12    a curve which sort of levels off to after  
13    about seven days. And that's why we picked  
14    the seven-day time window because we thought  
15    that would give us the best sort of quality  
16    signal for our measure.

17                So it doesn't -- and that was  
18    supported by our technical expert panel. It  
19    does mean that we miss some bleeding events  
20    that are delayed. But we specifically  
21    excluded them because we did not want to  
22    capture hospital events that aren't related to

1 the procedure.

2 CO-CHAIR HALL: Wes?

3 DR. FIELDS: Yes, a couple of  
4 comments to Sherrie's point and then one  
5 question.

6 The comments. Hopefully we'll see  
7 many outpatient measures in the future. I  
8 think this one actually has a pretty elegant  
9 design.

10 But to Sherrie's analogy one of  
11 the things I like about this is that they work  
12 pretty hard at the development level to  
13 identify what's essentially a well population.  
14 So that's quite different than the standard  
15 dialysis patient who's by definition  
16 chronically ill.

17 The other is this is pretty much  
18 of a 1 to 1 linkage between the physician  
19 doing the colonoscopy than the procedure and  
20 the outcome. And that's not necessarily true  
21 of dialysis centers in terms of who is  
22 actually providing the service and whether



1       it's a passive or active physician activity.

2                   But one question about the design  
3       measure. I'm just sort of curious why you  
4       chose not to include unscheduled follow-up  
5       with a primary care physician or clinic during  
6       the first seven days.

7                   DR. RANASINGHE: So that's a great  
8       question. So, it's very, firstly, we  
9       considered all outcomes that are possible.

10                  We felt the acute care user or  
11       visit to a hospital is something that's  
12       unexpected following a colonoscopy procedure.  
13       And so that we thought would reflect a clear  
14       quality signal.

15                  Whereas visits to a primary care  
16       provider could be planned, could be  
17       appropriate care, could be scheduled care.  
18       And that's very hard for us to identify from  
19       claims data. And that is I guess the primary  
20       reason.

21                  CO-CHAIR HALL: You okay with  
22       that, Wes?

1 DR. FIELDS: Oh, I'm very okay  
2 with it. And for Helen and many other people  
3 around the table I think the measure  
4 developers make the point that there are many  
5 situations where a component of primary care  
6 or first contact care can happen someplace  
7 besides a primary care clinician's practice.

8 And that's part of why I'm  
9 fundamentally uncomfortable along with 30,000  
10 of my close friends in emergency medicine with  
11 the implied negative metric that goes along  
12 with ED visits in many of the measures.

13 CO-CHAIR HALL: Point well taken.  
14 Ross?

15 DR. EDMUNDSON: Yes, thanks for  
16 bringing up the subject here.

17 I wrestled with this a lot because  
18 I was one of the telephonic calls saying well,  
19 my first impulse was this should be attributed  
20 to a physician.

21 And as I wrestled with it I  
22 thought, no, I have to address the methodology

1     that's in front of me. And I think there's  
2     very good value to knowing what particular  
3     facility had what kind of outcomes of  
4     increased visits into the emergency room or  
5     admissions.

6                 I think there's value there. I  
7     personally though, my bias is that if you did  
8     the study and you attributed it, it's the same  
9     information. And I agree with you it's a 1 to  
10    1 relationship with a provider, a physician at  
11    this point in time.

12                That physician is the one who will  
13    meet face to face with the patient beforehand,  
14    gives the instructions, gives the prep, does  
15    the same prep and in fact will very often say,  
16    well, where would you like to have this done.

17                We can do it in the hospital, you  
18    can do it in my center or you can do it at  
19    this -- based on their whim, their  
20    preferences, the day of the week, the  
21    convenience to the physician.

22                So, I think it would be a better

1     measure of quality tied to the physician. But  
2     I do think it does have as it's stated and  
3     presented to us some value as a facility as  
4     well.

5                   CO-CHAIR HALL: Thank you, Ross.  
6     Karen?

7                   DR. JOYNT: Just a quick question.  
8     First, I commend you for again trying to reach  
9     into the outpatient setting and look at  
10    something that I think is probably under-  
11    studied because of the difficulties like that.

12                   Is there anything we should be  
13    thinking about differently? Because this is  
14    a composite of things that are very different.  
15    Sort of a quick visit to the ED versus an  
16    observation stay versus a hospital admission.

17                   Or are these do you think, given  
18    the healthy population that you've selected we  
19    should consider them all to be within seven  
20    days equivalent events?

21                   DR. DRYE: So that's a great  
22    question. We like to think of them as like

1 they're above a certain threshold of acuity.  
 2 You feel bad enough that you have to go to the  
 3 ED.

4 And they may reflect different  
 5 things. They may reflect that you can't get  
 6 into your primary care doctor's office because  
 7 they're just not accessible to you the next  
 8 day or that evening or whatever.

9 And so we're just saying is this a  
 10 threshold effect, either because of the  
 11 serious problem or because of a problem that  
 12 could have been prevented, or could have been  
 13 cared for more efficiently in an outpatient  
 14 setting. That's where the patient is going.

15 Are they all equal? They're not  
 16 all equal. And I think, you know, again we  
 17 feel really strongly the data has to be  
 18 reported back at the patient level with the  
 19 reason and the location of the hospital visit  
 20 so that providers can look at that.

21 I think, my own view is if three,  
 22 you know, gastroenterologists or general

1 surgeons are at an ambulatory surgery center  
2 doing this care and one is having outcomes  
3 that are really driving those scores, that's  
4 a lot of peer review and direct pressure back  
5 on one provider.

6 So, but it gets back to your point  
7 about how things get put into use. I think  
8 with that information available to facilities  
9 this works well as a composite and it gives us  
10 the volume that we need.

11 CO-CHAIR HALL: Thank you. Ross,  
12 another question? You all right? I have a  
13 possibly small question but I'm curious as to  
14 why you risk-adjusted for polypectomy.

15 DR. RANASINGHE: So that's a great  
16 question. We know from the literature that  
17 polypectomy is associated with bleeding, GI  
18 bleeding, and that's the strongest risk factor  
19 for bleeding.

20 At the same time there's a lot of  
21 debate about, you know, removing the polyp  
22 could be discretionary, that some providers

1     may remove unnecessary polyps and you might be  
2     -- you're adjusting away that quality signal.

3             But we felt removing --  
4     identifying polyps and removing them is a  
5     quality indicator itself of colonoscopy. We  
6     did not want to -- you know, if somebody  
7     appropriately removes a polyp and that  
8     resulted in a high rate of hospital visits we  
9     didn't want to disadvantage these providers  
10    who are taking appropriate action to treat a  
11    condition.

12            CO-CHAIR HALL: I understand that,  
13    but you could also argue that there's perhaps  
14    proficiency involved in taking polyps out  
15    without causing bleeding.

16            DR. RANASINGHE: I just want to  
17    make clear that we do not adjust for the  
18    technique used in removing the polyp, the  
19    number of polyps. There's a number of  
20    specific techniques for removing polyps. So  
21    that technical component we do not adjust for.  
22    And that is up to the discretion of the

1 provider.

2 CO-CHAIR HALL: I understand. I  
3 guess it looks to me like a part of the  
4 therapy that could cause the event, the  
5 complication, and you may be adjusting for it.

6 Any other? Paul?

7 DR. HEIDENREICH: Well, just it  
8 sounds like that should be the next measure,  
9 a companion measure of polypectomy rates for  
10 those undergoing polypectomy.

11 CO-CHAIR HALL: Or adenoma  
12 detection rates perhaps. Other comments in  
13 the category of validity? Seeing none.

14 MS. SHAHAB: Voting for 2(b)  
15 validity, one high, two moderate, three low,  
16 four insufficient and time starts now.

17 All votes are in for 2(b)  
18 validity. The results are zero high, 18  
19 moderate, zero low, zero insufficient.

20 CO-CHAIR HALL: Feasibility.  
21 Opening remarks? Anyone? Sorry, go ahead,  
22 Cristie.



1 MS. TRAVIS: Administrative claims  
2 and therefore feasible to collect.

3 CO-CHAIR HALL: Other comments?  
4 Seeing none.

5 MS. SHAHAB: Voting for  
6 feasibility. One high, two moderate, three  
7 low, four insufficient and the time starts  
8 now.

9 All votes are in for feasibility  
10 and the results are 14 high, 4 moderate, zero  
11 low, zero insufficient.

12 CO-CHAIR HALL: Usability.  
13 Opening remarks? Ross or Cristie, any  
14 specific remarks?

15 MS. TRAVIS: Nothing specific.  
16 It's just not in use yet. But they did talk  
17 about the fact that if it was publicly  
18 reported or later used in payment  
19 methodologies and talked a little bit about  
20 using the same methodology as for some of the  
21 other CMS measures.

22 CO-CHAIR HALL: Kathy?

1 DR. AUGER: I just wanted to  
2 comment on a potential unintended risk. As  
3 the developer mentioned a few minutes ago if  
4 you're in a group of three people at an  
5 ambulatory care practice and one of those  
6 providers is really driving the outcome and  
7 you end up in an outlier as perhaps a bad  
8 performing site.

9 As a member of the public knowing  
10 that might actually give you anxiety about  
11 your physician's ability which may be  
12 completely misattributed. You might actually  
13 be wrongfully attributing risk to a good  
14 doctor as opposed to one that has higher  
15 adverse outcomes. So, there's the potential  
16 for misattribution of risk. But I suppose you  
17 could also argue that you could then put  
18 pressure on that lower performing physician as  
19 well. So I could go either way.

20 CO-CHAIR HALL: Karen.

21 DR. JOYNT: I may just be reading  
22 this wrong so feel free to correct me if I'm

1 mistaken.

2 But in the long report it looks  
3 like from the HCUP data that one facility was  
4 found to be better than expected and four were  
5 found to be worse than expected.

6 And I feel like from what you told  
7 us at the beginning about the variability in  
8 outcomes that that either strikes me as the  
9 sample size is too small or I misunderstood  
10 the variability. Or this isn't the same you  
11 were talking about. So just a clarification  
12 on sort of how this plays out in the real  
13 world data would be helpful.

14 DR. RANASINGHE: Okay, that's a  
15 great question. So, we developed our measure  
16 using a 20 percent Medicare sample. And  
17 because that's a sample we needed to actually  
18 test the measure score. We need a 100 percent  
19 sample.

20 And for that we used HCUP data  
21 from four states. And that outlier analysis  
22 is data from four states only. And that's

1     about 992 facilities. So we expect many more  
2     outliers. If you actually included the  
3     national population I think there's about  
4     8,000 facilities plus nationwide.

5             The other point I need to make is  
6     that that is using the 95th percentile and  
7     that's a policy decision. So if you wanted to  
8     capture more outliers you can change the  
9     cutoff interval.

10            CO-CHAIR HALL: So with the 5/95  
11     interval you're working at about a percent, 1  
12     percent roughly more or less? Okay.

13            Other comments? Usability, other  
14     comments or concerns? Not seeing any.

15            MS. SHAHAB: Voting for usability  
16     and use. One high, two moderate, three low,  
17     four insufficient information and the time  
18     starts now.

19            All votes are in for usability and  
20     use. And the results are 1 high, 16 moderate,  
21     1 low and zero insufficient information.

22            CO-CHAIR HALL: Any summary

1        comments for overall voting? I do not see  
2        any. Ross?

3                    DR. EDMUNDSON: I think this is a  
4        very -- a high-frequency outpatient procedure.  
5        And this is a start. This is shining the  
6        light on it.

7                    And I think that there's a lot  
8        that we're going to probably have to learn out  
9        of this one. And I think like as I say, my  
10       prejudice is that I think it will be better to  
11       look at this from an individual provider. But  
12       I'll leave that for time and further  
13       information to decide.

14                   CO-CHAIR HALL: Thank you. Any  
15        other comments. No? Let's move to vote.

16                   MS. SHAHAB: Voting for overall  
17        suitability for endorsement, one yes, two no.  
18        The time starts now.

19                   CO-CHAIR HALL: We're waiting for  
20        one more if you could just click it one more  
21        time.

22                   MS. SHAHAB: All votes are in for

1 overall suitability for endorsement for  
2 measure 2539 Facility 7-day Risk-standardized  
3 Hospital Visit Rate after Outpatient  
4 Colonoscopy. And the results are 17 yes, 1  
5 no.

6 CO-CHAIR HALL: We thank the  
7 developers for their effort and input.

8 And we will move into the review  
9 of 1789. I'm turning over to who? Who am I  
10 turning over to?

11 MR. AMIN: Okay, so --

12 CO-CHAIR KAPLAN: Before you  
13 start, is part of your start going to be what  
14 we're supposed to do here?

15 MR. AMIN: Yes.

16 CO-CHAIR KAPLAN: Thank you.

17 (Laughter)

18 CO-CHAIR HALL: And we welcome the  
19 Yale team back to the table. They'll  
20 introduce themselves in a moment.

21 MR. AMIN: Okay. So, as part of  
22 the 2011 evaluation of measure 1789 the

1 Hospital-wide All-cause Unplanned Readmissions  
2 Discussion there was a number of elements that  
3 the steering committee requested from the  
4 developer post dry run, especially trying to  
5 understand the results of the dry run,  
6 specifically an analysis of the distribution  
7 of performance between hospitals with varying  
8 proportions of low SES patients and the  
9 proportion of the measure result variation  
10 that is attributable to providers compared to  
11 patients.

12 This information was not available  
13 during the initial endorsement of this measure  
14 and so given that we -- this is the first time  
15 this committee has met since the evaluation of  
16 1789 we've asked the measure developers to  
17 provide this information to the committee.

18 And I will turn it back over to --  
19 and provide a quick update on the progress  
20 related to harmonization to measure 1768 which  
21 was provided to members of the committee that  
22 are returning.

1                   So there are a number of members  
2                   of the committee that are aware of this issue.  
3                   And I would sort of invite you to participate  
4                   in this conversation.

5                   I'll just note who that is.  
6                   Bruce, Cristie, Jo Ann Brooks, Paula, Larry  
7                   Glance, Leslie Kelly Hall and Sherrie Kaplan  
8                   of course.

9                   So, that is the topic of the next  
10                  half hour.

11                  CO-CHAIR HALL: Thank you. And  
12                  just to clarify, we will not actually be asked  
13                  to vote on anything.

14                  MR. AMIN: No.

15                  CO-CHAIR HALL: We're being asked  
16                  to review the information.

17                  MR. AMIN: Yes, these are purely  
18                  updates from the developer and conversations  
19                  that the committee may want to have with the  
20                  developer related to those topics. But this  
21                  measure is not up for review and there will  
22                  not be an endorsement decision from this



1 conversation.

2 CO-CHAIR KAPLAN: And the goal of  
3 this conversation is to generate?

4 MR. AMIN: Is to provide an update  
5 to the committee. This was --

6 CO-CHAIR KAPLAN: Not on their  
7 side, on our side. What are we to do? We're  
8 to provide what?

9 MR. AMIN: This was a request by  
10 this committee at the end of the last review.  
11 So this is an update on these particular  
12 issues. There's no action required by the  
13 committee at this point.

14 DR. BURSTIN: And just to add to  
15 that. So, when the decision was made to  
16 endorse this measure there was -- some of you  
17 may remember this was not without controversy.  
18 Susannah is still smiling, that's good.

19 But part of the agreement  
20 particularly with the NQF board as well as  
21 with the steering committee was that they  
22 wanted us to take a look back to see what the

1     experience has been, to see if there is any  
2     evidence of unintended consequences and sort  
3     of monitor the situation. This is essentially  
4     that monitoring update.

5                   CO-CHAIR KAPLAN: So, essentially  
6     -- not to keep beating this horse, but  
7     essentially our role is to thank you for  
8     sharing and we are -- any comments we have for  
9     the developer will be communicated to --

10                  MR. AMIN: They will be  
11     communicated in the report around the updates  
12     on these topics.

13                  DR. BURSTIN: And certainly since  
14     the developers and CMS are here we want them  
15     to be part of this discussion. If there are  
16     issues that are raised that need further  
17     discussion we will encourage those  
18     discussions.

19                  CO-CHAIR KAPLAN: Could the  
20     developers please re-introduce yourselves for  
21     the record and then present your findings.

22                  DR. HOROWITZ: I'm Leora Horowitz

1 from Yale.

2 DR. BERNHEIM: And I'm Susannah  
3 Bernheim.

4 DR. HOROWITZ: So I led the  
5 development of this measure and presented to  
6 this committee in 2011. And thank you. I  
7 know it's been a long two days so thanks for  
8 bearing with us.

9 So, as you know this measure was  
10 endorsed in the spring of 2012 and at that  
11 time you had asked us to come back earlier  
12 than the three years to talk about the dry run  
13 and the harmonization. And so I'm going to  
14 just quickly summarize those. And I believe  
15 you've received those materials as well.

16 So, we had the dry run in the fall  
17 of 2012. Dry run means that CMS sends  
18 hospitals a confidential report of what the  
19 measure results look like but without publicly  
20 reporting them.

21 And so hospitals received the  
22 overall score. They also received the scores

1 for each of the five specialty cohorts that  
2 make up this measure. And they received a  
3 list of every one of their patients that was  
4 in the measure along with whether that patient  
5 had been readmitted and if so to which  
6 hospital and what date and what the procedures  
7 and the diagnoses were.

8 And there was a lot of interest in  
9 that dry run. CMS sent results to 4,652  
10 hospitals. Seventy-two percent of them  
11 downloaded their data. We received 163  
12 questions about the measure after that dry run  
13 and we had 2,400 people approximately register  
14 for two phone calls that we had to explain the  
15 measure and answer questions.

16 Most of the questions were about  
17 the methodology in various ways.

18 So based on the feedback and the  
19 questions that we got in that dry run we made  
20 several changes to the measures. And I want  
21 to make sure that you're aware of those now.

22 We updated our planned readmission

1 algorithm. At that time we added nine  
2 procedure categories to the list of things  
3 that could qualify you as having a planned  
4 readmission. We also removed a diagnosis code  
5 from the acute diagnosis list which would have  
6 otherwise disqualified a readmission from  
7 being called planned.

8 And those changes were already  
9 brought before NQF in the context of the re-  
10 endorsement of our other -- various other  
11 condition-specific measures.

12 For this measure, for the  
13 hospital-wide measure those changes increased  
14 the proportion of readmissions that we called  
15 planned. So before we called 5.1 percent of  
16 readmissions planned and with the changes we  
17 called 8.3 percent of them planned. So that  
18 decreased the national unplanned hospital  
19 readmission rate from 16.8 to 16.2 percent.

20 I should add that we subsequently  
21 conducted a chart validation of the planned  
22 readmission algorithm and have made several

1 more small changes that have also slightly  
2 changed the readmission rate. But those  
3 changes are smaller.

4 Based on the feedback that we got  
5 in the dry run we also altered the assignment  
6 of some patients from the surgical cohort to  
7 other cohorts, so about 200,000 patients  
8 overall moved. And we changed the way -- the  
9 unplanned readmission following a planned  
10 readmission was counted in the measure.  
11 Again, that change has been brought before NQF  
12 for other measures.

13 So, with regard to harmonization  
14 we did include in our materials an updated  
15 memo from both us and NCQA. NCQA is the owner  
16 of the Plan All-cause Readmission measure  
17 which is another all-cause readmission measure  
18 but targeted at the health plan level, not at  
19 the hospital level.

20 And at the time when we originally  
21 had the endorsement we were asked to talk  
22 about eight different areas in which we were

1 not harmonized to see if we could harmonize on  
2 them.

3 So, one it turned out we were  
4 already harmonized on so that was easy.

5 Two more NCQA is planning  
6 hopefully to harmonize on. But they have put  
7 those decisions out to public comment and then  
8 it needs to be voted on by their board of  
9 directors. So their plan is to harmonize on  
10 two other topics which is the planned  
11 readmission algorithm and counting  
12 readmissions as new index admissions. And so  
13 we will hear about that when that vote  
14 happens.

15 For two other areas in which we're  
16 not harmonized NCQA did several analyses.  
17 Those are the exact form of the risk  
18 adjustment variables that we used and using  
19 hierarchical versus non-hierarchical modeling.

20 When they analyzed those two areas  
21 they found it made almost no difference at all  
22 to the measure. And so for the purposes of

1 just sort of practicality and simplicity we  
2 are both going to continue with the approaches  
3 that we take knowing it doesn't really matter  
4 very much.

5 And then there are the remaining  
6 issues that we have so far agreed to disagree  
7 on still.

8 One is patients receiving medical  
9 treatment for cancer. We exclude those  
10 patients from the hospital measure. They have  
11 extremely high post-discharge mortality rates  
12 and we're worried about the competing risk.

13 On a plan level that's less  
14 relevant to the plan population. NCQA prefers  
15 to keep those patients.

16 The other area that we are going  
17 to continue to disagree on is psychiatric  
18 patients. We both include patients who are  
19 admitted with substance abuse or other sort of  
20 medical psychiatric problems.

21 But patients who are only admitted  
22 for a psychiatric disease, like for an acute



1 schizophrenia or acute bipolar disorder are  
2 not in our measure because we -- our measure  
3 doesn't have psychiatric hospitals.

4 And so psychiatric hospitals and  
5 psychiatric units are not in our measure.  
6 They are in the NCQA, sort of the plan  
7 measure.

8 And so there's a very small  
9 fraction, about 3 percent of all psychiatric  
10 admissions come into medical hospitals perhaps  
11 because we just can't exclude them well. And  
12 so we exclude that tiny fraction because  
13 they're just a very small fraction of all  
14 psychiatric patients. So we're going to  
15 continue to disagree on that point.

16 And lastly with regard to  
17 socioeconomic questions it's obviously  
18 extremely complicated and difficult.

19 So after the original committee  
20 meeting we put together a variety of analyses  
21 trying to understand what the relationship of  
22 hospital and patient kind of level variability

1 was.

2 And we sent those analyses to the  
3 board after the committee had met. But the  
4 committee never got a chance to see them. So  
5 we included those analyses in the materials we  
6 sent to you.

7 And the 30,000 foot view very  
8 quickly is just that hospitals that have  
9 higher rates of patients with lower  
10 socioeconomic status which in itself is a very  
11 hard thing to kind of get your brain around,  
12 but we did that in four or five different ways  
13 so we could try to capture that.

14 Those hospitals that have a lot of  
15 those patients do have slightly higher risk-  
16 standardized readmission rates. Although the  
17 overlap is really profound so there's just a  
18 huge amount of overlap in the rates.

19 And then -- but that didn't  
20 particularly help us much because that could  
21 have been because there's an intrinsic risk to  
22 having low socioeconomic status. Or it could

1 have been because patients with low  
2 socioeconomic status may cluster in hospitals  
3 with lower quality. And so it's so hard to  
4 disentangle what that means.

5 So, the last thing that we did is  
6 we just took all of those patients out as best  
7 we could. So, in one analysis we removed all  
8 Medicaid patients from the data. So we tried  
9 as best we could to take out those  
10 socioeconomic status patients altogether. And  
11 then we redid the analyses and still we find  
12 a slightly higher risk-standardized  
13 readmission rate in the hospitals that have a  
14 lot of those patients even though we're not  
15 putting them in the measure.

16 And so again, it's hard to exactly  
17 know what that means but it's at least  
18 suggested that this is not purely a patient-  
19 level problem, that there's some component  
20 relating to the hospital.

21 CO-CHAIR HALL: Thank you. Leora,  
22 would you mind just reminding us how you --

1     you touched on it, but you didn't state it in  
2     detail, how readmission is considered or not  
3     considered an index as well in your algorithm?

4             DR. HOROWITZ:  So, in this measure  
5     every readmission is newly considered an index  
6     admission.  And so a readmission counts as a  
7     readmission, and then it also counts as an  
8     index and we look to see forward if there's a  
9     readmission after it.

10            CO-CHAIR HALL:  Thank you.  Any  
11     questions from the group?  Wes.

12            DR. FIELDS:  Just one small one.  
13     I wasn't in the room for this prior  
14     discussion.  So I'm not clear.  Is this an  
15     all-plan analysis or analysis of CMS  
16     populations?

17            DR. HOROWITZ:  This is endorsed  
18     for 18 and over but it's in use currently only  
19     for Medicare patients.

20            DR. FIELDS:  So when you said you  
21     removed the Medicaid patients, you're talking  
22     about the dual eligible population?

1 DR. HOROWITZ: Correct.

2 CO-CHAIR HALL: But the removal  
3 was just a sensitivity test. It wasn't  
4 actually how it's -- yes, okay.

5 CO-CHAIR KAPLAN: So, I was out of  
6 the room as well. Just -- but recalling these  
7 data, no matter that it looked like robust  
8 across disproportionate share hospitals,  
9 whether or not your status was a public  
10 hospital, proportion of Medicaid patients, and  
11 I forget what the fourth one was.

12 But robust across about four or  
13 five different considerations of things that  
14 actually could be a proxy. We can argue about  
15 what they're actually a proxy for. But at  
16 least for robust across those treatments of  
17 potential differences in socioeconomic status.  
18 Non-random clustering by patients within  
19 hospital. Your findings are reasonably robust  
20 across pretty much everything you tried.

21 DR. HOROWITZ: Yes. As Sherrie  
22 said, we defined SES in every way we could

1 knowing we only had administrative data. And  
2 so the things that often people really care  
3 about, whether they are literate or are  
4 homeless or things like that, we just don't  
5 have that data.

6 But what we did was we looked at  
7 proportion of patients that are dual eligible  
8 that have Medicaid at the hospital.

9 We looked at whether the hospital  
10 was a safety net hospital which we defined as  
11 being more than a standard deviation above the  
12 state average for its dual eligible patients.

13 We looked at whether the hospital  
14 was considered a disproportionate share  
15 hospital by the government. And we looked at  
16 whether the hospital was a public hospital.  
17 So, those are all ways we tried to get at  
18 whether a hospital was going to see a  
19 disproportionate number of low-SES patients.

20 And of all of those the tightest,  
21 the most conservative definition we used was  
22 proportion of Medicaid. So we looked at

1 hospitals that had 30 percent or more of their  
2 patients having Medicaid. That was our  
3 smallest, most extreme sample. We only had  
4 300-something, 331 hospitals like that. So  
5 that's where you're going to see the biggest  
6 differences. If we're going to see anything  
7 it should be in those hospitals.

8 CO-CHAIR HALL: Any other delving  
9 into any other geographic qualifiers?

10 DR. HOROWITZ: We did not look at  
11 any other geographic differences?

12 MS. MINTON-FOLTZ: Did you account  
13 for no-pay or undocumented?

14 DR. HOROWITZ: So again, because  
15 we did this in Medicare data all of our  
16 patients by definition have Medicare. And so  
17 all we really had was the dual eligible  
18 Medicaid and Medicare patients.

19 CO-CHAIR HALL: Any other comments  
20 or questions? I'll look back to our NQF  
21 colleagues. Do we just thank the developers  
22 or is there any other?

1 MR. AMIN: Yes, that's it.

2 CO-CHAIR HALL: Thank you for this  
3 update.

4 DR. HOROWITZ: Thank you for  
5 having us.

6 MR. AMIN: Okay, so we have two  
7 other items. We have public and member  
8 comment at 2:30.

9 I just wanted to point out a few  
10 next steps. I'm just going to turn it over to  
11 Adeela to talk through some of the next steps.

12 One of the immediate next steps  
13 that I want the committee to be aware of is  
14 that we have a call scheduled on May 16 from  
15 2 to 4. And we will use that call, the  
16 majority of that call to discuss the  
17 harmonization of competing measures  
18 discussion.

19 So we have three sets of competing  
20 measures discussions that we're going to have.  
21 Just so that there's a few folks in the room  
22 that we're going to ask you to play a little



1 bit of a role during that conversation.

2 Those that have been lead  
3 discussants for the measures, Wes Fields and  
4 Pam Roberts, for the two -- there's the 2505,  
5 the ED use within 30 days of home health.  
6 There are two measures that are related to  
7 this measure. And we'll send you a side-by-  
8 side table to give you a description of what  
9 they look like. But just so you're aware. So  
10 again, Wes and Pam, we're going to ask you to  
11 lead this discussion during the call on the  
12 16th.

13 So 2505 relates to 0173 which is  
14 the acute hospitalizations for home health  
15 patients. And 0171 which is ED use post home  
16 health without the 30-day qualifier. And so  
17 we're going to have to have a conversation  
18 related to how these are related and whether  
19 we should be selecting one of the measures for  
20 endorsement.

21 The other set of measures, Helen,  
22 we're going to ask you to take the lead on

1     since you were the lead discussant on is 2375  
2     the SNF all-cause readmission measures and the  
3     2510 also the SNF all-cause readmission.

4             And then the third set, you know,  
5     there are a number of lead discussants.  
6     Bruce, Paul, Ross and John, you guys were all  
7     part of the discussions around the CABG  
8     readmission measures. So we'll send a side-  
9     by-side table related to those two measures.  
10    But we'll have to have a conversation related  
11    to potentially selecting a best in class.

12            We'll also send along prior to  
13    that call a description of the decision logic  
14    of how we will go through the discussion  
15    around either selecting one as a best in class  
16    measure or potential harmonization. But the  
17    nature of that call will be to discuss  
18    harmonization or selecting a best in class  
19    measure.

20            Again, we'll follow up with much  
21    more detail in an email with some descriptions  
22    of those measures and who's responsible. But

1 before we leave today I wanted to make sure  
2 that we at least had a little bit of, you  
3 know, these recommendations are contingent on  
4 the fact that we have a discussion around  
5 selecting or at least addressing the question  
6 of harmonization or best in class.

7 I think there are a few questions  
8 on that topic so I welcome them.

9 MS. SHIPPY: Weill we be asked to  
10 vote on the phone call?

11 MR. AMIN: We will -- I don't know  
12 the answer to that yet. But likely we won't  
13 be -- we'll have to make a decision. So  
14 likely it will be through a follow-up  
15 SurveyMonkey and not voting on the call  
16 itself.

17 Again, we'll follow up with a lot  
18 more detail of exactly what will be kind of  
19 expected during that conversation. But it  
20 will be more of a lead discussant on the  
21 measures that you've already reviewed for the  
22 committee. So there shouldn't be anything new

1       there.

2                       So, Adeela, I'll turn it over to  
3       you in terms of summary and follow-up in terms  
4       of next steps.

5                       MS. KHAN:   Sure.   You can look for  
6       that email around Friday.   You'll get it in  
7       your inboxes by then.

8                       Just a quick summary of the  
9       measures that we've gone through today.   2515,  
10      the Hospital 30-day All-cause Unplanned Risk-  
11      standardized Readmission Rate Following  
12      Coronary Artery Bypass Graft Surgery passed.

13                      2514 Risk-adjusted Coronary Artery  
14      Bypass Graft Readmission Rate also passed.

15                      2393 Pediatric All-Cause  
16      Readmission Measure passed.

17                      2414 Pediatric Lower Respiratory  
18      Infection Readmission Measure passed.

19                      2513 Hospital 30-day All-cause  
20      Risk-standardized Readmission Rate Following  
21      Vascular Procedures passed.

22                      0695 Hospital 30-day Risk-

1 standardized Readmission Rates Following  
2 Percutaneous Coronary Intervention passed.

3 0505 Hospital 30-day All-cause  
4 Risk-standardized Readmission Rate Following  
5 Acute Myocardial Infarction Hospitalization  
6 passed.

7 And 2539 Facility 7-day Risk-  
8 standardized Hospital Visit Rate after  
9 Outpatient Colonoscopy also passed.

10 In terms of next steps after this  
11 meeting we're going to have our post-meeting  
12 call that Taroon mentioned. It's scheduled  
13 for May 16 2 to 4. You should have that on  
14 your calendars already. If you don't let me  
15 know right away.

16 After the in-person meeting we're  
17 going to start writing the report. And we  
18 expect the report to go out to public comment  
19 in June, early June, June 6 through July 7.  
20 That will be about a 30-day public comment.  
21 We have to accommodate for the July 4 holiday.  
22 But it will be 30 days.

1                   And we encourage all of you to  
2                   pass the report around and get as many  
3                   comments as we can.

4                   We'll have a steering committee  
5                   call to review and respond to the comments.  
6                   That's July 30. Again you should have that on  
7                   your calendars.

8                   In August we expect the measures  
9                   to go through the NQF member vote and to CSAC  
10                  followed by endorsement by the board in  
11                  September.

12                  And we will have a 30-day appeals  
13                  period we'll start in October. And we'll have  
14                  exact dates for you once the time is closer.

15                  That's all I have for today. I'll  
16                  turn it back to Taroon.

17                  MR. AMIN: So, I would just say  
18                  from the NQF team a profound thank you very  
19                  much to the committee for all of the hours  
20                  that you spent reviewing all of these  
21                  measures, all of the workgroup calls that you  
22                  spent and obviously this very entertaining but

1     exhausting two days that I'm sure we've had  
2     here.

3                   And a particular thank you to the  
4     co-chairs who have led us through this on time  
5     across the two days. You've saved us a lot of  
6     work in terms of scheduling follow-up  
7     conference calls to review measures. So thank  
8     you to Bruce and Sherrie for all of your work  
9     here.

10                  And we're just -- I'll ask for  
11     some reflections from the chairs. But I also  
12     want to be cognizant that we have the 2:30  
13     public comment period. So thank you.

14                  CO-CHAIR HALL: Well, I will just  
15     briefly say that Sherrie and I are thrilled to  
16     preside over such a wonderful group of experts  
17     in these areas. So the privilege has been all  
18     ours, all mine. I always, always learn from  
19     this process so I'm always thrilled to take  
20     part. And being with such a great group is  
21     what makes it worthwhile.

22                  CO-CHAIR KAPLAN: Ditto.

1                   MR. AMIN:   So, Operator, I want to  
2                   see if there are public comments on the phone.  
3                   And we'll also take any public comments in the  
4                   room.

5                   OPERATOR:   Okay.   If you'd like to  
6                   make a public comment please press \* then the  
7                   number 1.   There are no comments at this time.

8                   MR. AMIN:   Are there any comments  
9                   in the room?   No.   Okay.

10                  Again, thank you all very much.  
11                  And we again, we appreciate all of your work  
12                  on this.   Look forward to the follow-up call.

13                  (Whereupon, the foregoing matter  
14                  went off the record at 2:25 p.m.)

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