

NATIONAL QUALITY FORUM

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PULMONARY AND CRITICAL CARE  
STANDING COMMITTEE

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TUESDAY  
MARCH 15, 2016

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The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:00 a.m., Dale Bratzler and David Lang, Co-Chairs, presiding.

PRESENT:

DALE BRATZLER, DO, MPH, Chief Quality Officer,  
OU Physicians - Oklahoma University Health  
Sciences Center, Co-Chair

DAVID LANG, MD, Chair, Department of Allergy and  
Clinical Immunology, Respiratory  
Institute, Cleveland Clinic, Co-Chair

GERENE BAULDOFF, PhD, RN, FAAN, Professor of  
Clinical Nursing, The Ohio State  
University College of Nursing

KENNETH BENSON, Board Member, US COPD Coalition

CURTIS COLLINS, PharmD, MS, Specialty  
Pharmacist, Infectious Diseases, St.  
Joseph Mercy Health System

BRUNO DIGIOVINE, MD, MPH, Division Head,  
Pulmonary, Critical Care and Sleep  
Medicine, Henry Ford Medication Group

TODD DORMAN, MD, FCCM, Professor and Vice Chair  
for Critical Care Services, The Johns  
Hopkins Hospital

KIM ELLIOTT, Q, PhD, CPH, Administrator,  
Clinical Quality Management, AHCCCS

WILLIAM BRENDLE GLOMB, MD, FCCP, FAAP, Senior  
Medical Director, Superior HealthPlan

STEPHEN GROSSBART, PhD, Senior Vice President  
and Chief Quality Officer, Mercy Health

JAMES "MITCH" HARRIS, PhD, Director, Research &  
Statistics, Children's Hospital  
Association \*

EDGAR JIMENEZ, MD, FCCM, Vice President,  
Critical Care Integration and eICU -  
System, Baylor Scott & White Health

ELLA KAZEROONI, MD, MS, Professor, Department of  
Radiology Cardiothoracic Radiology  
Division, University of Michigan Health  
System \*

THOMAS LAMPONE, MD, Senior Medical Director,  
Florida Blue

RICHARD MURRAY, MD, Vice President and Deputy  
Chief Medical Officer, Merck and Co., Inc.

JAMES O'BRIEN, MD, MS, VP, Quality and Patient  
Safety, OhioHealth Riverside Methodist  
Hospital

PATRICIA J. OHTAKE, PT, PhD, Associate  
Professor, University of Buffalo

SUSAN POLLART, MD, Associate Tenured Professor;  
Senior Associate Dean for Faculty Affairs  
and Faculty Development, University of  
Virginia, Department of Family Medicine \*

CRYSTAL RILEY, PharmD, MHA, MBA, CPHQ, CHPIT,  
Manager, Healthcare Policy, Baxter  
Healthcare

CHRISTINE SCHINDLER, PhD, RN, CPNP-AC/PC, WCC,  
Clinical Assistant Professor of  
Pediatrics, Marquette University College  
of Nursing

DAVID STOCKWELL, MD, MBA, Associate Professor of  
Pediatrics, Children's National Medical  
Center \*

CHANA WEST, RN, MSN, Associate, Booz Allen  
Hamilton

**NQF STAFF:**

HELEN BURSTIN, MD, MPH, Chief Scientific Officer  
ANN HAMMERSMITH, JD, General Counsel  
ELISA MUNTHALI, Vice President, Quality  
Measurement  
JANINE AMIRAULT, Project Analyst  
POONAM BAL, Project Manager  
SHACONNA GORHAM, Senior Project Manager  
ROBYN Y. NISHIMI, PhD, Consultant

**ALSO PRESENT:**

MARY BARTON, MD, MPP, National Committee for  
Quality Assurance  
CHARLIE BRUETMAN, MD, The Lewin Group  
SUE FRECHETTE, BSN, MBA, American Thoracic  
Society  
BEN HAMLIN, MPH, National Committee for Quality  
Assurance  
ELIZABETH HERMAN, MD, MPH, CDC \*  
LARRY KLEINMAN, MD, The Mount Sinai Hospital  
JASMINE LARSON, MBA, CPHQ, Minnesota Community  
Measurement \*  
COLLEEN M. McKIERNAN, MSPH, The Lewin Group  
BELA PATEL, MD, American Thoracic Society \*  
LINDSEY ROTH, MPP, National Committee for Quality  
Assurance  
JOHN SCHALL, MPP, PCORI \*  
  
REBECCA SWAIN-ENG, MS, CAE, American Academy of  
Asthma, Allergy, and Immunology

\* present by teleconference

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

2 9:07 a.m.

3 MS. GORHAM: All right. Good morning,  
4 and welcome to the Pulmonary and Critical Care  
5 CDP Standing Committee Meeting. Thank you for  
6 joining us for our PCC measure evaluation and  
7 being Members of the Standing Committee.

8 My name is Shaconna Gorham, and I am  
9 a senior project manager here at NQF. We are  
10 going to kick off introductions, and later, we  
11 will introduce our Co-Chairs, David Lang and Dale  
12 Bratzler, but before then, we want the NQF staff  
13 to go ahead and introduce themselves.

14 Poonam?

15 MS. BAL: Hi, I am Poonam Bal, the  
16 project manager on the Pulmonary Project.

17 MS. AMIRAULT: Hi, I am Janine  
18 Amirault. I am the project analyst.

19 MS. GORHAM: Robyn? Yes.

20 DR. NISHIMI: Robyn Nishimi, I am a  
21 consultant here. I was the founding Chief  
22 Operating Officer. And I also wanted to make a

1 note that I recuse myself from 1893. I work  
2 closely with a member of that measure's steering  
3 committee, so even though I wasn't part of that  
4 project with him, I just decided to recuse myself  
5 from that one.

6 MS. GORHAM: All right. Elisa?

7 MS. MUNTHALI: Good morning. My name  
8 is Elisa Munthali. I am Vice President for  
9 Quality Measurement at NQF. I wanted to welcome  
10 everyone and thank you for being on the  
11 Committee.

12 MS. GORHAM: Helen?

13 DR. BURSTIN: Great, hi, I am Helen  
14 Burstin, the Chief Scientific Officer here at  
15 NQF. Delighted to have you here with us today.  
16 Ann Hammersmith will do disclosures with you in a  
17 moment.

18 But I'll be popping in and out of the  
19 meeting at any point during the day today if you  
20 have any questions that Elisa or these  
21 ridiculously smart people lined up here can't  
22 answer about our process or our criteria. I am

1 happy to come back up and assist you, but you are  
2 in excellent hands, and just want to say thank  
3 you.

4 We have really found that moving to  
5 standing committees has been very helpful. I  
6 know this is the first rodeo for you guys, but  
7 the idea that you'll stay together over time and  
8 really kind of oversee this portfolio we have  
9 found to be really, really helpful in that  
10 ongoing continuity.

11 So thank you so so much, and with  
12 that, I am going to turn it over to Ann to do  
13 introductions. Welcome, Ann.

14 MS. HAMMERSMITH: Thank you, Helen.

15 I am Ann Hammersmith. I am NQF's  
16 General Counsel, and as Helen said, I am here to  
17 lead you through the disclosures of interest.

18 If you recall, when you applied for  
19 the Committee, you filled out a somewhat lengthy  
20 form, we wish we could make it shorter but we  
21 haven't been able to, asking you about your  
22 professional activities. And the information you

1 gave on that form was an ingredient in deciding  
2 who would sit on the Committee and who would not.  
3 In the spirit of openness, at the first public  
4 meeting of a committee, we ask you to do oral  
5 disclosures.

6 When you do this, we don't want you to  
7 summarize your resume, please. We just want you  
8 to disclose anything that you believe is relevant  
9 to your service on the Committee. Just because  
10 you disclose does not mean you have a conflict.  
11 I want to emphasize that.

12 So what we're looking for you to do is  
13 to disclose any activities that you believe are  
14 relevant to the work before the Committee, such  
15 as consulting, speaking engagements, grants,  
16 research, and so on.

17 I want to remind you that you sit on  
18 the Committee as an individual. You do not  
19 represent your employer. You do not represent an  
20 organization that you belong to. You do not  
21 represent anyone or any organization who may have  
22 nominated you to serve on this Committee.



1                   And the last thing I want to remind  
2                   you of is that people will often say I don't have  
3                   any financial disclosures, which is, you know,  
4                   that's fine, great if you don't have financial  
5                   conflicts, but the way NQF's disclosure of  
6                   interest process works is that it's -- the  
7                   disclosures aren't strictly driven by money  
8                   exchanging hands.

9                   So in other words, you may have served  
10                  on a committee for your professional society that  
11                  is relevant to the work before the Committee.  
12                  You're not paid, but we would look for you to  
13                  disclose that, but only things that are relevant  
14                  to service before the Committee.

15                  So what we'll do is we will go around  
16                  the table, ask you to give your name, who you're  
17                  with, if you have anything you would like to  
18                  disclose. If you're on the phone, I will call on  
19                  you.

20                  So let's start with the Chairs.

21                  CO-CHAIR BRATZLER: Hi. I am Dale  
22                  Bratzler. I am with the University of Oklahoma,

1 both the College of Medicine and College of  
2 Public Health.

3 I actually have no formal disclosures  
4 at this point, financial or otherwise. I did  
5 recuse myself from one of the measures, CMS 0468,  
6 which is a measure that I had worked on  
7 extensively in the past.

8 CO-CHAIR LANG: Good morning. I am  
9 David Lang, and I have engaged in clinical  
10 research with, have received honoraria from,  
11 and/or have served as a consultant for Merck,  
12 GlaxoSmithKline, Genentech, Novartis, Meda  
13 Pharmaceuticals. I am the Department Chair of  
14 Allergy and Clinical Immunology at the Cleveland  
15 Clinic and Co-Director, Asthma Center. I am  
16 involved with quality measures at the Cleveland  
17 Clinic, and I also serve as the chair of the  
18 Measure Stewardship Committee of the American  
19 Academy of Allergy, Asthma & Immunology, and I am  
20 one of the two co-chairs of our Practice  
21 Parameters Task Force for Allergy Immunology.  
22 That is our guidelines development group.

1 Thank you.

2 MR. BENSON: Good morning. My name is  
3 Ken Benson. I am a patient advocate representing  
4 the COPD Foundation. I have no involvement with  
5 any of the measures before us other than being a  
6 patient.

7 MS. FRECHETTE: I am not on the  
8 Standing Committee. I am Sue Frechette, measure  
9 developer representing ATS.

10 DR. DORMAN: Hi, sorry. Todd Dorman,  
11 I work at Johns Hopkins where I do both critical  
12 care and am the Associate Dean for Continuing  
13 Medical Education.

14 I am here -- I don't have any  
15 conflicts based upon your definitions.

16 DR. GLOMB: Good morning. I am  
17 Brendle Glomb. I am Chief Medical Officer for  
18 Superior HealthPlan, which is the largest  
19 subsidiary of the Centene Corporation. We do  
20 entitlement insurance, Medicaid, Medicare  
21 exchange, et cetera.

22 And I work hand-in-hand with our Vice

1 President for Quality, so I am -- I am one of  
2 those evil-side people who puts these measures  
3 into play in the field with managed care. I am a  
4 pediatric pulmonologist and neonatologist. I  
5 have nothing to disclose.

6 MS. WEST: Good morning. My name is  
7 Chana West. I work for Booz Allen Hamilton. I  
8 have no direct disclosures, although I have  
9 worked in the past on measure development  
10 contracts, but none in this realm.

11 DR. OHTAKE: Good morning. My name is  
12 Patricia Ohtake. I am at the University of  
13 Buffalo in the School of Public Health and Health  
14 Professions, and I have no disclosures to report.

15 DR. ELLIOTT: Hi, I am Kim Elliott.  
16 I work for the Arizona Health Care Cost  
17 Containment System, better known as AHCCCS, which  
18 is the Medicaid program in Arizona. I am the  
19 Clinical Quality Management Administrator, so I  
20 am responsible for all of the clinical programs  
21 for the Medicaid program, and I have nothing to  
22 disclose.

1 MS. HAMMERSMITH: Could you use your  
2 neighbor's while we get you another mic?

3 DR. RILEY: Hi. I am Crystal Riley.  
4 I work for Baxter Healthcare Corporation as their  
5 Senior Manager of Healthcare Policy and  
6 Reimbursement. I have no disclosures.

7 DR. LAMPONE: Good morning. I am Tom  
8 Lampone. I work for Florida Blue. I am also a  
9 member of the Pharmacy Measurement Development  
10 Committee, and I have no other disclosures.

11 DR. COLLINS: Hi, good morning.  
12 Curtis Collins. I am a clinical pharmacy  
13 specialist at St. Joseph Mercy Health System in  
14 Ann Arbor, Michigan, which is part of Trinity  
15 Health as well. I have no disclosures.

16 DR. DiGIOVINE: Hi, I am Bruno  
17 DiGiovine. I am the Division Head for Pulmonary  
18 and Critical Care Medicine at Henry Ford Hospital  
19 in Detroit. I am a consultant for the Michigan  
20 Hospital Association, do quality improvement work  
21 for ICUs throughout the State of Michigan, but  
22 otherwise I have no disclosures.

1 DR. BAULDOFF: Hi, I am Gerene  
2 Bauldoff. I am a professor at Ohio State in the  
3 College of Nursing, and my only disclosure is  
4 that I've served as the developer of other  
5 measures in pulmonary rehabilitation.

6 DR. JIMENEZ: Hi, good morning. I am  
7 Edgar Jimenez. I am Vice President of Critical  
8 Care for the Baylor Scott & White System in  
9 Texas. I have served as a board member from the  
10 American College of Critical Care, and I was Vice  
11 President of the World Federation -- and I still  
12 am Vice President of the World Federation of  
13 Critical Care.

14 I currently sit on the ABIM Committee  
15 for Critical Care, and I have no disclosures.

16 DR. GROSSBART: Hi, I am Stephen  
17 Grossbart. I am the Chief Analytics Officer at  
18 Mercy Health in Cincinnati, Ohio. I have no  
19 disclosures. I have served on the Agency for  
20 Healthcare Research and Quality, CAUTI technical  
21 expert panel, and done some -- received some  
22 honorariums from the American Hospital

1 Association not related to measurement  
2 development, and formerly worked with Premier, or  
3 did work on a measure development. That was over  
4 12 years ago.

5 DR. O'BRIEN: Good morning. I am Jim  
6 O'Brien. I am the Vice President of Quality and  
7 Patient Safety at OhioHealth Riverside Methodist  
8 Hospital, so my day job involves reporting on  
9 these measures.

10 I am also a consultant to the Ohio  
11 Hospital Association regarding a statewide effort  
12 towards sepsis care, and I am the chairman of the  
13 board of directors of Sepsis Alliance, a not-for-  
14 profit dedicated toward sepsis awareness.

15 As a result of that, I do a number of  
16 speaking and advisory board roles and donate the  
17 honoraria back to that charity. That includes  
18 engagements with Tenex, Abbott, Medical  
19 Simulation Corporation, GE, and Ortho Clinical  
20 Diagnostics.

21 DR. MURRAY: Good morning. Richard  
22 Murray, Deputy Chief Medical Officer at Merck.

1 My disclosures are I'm a full-time employee of a  
2 manufacturer. We do manufacture several drugs  
3 that are used in testing.

4 DR. SCHINDLER: Good morning. My name  
5 is Christine Schindler. I am a nurse  
6 practitioner with a joint appointment at American  
7 University and the Medical College of Wisconsin.

8 I -- the only -- I don't have any  
9 financial disclosures. I was an expert  
10 consultant for the AHRQ pressure ulcer quality  
11 work. That's it.

12 MS. HAMMERSMITH: Okay, thank you.  
13 Now I'm going to turn to the people who are on  
14 the phone. I will call you by name.

15 Susan Pollart?

16 DR. POLLART: Hi. I am Susan Pollart.  
17 I am a family physician at the University of  
18 Virginia and the Senior Associate Dean for  
19 Faculty Affairs and Faculty Development. My only  
20 disclosure is service on the TEVA Respiratory  
21 Healthcare Advisory Board that occurred more than  
22 four years ago.



1 MS. HAMMERSMITH: Okay. Thank you.  
2 Mitch Harris?

3 DR. HARRIS: Hi, I am Mitch Harris.  
4 I am a health services researcher who works for  
5 the Children's Hospital Association focusing  
6 mostly on quality advocacy.

7 I -- disclosure, I have been on a  
8 couple of AHRQ time-limited work groups that have  
9 focused on the PDIs and some of the other  
10 measures that might be up for this group, and  
11 also by association the part owner of a company  
12 that has -- has developed some of the measures  
13 that are under review today, and so I've been  
14 recused from a number of the measures for  
15 discussion.

16 MS. HAMMERSMITH: Okay. Thank you.  
17 David Stockwell?

18 DR. STOCKWELL: Good morning. I am a  
19 pediatric intensivist at Children's National  
20 there in Washington, D.C. Sorry I can't be there  
21 today.

22 I -- by way of disclosures, I also am

1 partially employed by Pascal Metrics, which is a  
2 patient safety organization, but I don't believe  
3 there's any conflicts. Thank you.

4 MS. HAMMERSMITH: Okay. Thank you.

5 Is there anyone else on the phone that  
6 I missed?

7 (No audible response.)

8 MS. HAMMERSMITH: Okay. Thank you for  
9 those disclosures. Based on the disclosures, do  
10 you have any questions of me, or do you have  
11 anything that you want to raise with your fellow  
12 Committee Members?

13 (No audible response.)

14 MS. HAMMERSMITH: Okay. Before I  
15 leave you today, just one more reminder, then I  
16 promise I'll go away.

17 In order to make the conflict of  
18 interest process work, we rely on all of you.  
19 Everybody has a role to play in this. So if  
20 during the meeting you think you have a conflict,  
21 or if you think one of your Committee Members has  
22 a conflict, or if you think someone is behaving

1 in a very biased way, we're looking for you to  
2 speak up. Please don't sit there in silence and  
3 then a month later say you know, I think I had a  
4 conflict, or I think somebody else had a  
5 conflict.

6 You are always welcome to bring up an  
7 issue in open session. If you don't want to do  
8 that, you can approach your Chairs, and they will  
9 bring it to staff, and it will be taken care of,  
10 figured out, or you can go directly to staff.

11 So thank you, and have a good meeting.

12 (Pause.)

13 MS. GORHAM: All right, so we will  
14 briefly do an overview of the Pulmonary and  
15 Critical Care, you may hear me say PCC just to  
16 shorten it, Portfolio. Next slide.

17 So these -- the next couple of slides  
18 are not foreign. We also reviewed them during  
19 the orientation call. So today we've convened to  
20 evaluate the measures related to the PCC  
21 conditions measures that are used for  
22 accountability and public reporting for all

1 populations in all care settings.

2 The next few slides, you will see the  
3 measures that are included in the -- in the  
4 portfolio. Those measures in purple with the  
5 asterisk next to them indicate the maintenance  
6 measures that we will review. There are 18  
7 maintenance measures in this project, and there  
8 are four new measures in the project.

9 The measures that are in orange are  
10 part of the portfolio, but they will not be  
11 reviewed in this project.

12 So this first slide indicates that  
13 there are four asthma measures and one asthma and  
14 COPD measure.

15 We also have four COPD measures, three  
16 pneumonia, and one imaging measure. We have five  
17 critical care measures, and then again, at the  
18 bottom, you will see the four new measures that  
19 we will review.

20 There are a mix of outcome and process  
21 measures in this portfolio, and of course, it is  
22 always good to see outcome measures in the

1 portfolio as NQF puts a premium on outcome  
2 measures.

3 As Standing Committee Members, we ask  
4 you to take ownership of the portfolio, so not  
5 only the review today, but also because you are  
6 experts in the field, as we go through the day,  
7 you will start to notice gaps in the portfolio,  
8 so we ask you to identify those gaps as well as  
9 help us to identify new measures that can make  
10 the portfolio more robust.

11 So as a matter of full disclosure,  
12 there are some measures that are part of the  
13 portfolio, but they are being retired by the  
14 developer. So those are the measures on the  
15 screen in this slide as well as the next slide.

16 Okay. Okay. So our activities and  
17 timelines. Of course, over the next two days, we  
18 will evaluate the measures and make  
19 recommendations for those measures. At the post-  
20 meeting webinar, if we are not -- if we do not  
21 have the time or for some reason cannot evaluate  
22 all of the measures today, we will have a post-

1 meeting webinar. If we are successful and we  
2 finish all of our measure review today and  
3 tomorrow, we will not have the post-meeting  
4 webinar, but it is scheduled for March 22 at 12  
5 o'clock.

6 And then we also, after the webinar if  
7 we have one, after you all make your evaluation  
8 and you have your initial review of the measures  
9 today and tomorrow, we will develop the draft  
10 report, we being the staff, we'll have a draft  
11 report of the evaluation and the recommendations.

12 That draft report will be posted on  
13 April 21. It is a 30-day comment period, so that  
14 would end on May 20. And then we will convene  
15 you all back together via telephone call where  
16 you can review the comments made to the report,  
17 and that call will be on June 13. That is at 1  
18 o'clock. And then the draft report will be  
19 posted for NQF Member vote.

20 After NQF Member vote, CSAC will  
21 review the information that we -- that you all --  
22 the evaluation from -- from today and tomorrow as

1 well as the comments as well as the Member vote,  
2 and CSAC will convene and review and improve the  
3 measures in the evaluation on July 13 and 14.  
4 Then the endorsement by the Board would be August  
5 3, and then if we receive an appeal to one of the  
6 endorsement decisions, then that will happen on  
7 August the 5th to September 30. It is a 30-day  
8 appeals process, so an appellant can make an  
9 appeal, they have 30 days to do so.

10 Okay. Okay. So the ground rules for  
11 today's meeting. I am not going to read them  
12 verbatim. However, as a result of the work group  
13 calls that we've had, you all have had a chance  
14 to actually look at the measures, so we have  
15 definitely prepped for today's call, and the  
16 measure discussion script has been provided. It  
17 was emailed to you all. But also there was a  
18 handout at your seat, and so you also have that  
19 in front of you.

20 So if you all could just take a minute  
21 to review the ground rules, and if there are no  
22 questions -- just a bit of housekeeping. Only

1 three mics can be on at one time, so after you  
2 finish speaking, if you can cut your mic off.  
3 And remember to speak directly in the mic. Our  
4 transcriptionist will be taking notes throughout  
5 the meeting.

6 Okay. Okay. So NQF continually  
7 strives to improve our Committee meetings, and so  
8 measure developers have been invited to our  
9 meeting. At the beginning of each measure  
10 discussion, they will have two to three minutes  
11 to briefly introduce themselves. They will sit  
12 to the left of me.

13 Committee Members, of course, we have  
14 assigned discussants for each measure, and so we  
15 have lead discussants. You all will begin to  
16 explain the measure, start with the criteria and  
17 go through that, and then the measure developers  
18 will have an opportunity to answer any questions  
19 that you all may have or to clarify any  
20 information. They will be invited to respond to  
21 the questions at the discretion of the Committee,  
22 so the conversation is mainly for Committee



1 Members, but the developers are definitely here  
2 to answer any of your questions or to clarify  
3 anything.

4 Committee Members often offer  
5 suggestions for improvement to the measures.  
6 Suggestions can be considered by the developers  
7 for future improvement, but we do expect you to  
8 evaluate and make recommendations on the measures  
9 based on the information that you have in front  
10 of you today.

11 Committee Members act as proxies for  
12 NQF membership, and so we really do value the  
13 multi-stakeholder perspective that you all bring  
14 to the table.

15 Okay. So voting for endorsement  
16 criteria. Again, we went through these criteria  
17 on the work group calls as well as the  
18 orientation call, but just to remind you,  
19 importance to measure and report and scientific  
20 acceptability are must pass. Under importance to  
21 measure and report, we have evidence as well as  
22 gap, and that is also where we will discuss

1 disparities in information if provided by the  
2 developers.

3 Reliability and validity of the  
4 measure is really the crux of the measure. We  
5 want to make sure that the measure is reliable  
6 and valid.

7 Feasibility is also critical. We want  
8 to make sure that the measure can be implemented  
9 with less burden as possible. We want to look at  
10 usability and use as well as we'll look at  
11 related and competing later on. We don't have  
12 any competing measures in this portfolio, but we  
13 do have quite a few related measures.

14 Okay. I will hand it over to Poonam  
15 to discuss the next few slides.

16 MS. BAL: Okay, so this is where we're  
17 getting a little active, voting during today's  
18 meeting, so I am sure you all have been waiting  
19 for this.

20 So it is a -- all in-person voting  
21 members have a clicker, so please make sure you  
22 have one of these blue clickers. The person who

1 are on the phone will be chatting us their votes,  
2 and staff members have clickers designated for  
3 them to vote on their behalf.

4 All voting Members -- sorry, never  
5 mind.

6 Instructions: so for that, please  
7 click your -- point your clicker towards Janine  
8 over here. I know you're going to have an urge  
9 to point it over there because that's the screen  
10 that you're going to see, but we need it to go to  
11 the system.

12 When voting, you'll -- your remote  
13 will tell you right here in this little screen  
14 what your vote was, so if it didn't match up to  
15 what you wanted to vote on or you get any sort of  
16 error message, please let us know. We're going  
17 to do a test run in just a couple seconds, and so  
18 we want to make sure everybody's remote is  
19 working.

20 And then also, let's say within the  
21 time that you have, you decide oh, never mind, I  
22 no longer like my response. You can just click

1 the number, and whatever your last response was  
2 is the one that will be registered, so don't feel  
3 that you're stuck with whatever you respond with.

4 Okay. So with that said, we're  
5 actually going to do a test run. Janine, could  
6 you just pull up an evidence slide, please?

7 (Pause.)

8 MS. BAL: So I ask that everyone that  
9 is on the phone please message us either 1 or 2  
10 on the chat feature, and everybody in the room  
11 please also click either 1 or 2 on your remote,  
12 and if you don't see the number, please let us  
13 know.

14 (Pause.)

15 MS. BAL: So we did not receive one on  
16 the chat. Can everybody in the room please just  
17 click their number again just so we can make sure  
18 it works.

19 MS. GORHAM: David, we're still  
20 waiting for your vote through chat.

21 DR. KAZEROONI: This is Ella  
22 Kazerooni. I am trying to chat, but when I --

1 the send button does not seem to be sending.

2 MS. BAL: Actually, Ella, we received  
3 your vote. Thank you.

4 DR. KAZEROONI: Oh, you did? Thank  
5 you.

6 MS. BAL: Yes.

7 DR. STOCKWELL: Hey, I am sorry, it's  
8 David. But I've sent it a couple times. You  
9 haven't received it?

10 MS. BAL: Not yet. Could you just --  
11 Operator, could you work with David to make sure  
12 he's able to chat us his responses?

13 (No audible response.)

14 MS. BAL: All right. So Janine, could  
15 you do a test run of -- showing the votes?

16 MS. AMIRAULT: Okay, so as you can  
17 see, we have twelve -- twelve votes for yes, and  
18 nine for no, with a total of 21.

19 MS. BAL: So that went pretty  
20 efficiently. No one had any error message.  
21 We'll work out what's going on with David on  
22 line, and if not, we'll get another method for

1 getting him to vote.

2 Okay. So we'll move forward to the  
3 next slide, Janine. Next slide, please. Over  
4 here.

5 Thank you. Okay. So achieving  
6 consensus: so a pass or a recommended vote will  
7 be anything greater than 60 percent, and that  
8 does not include 60 percent, only greater, and a  
9 yes vote would be considered the sum of a high  
10 and moderate if we have a for-decision point. If  
11 we just have a yes or no question, then it would  
12 just be yes.

13 Consensus is considered not reached if  
14 we are between the 40 to 60 threshold, and again,  
15 that includes 40 and 60 in that number. If we do  
16 not get at least 40 percent, then it's considered  
17 a do not pass and not recommended. Again, these  
18 numbers really matter for the first two criterion  
19 because those are must pass.

20 For the second two, if -- if they do  
21 not pass, we do still move forward, but that's  
22 included in the draft report, and we will ask

1 public comment on that.

2 And quorum is considered 66 percent of  
3 the Committee. We are definitely way beyond that  
4 number right now, and we'll continue to monitor  
5 as that -- as we go through the meeting. Next  
6 slide, please.

7 Okay. So the last little aspect is  
8 related and competing. During the work group  
9 calls, we did have some Committee Members that  
10 wanted to review a measure based on another  
11 measure that was very similar. However, we  
12 really like to review the measure based on its  
13 merits solely.

14 So as the measure is with basically  
15 just your knowledge of the -- the community, but  
16 not the knowledge of other measures, how does it  
17 pan out? And then once, if it does reach  
18 endorsement, we will compare that measure to the  
19 -- any other similar measures that are also  
20 recommended for endorsement. We want to make  
21 sure that they are -- none of the other thoughts  
22 are conflicted with that, and that point, as

1       Shaconna mentioned, we do not have any competing  
2       measures, so you will not be making a best-in-  
3       class decision.

4               However, you will be making  
5       recommendations on harmonization. You will be  
6       making the decision on if developers should  
7       harmonize further or if you feel that the way  
8       that the measures are, even though that they're  
9       related, they have their own unique point of view  
10      and they do not need to be harmonized any  
11      further.

12             All right. Were there any questions  
13      about that?

14             (No audible response.)

15             MS. BAL: Okay, perfect. Next slide,  
16      please.

17             So with that, I'll give it to the Co-  
18      Chairs. Shaconna, did you want to say something?

19             MS. GORHAM: Just real quickly, if --  
20      to the extent possible, I know it won't happen  
21      all the time, but to the extent possible, if you  
22      could remain in the room until break, because we



1 want to make sure we maintain quorum so that when  
2 we vote we have the needed number in the room,  
3 and so quorum for this Committee is 15, so to the  
4 extent possible, I know we all have to step out  
5 when we need to, but to the extent possible,  
6 thank you.

7 And we're going to turn it over to  
8 David for the first measure.

9 CO-CHAIR LANG: Thank you, Shaconna.

10 Prior to getting into the first  
11 measure, Ella has joined us on the phone. Ella,  
12 could you please elaborate for us on your  
13 disclosures?

14 DR. KAZEROONI: I have no disclosures.

15 CO-CHAIR LANG: Thank you.

16 So with that, we will proceed to  
17 consider the first measure, which is 2852:  
18 Optimal Asthma Control, Minnesota Community  
19 Measurement. Do we have Jasmine on the phone?

20 MS. LARSON: Yes, I am here.

21 CO-CHAIR LANG: Please, Jasmine, would  
22 you like to give us a brief two- to three-minute

1 summary of the measure?

2 MS. LARSON: Sure, I'd be happy to.

3 Thank you.

4 So this measure is a patient-level  
5 all-or-none composite. As you likely already  
6 know, a version of it was brought to this  
7 Committee in 2012. That was a three-component  
8 all-or-none composite measure. However, due to a  
9 lack of a strong and consistent body of evidence  
10 for the third component, which was a written  
11 asthma action plan, the measure did not pass the  
12 evidence criteria at that time.

13 In follow-up, we reconvened our  
14 measure development work group and ultimately  
15 ended up removing that third component from the  
16 measure, so we're presenting to you today a two-  
17 component composite, one of which utilizes  
18 patient-reported outcomes based on the use of any  
19 of the three tools, four tools actually,  
20 specified, which all have been validated with --  
21 to have clear-cut points that define control.

22 And the second component is a patient

1 recall of the last 12 months of emergency  
2 department or hospitalizations due to asthma, and  
3 for numerator compliance for that component to  
4 meet the target, there has to be zero or one  
5 events of that nature.

6 This measure is reported -- attributed  
7 to the provider, reported at the clinical --  
8 clinic site or large-practice level.

9 And that's all I have for you this  
10 day. Thank you.

11 CO-CHAIR LANG: Thank you, Jasmine.

12 We have two discussants, Steve  
13 Grossbart, Christine Schindler. Please take it  
14 away.

15 DR. GROSSBART: We didn't rehearse, so  
16 we don't know who is going to go first.

17 Well, I will introduce the measure  
18 then. As already noted by the developer, this is  
19 an all-or-nothing composite consisting of two  
20 components.

21 The -- the -- this is a new measure.  
22 Again, it was considered in an earlier version

1 before the revisions by this -- the predecessor  
2 committee of this Committee. It is an outcome  
3 measure, and I just, I am trying to go through my  
4 guidelines.

5 So I think we want to move to the  
6 discussion of the first components of the -- the  
7 measure evaluation.

8 DR. SCHINDLER: Right. So I think  
9 that --

10 CO-CHAIR LANG: So initially, we  
11 should be discussing the evidence --

12 DR. SCHINDLER: Right --

13 CO-CHAIR LANG: -- and then --

14 DR. GROSSBART: Which is the evidence  
15 --

16 CO-CHAIR LANG: -- then --

17 DR. GROSSBART: -- that's --

18 CO-CHAIR LANG: -- yes --

19 DR. GROSSBART: -- what I meant, the  
20 first component of the evaluation would be the  
21 evidence, correct?

22 CO-CHAIR LANG: Yes.

1 DR. GROSSBART: Okay.

2 DR. SCHINDLER: So we appreciated, it  
3 sounds like the developers did take into  
4 consideration the comments from the last group,  
5 including there wasn't clear evidence that if  
6 they had fewer ED visits and better report of  
7 control, why we also needed to have the written  
8 asthma action plan in place. There weren't good  
9 data to support that.

10 One of the questions we did have this  
11 time around was that there really wasn't new  
12 evidence related to the two composite -- or the  
13 two measures that were left. There's some graded  
14 clinical evidence for component one, but there  
15 was no clear graded evidence for component two,  
16 which was the self-report of ED visits.

17 DR. GROSSBART: Or hospitalizations.

18 DR. SCHINDLER: Or hospitalizations,  
19 right, thank you.

20 DR. GROSSBART: One of the -- the  
21 points of discussion within the work group was  
22 that the components have a -- a -- draw heavily

1 on the clinical guidelines, and there is evidence  
2 for them. These are -- these are the -- the  
3 first numerator is -- is asthma well-controlled  
4 as defined by the most recent asthma control  
5 tools, so there's evidence for that measure, and  
6 then the second one is -- is the occurrence of a  
7 -- more than one ED or inpatient admission visit,  
8 inpatient visit, in the course of the measurement  
9 period.

10 What their measure developer has not  
11 provided is the evidence base for the overall  
12 composite.

13 CO-CHAIR LANG: Closer.

14 DR. GROSSBART: Talk louder?

15 CO-CHAIR LANG: Closer to the mic,  
16 yes.

17 DR. GROSSBART: Okay, closer to the  
18 mic, sorry.

19 So we don't -- we don't -- the measure  
20 itself hasn't been tested or hasn't -- there  
21 hasn't been the evidence base as robust in that  
22 area. That was one of the points raised in our -

1 - our initial evaluation.

2 And -- and actually, the other point  
3 was the ED and inpatient visit intuitively makes  
4 sense, but there was no graded evidence for that  
5 component. I misspoke earlier. So there's no  
6 graded evidence for ED/inpatient visit as being  
7 evidence of -- of well-controlled asthma, and  
8 there was graded evidence for component one,  
9 which is the Asthma Control Plan Questionnaire.

10 CO-CHAIR LANG: So before reflecting  
11 this back to the group, just a -- a mention that  
12 if you wish to comment, those around the table,  
13 oops, please put your name badge in this -- or,  
14 you know, reorient yourself 90 degrees, and that  
15 way, I will know to call on you.

16 For those of you on the phone, there  
17 is a mechanism whereby you can quote unquote  
18 "raise your hand" so that we know that you have  
19 something to say and contribute.

20 So with that said, are there any other  
21 comments from the group? Please.

22 DR. DiGIOVINE: Yes, I had two

1 questions that I couldn't quite figure out.

2 One was in terms of the Asthma Control  
3 Test, I'm not sure I get where the -- where that  
4 measure would be gotten from and how it would be  
5 scored if there was not one that was available in  
6 the last I guess 12 months.

7 The second was do -- do the developers  
8 provide any sense of whether a self-controlled --  
9 a self-reported ER or hospitalization actually  
10 correlates with actual ER and hospitalizations?  
11 To what degree is patient recall accurate?

12 MS. LARSON: This is the developer.  
13 Would you like me to respond?

14 CO-CHAIR LANG: Please.

15 MS. LARSON: Okay.

16 Well first, I want to comment on the  
17 evidence in that this is an outcome measure, and  
18 the evidence requirement for that is just that a  
19 rationale supports the relationship of the  
20 outcome to a process or structure of care, so  
21 graded evidence is not part of the requirement as  
22 we understand it for endorsement.



1           In regards to the Asthma Control Test,  
2 we are looking for a tool result in the 12-month  
3 period, and the absence of a tool result is  
4 judged as not in control. It is -- it is a  
5 numerator miss, as these patients to come into  
6 the denominator do require a face-to-face visit  
7 with the provider, and if they are having a face-  
8 to-face visit and they have a diagnosis of  
9 asthma, the expectation is that they are assessed  
10 for control.

11           In regards to the evidence for patient  
12 recall, there is strong evidence to support that  
13 patient recall is accurate in the last 12 months  
14 regarding emergency room and inpatient  
15 hospitalizations.

16           CO-CHAIR LANG: Thank you for your  
17 response.

18           MS. LARSON: You're welcome.

19           DR. GLOMB: With regard to the second  
20 numerator and the patient recall -- with regard  
21 to the second numerator and the patient recall of  
22 their emergency room visits, we routinely contact

1 a patient within 72 hours of receiving a claim  
2 for an emergency room visit with asthma, and that  
3 claim of course can be anywhere from minutes to -  
4 - to three months later.

5 Nevertheless, the patient recall even  
6 on that -- on that call directed at a specific  
7 date with -- with my company knowing that is --  
8 is often very difficult to -- for them to -- to  
9 recall. So again, I am concerned that without  
10 some sort of a verification, i.e. a claims-based  
11 database for the emergency room visit, that this  
12 -- this measure is subject to a lot of -- of  
13 vagary.

14 CO-CHAIR LANG: All right. I am  
15 actually going to call on myself now.

16 And I have a question for the  
17 developer, and it is this: you have, among the  
18 asthma control instruments in the numerator, you  
19 have the Asthma Control Test, including the  
20 Childhood Asthma Control Test; the Asthma Therapy  
21 Assessment Questionnaire; and the Asthma Control  
22 Questionnaire.

1           The ACT and the ATAQ have been well  
2     validated, and they are four-week instruments.  
3     The Asthma Control Questionnaire I have seen used  
4     largely in clinical research studies, and the  
5     recall period is only one week as I recall based  
6     on that instrument, so I am wondering whether you  
7     can help us reconcile this in terms of the use of  
8     the Asthma Control Questionnaire.

9           MS. LARSON: The Asthma Control  
10    Questionnaire is validated with a control cut  
11    point defined as 0.75. It is true that there is  
12    an indeterminate range of 0.75 to I believe 1.25  
13    or 1.5 for determining truly out of control or in  
14    control, but the group felt strongly about using  
15    the 0.75 cut point, as that is what is specified  
16    in the NHLBI Guidelines where they talk about the  
17    identification -- let's see here --  
18    classifications of asthma control.

19           The three tools selected were based on  
20    those guidelines. Those are the three and only  
21    three that are identified, and those are the cut  
22    points identified as well.

1 CO-CHAIR LANG: Thank you. Are there  
2 any other comments? Please.

3 DR. GROSSBART: So just one real  
4 quick.

5 Can you tell me exactly how this  
6 composite is calculated? I mean, so you have an  
7 Asthma Control Questionnaire, and you have this  
8 recall of ED or inpatient visit, so how is the  
9 composite actually calculated? I see the rates  
10 that you report in the metric, but how is it  
11 calculated?

12 MS. LARSON: Sure, so it's an all-or-  
13 none composite at the patient level, meaning that  
14 all patients who have that -- established  
15 patients who have that face-to-face contact with  
16 an eligible provider and the diagnosis are in the  
17 denominator, and then to be in the numerator,  
18 it's an "and" statement. The patient needs to  
19 have an Asthma Control Tool result in control and  
20 report less than two emergency department visits  
21 and/or hospitalizations due to asthma in the last  
22 12 months.

1 Does that answer your question?

2 DR. GROSSBART: Yes. I -- I've just  
3 worked with all-or-none composites in the past.  
4 I think this one is okay, but sometimes if you  
5 have multiple components of a composite,  
6 particularly the all-or-none, if the numerator of  
7 one of the two components or multiple components  
8 is more than others, it can skew the results.  
9 But this one, I don't think that's a problem. I  
10 just wanted to make sure I understood how it was  
11 calculated.

12 MS. LARSON: Okay. Great.

13 DR. GROSSBART: I do have a point of  
14 -- just a question for the staff.

15 So as an outcome measure, the evidence  
16 bar is different than from a process measure.  
17 But this is a composite that includes a process  
18 measure plus an outcome measure, and what is --  
19 what is the -- what is the bar for the evidence  
20 for the process measure that is -- is a subset of  
21 the overall measure?

22 And then the other comment is that in

1 -- in the past, I don't know that this is  
2 absolutely true, but in the past, the composites  
3 I've seen that have been approved, including one  
4 developed by this -- this -- the -- this  
5 developer, consisted of all NQF-endorsed  
6 measures, and neither of these are NQF-endorsed,  
7 and should that be a factor in our evaluation or  
8 not? Should a composite consist of sub-  
9 components that have been endorsed by the NQF?

10 MS. BAL: So we've put up a slide for  
11 you for the voting so you'll understand that the  
12 vote is different based off of the fact that it's  
13 a composite. You'll be looking for slightly  
14 different things.

15 So unfortunately I can't read from  
16 here, but basically, you are seeing how the  
17 composite works together and if there's evidence  
18 to support it, and I'll see if anybody from NQF  
19 staff want to add any more detail.

20 MS. GORHAM: Robyn? Could you answer  
21 his question regarding the difference between the  
22 process and outcome?

1 DR. NISHIMI: So the process measure  
2 has to stand by itself, and the outcome measure  
3 has to stand by itself. As to whether --

4 PARTICIPANT: And this is the tool  
5 developer. I -- I am a little confused about the  
6 classification of one of these components as a  
7 process measure.

8 DR. NISHIMI: I was just --

9 CO-CHAIR LANG: I would agree.

10 DR. NISHIMI: -- I was just going to  
11 say --

12 CO-CHAIR LANG: It's an outcomes  
13 measure.

14 DR. NISHIMI: -- they -- they call  
15 both of them outcome measures, so in that case,  
16 each component as an outcome measure --

17 CO-CHAIR LANG: So asthma --

18 DR. NISHIMI: -- needs to stand --

19 CO-CHAIR LANG: -- control, she being  
20 asthma control is an outcome.

21 DR. NISHIMI: -- as itself. So they  
22 characterized it --

1 CO-CHAIR LANG: And I don't think of  
2 it as --

3 DR. NISHIMI: -- as an outcome  
4 measure.

5 CO-CHAIR LANG: -- giving the  
6 questionnaire. Got it. I stand corrected.

7 DR. NISHIMI: Oh sorry, and Stephen,  
8 to your -- your other question about whether each  
9 had to be individually NQF-endorsed, no, they  
10 don't, but they do have to stand alone on  
11 themselves, and you will consider them in that  
12 manner.

13 Were there any other questions on how  
14 you're going to consider the evidence here?

15 (No audible response.)

16 CO-CHAIR LANG: Are we ready to vote?

17 MS. BAL: Okay. So as a reminder,  
18 everyone that's on the phone, please chat your  
19 response. We're now voting for the evidence, the  
20 composite for 2852. Your options are 1 high, 2  
21 moderate, 3 low, 4 insufficient, and we're  
22 looking at this composite, specifically



1 articulates and is logical, and that includes all  
2 components and rationale.

3 DR. STOCKWELL: Could you say the  
4 choices again please?

5 DR. NISHIMI: Repeat the choices.

6 CO-CHAIR LANG: The choices are 1  
7 high, 2 moderate, 3 low, 4 insufficient.

8 (Pause.)

9 MS. BAL: Sorry for the delay. We're  
10 still trying to get the logistics of having  
11 people on the phone. Give us one second.

12 (Pause.)

13 DR. NISHIMI: She has to reset the  
14 system, basically.

15 (Whereupon, the meeting went off the  
16 record at 9:57 a.m. and resumed at 10:02 a.m.)

17 DR. NISHIMI: Okay. We're ready to get  
18 started again. Sorry about that. We're going to  
19 revote on that last slide. So, as soon as we get  
20 everyone settled, we'll revote.

21 For folks who are on the phone, we  
22 have your votes in chat, so you don't need to

1 retransmit.

2 (Pause.)

3 MS. BAL: All right, everyone. Thank  
4 you for your patience while we had some technical  
5 difficulties. So, we're actually going to start  
6 the vote on evidence health outcome. And the  
7 composite vote will come after the Outcome and  
8 gap vote. Is that clear to everyone? So, we  
9 will need to have -- they are different  
10 selections, so everyone will need to revote.

11 So, now we are voting on evidence for  
12 2852, health outcome. Your options are 1 yes, 2  
13 no. People on the phone, we do need you to  
14 revote. Again, the options are 1, Yes, 2, No.

15 And so, the vote is that the rationale  
16 supports the relationship of the health outcome  
17 to at least one healthcare structure, process,  
18 intervention or service. And the responses are 1  
19 yes, 2 no.

20 DR. DiGIOVINE: Can I ask a point of  
21 order? I'm sorry. Since it's a composite  
22 measure, I know this was probably already asked,

1 but I'm still -- so if you think for one of the  
2 composite answers the answer is yes and for one  
3 it's no, how would you answer this question?  
4 Because it says at least, so I'm not sure I  
5 understand how I would answer this in a composite  
6 measure. I guess no one else does.

7 CO-CHAIR BRATZLER: I mean, I'm reading  
8 this as the measure is Optimal Asthma Control.  
9 That is the outcome that is be measured. There  
10 are two components to the measurement, but the  
11 measure is Optimal Asthma Control. So, is that  
12 linked to at least one healthcare structure,  
13 process, intervention or service?

14 DR. DiGIOVINE: Thank you.

15 DR. NISHIMI: And you will have a  
16 chance to vote on the composite as a whole.

17 MS. BAL: Okay. Does everybody feel  
18 comfortable voting now? Okay. So please put in  
19 your votes. Again, the options are 1 yes, 2 no,  
20 for evidence for 2852. Yes, please point at me,  
21 not Janine this time, with the remote.

22 Okay. So, the results for 2852 for

1 evidence health outcome is 100 percent yes, zero  
2 percent no. And we can move forward to the  
3 discussion on gap.

4 DR. SCHINDLER: On this measure, I  
5 think the developer did a nice job describing the  
6 gap. They're certainly -- they've been using  
7 this composite measure in Minnesota and they  
8 identified -- it was optimal asthma control is 47  
9 percent in adults and 56 in children. They also  
10 -- there appears to be some racial, language, and  
11 ethnic gaps that they were able to identify. So  
12 I felt like they did a nice job on outlining the  
13 gaps.

14 CO-CHAIR LANG: Is there any additional  
15 discussion?

16 MS. BAL: Okay. So we can vote on gap.  
17 People on the phone, please put your vote in.  
18 So, performance gap for 2852; the options are 1  
19 high, 2 moderate, 3 low, 4 insufficient. Again,  
20 the options are 1 high, 2 moderate, 3 low, 4  
21 insufficient. And you're voting on performance  
22 gap, the data demonstrates considerable variation

1 or overall less than optimal performance across  
2 providers and/or population groups, and this  
3 includes disparities in care. Okay.

4 (Voting.)

5 MS. BAL: So, the results for  
6 performance gap for 2852 is 73 percent high, 27  
7 percent moderate, zero percent low, zero percent  
8 insufficient. And we can move forward to the  
9 composite vote.

10 So, again, this is the composite vote.  
11 This is the whole -- the composite as a whole and  
12 your options are 1 high, 2 moderate, 3 low, 4  
13 insufficient. And just so everybody in the room  
14 knows, the magical number we're looking for is  
15 22.

16 DR. NISHIMI: Ella, we're still waiting  
17 for yours in the chat box.

18 (Voting.)

19 MS. BAL: Okay. Thank you for your  
20 patience. So the results are 14 percent high, 45  
21 percent moderate, 36 percent low, five percent  
22 insufficient. And we can move forward.

1       Actually, no, I'm sorry, we're consensus not  
2       reached, my math is a little slow. Fourteen and  
3       45, yes, so we are in consensus not reached,  
4       however, that just means that we will ask for  
5       comments from the general public, but we do  
6       continue to move on with considering this measure  
7       and voting on the next sections. Thank you.

8                   CO-CHAIR LANG: Reliability?

9                   DR. GROSSBART: So, in the area of  
10       specification and reliability, there were  
11       concerns about the specifications regarding the  
12       second component; this is patient recall of one  
13       or more ED or hospital visits in the course of a  
14       12 month period. And, the reliability testing of  
15       the measure we did feel demonstrated sufficient  
16       validity so that you can make conclusions about  
17       quality, but we were a little -- there was -- the  
18       main validity of the developer's testing of this  
19       measure was to see if there was a high  
20       correlation between clinics that performed well  
21       on the developer's optimal diabetes care measure  
22       and if that correlated with performance on the

1 optimal asthma care measure.

2 Correlation, we did not believe was  
3 very strong, 0.62 for adults and 0.66 for  
4 children, we felt those were on the weak side;  
5 and those were major points that I wanted to  
6 raise. Just scrolling through the -- in terms of  
7 the measure, other aspects of the validity  
8 testing. Missing data is not a challenge.

9 Exclusions of the measure, which  
10 include -- the exclusions are appropriate, such  
11 as patients with COPD. There is a risk  
12 adjustment within the measure, which adjusts for  
13 depression, tobacco use, and tobacco exposure.  
14 The risk model didn't seem to be that strong in  
15 explaining away variation. Those are the --

16 CO-CHAIR LANG: Risk adjustment would  
17 be in the area of validity.

18 DR. GROSSBART: Am I jumping ahead  
19 here?

20 CO-CHAIR LANG: Yes.

21 DR. GROSSBART: I'm sorry.

22 CO-CHAIR LANG: That's okay, Steve; go

1 ahead.

2 DR. GROSSBART: Okay. Well, then I'll  
3 just turn it over to my partner here --

4 DR. SCHINDLER: Right.

5 DR. GROSSBART: -- for additional  
6 comments.

7 DR. SCHINDLER: I think you hit all the  
8 main reliability points that we had discussed. I  
9 had a couple for validity, but --

10 CO-CHAIR LANG: Are there any other  
11 comments from members of the committee concerning  
12 reliability?

13 DR. DiGIOVINE: Yes. We brought it up  
14 earlier, I just -- in terms of validity, it would  
15 seem like this would be the --

16 CO-CHAIR LANG: We're not there yet.

17 DR. DiGIOVINE: Okay, then I will hold  
18 my point.

19 CO-CHAIR LANG: Dale?

20 CO-CHAIR BRATZLER: So just one real  
21 quick question and perhaps the developer -- I  
22 mean, there's been a lot of question raised about



1 the recall of ED or inpatient admission. So, has  
2 the developer considered using -- since I suspect  
3 this would be calculated at the plan level often  
4 -- claims data or other sources, rather than  
5 patient recall for that component of the  
6 composite? The ED or inpatient visit?

7 MS. LARSON: Yes. This is Jasmine.  
8 Because our data source is the medical record  
9 provided and the data is provided by the  
10 provider, the practices themselves, we have not  
11 explored merging data from different data sources  
12 to get at ED visits or hospitalizations due to  
13 asthma. Also, and part of that was due to our  
14 evidence review and the articles we found that  
15 demonstrated that recall was a reliable way to  
16 capture these events.

17 CO-CHAIR LANG: Thank you, Jasmine.  
18 Are there any other comments, questions  
19 concerning reliability? Please, go ahead Bill.

20 DR. GLOMB: Yes. Just to follow up on  
21 what Dale said, again, I commented on this  
22 earlier, I don't know at what point we can

1 interject suggestions, but I think it's time to  
2 interject that that data sources needs to be  
3 different than the provider record. All of us as  
4 providers know that even when we ask, we don't  
5 always incorporate the answer or get an answer in  
6 the medical record as to have you been in the  
7 emergency room since our last visit?

8 And so I'm just very concerned that  
9 that then would be used as a marker of how well  
10 the primary care physician, for instance, might  
11 be taking care of the patient's asthma, when in  
12 reality they simply may not have that number or  
13 the number might be incorrect based on patient  
14 not -- misremembering, shall we say.

15 CO-CHAIR LANG: The other issue, just  
16 to mention this, I recall when this quality  
17 measure was addressed a few years ago that we  
18 discussed the issue of hospitalization versus an  
19 emergency department visit not being apples and  
20 apples in terms of what it means with regards to  
21 the patient and the risk domain. That there's a  
22 subjective component in terms of whether one goes

1 to the emergency department, but then there are  
2 more objective criteria as to whether someone  
3 gets hospitalized.

4 So, Jasmine, I'm wondering whether you  
5 can comment on that issue, which was raised  
6 previously and I'm raising it again at this time.

7 MS. LARSON: Certainly, I'll do my  
8 best. Again, the measure development work group  
9 relied heavily on the NHLBI Guideline. And in  
10 their classification of asthma control, when they  
11 are evaluating potential risk of exacerbations,  
12 zero to one events, whether they be ED or  
13 hospitalizations, were defined as well controlled  
14 in the last 12 months.

15 MS. BAL: Okay. So, we're now going to  
16 vote on reliability for 2852. The options are 1  
17 high, 2 moderate, 3 low -- I'm sorry.

18 CO-CHAIR LANG: Excuse me.

19 MS. BAL: Sorry, hold on one second on  
20 the vote.

21 CO-CHAIR LANG: Excuse me, we have one  
22 more comment.

1 DR. MURRAY: Well, I'd say it's a  
2 question. Are there any NQF endorsed measures  
3 that are currently in use that have been based on  
4 this type of a recall construct? And, if so, are  
5 they working well for improving quality? Do we  
6 know anything like that?

7 DR. NISHIMI: Not in the pulmonary  
8 portfolio, but I couldn't speak to the rest of  
9 the portfolio frankly.

10 MS. BAL: Not as far as we know.

11 DR. MURRAY: And then as a follow-on  
12 question, did the developers consider an  
13 alternative indicator that perhaps might be  
14 easier to remember or might actually be reported  
15 in the chart, which would be oral prednisone as  
16 an alternative to ED and hospital visits?

17 MS. LARSON: Actually -- so, this is  
18 Jasmine. The measure development work group did  
19 consider that and the evidence showed that recall  
20 of oral prednisone use was actually poorer than  
21 recall of ED and hospitalizations. And I will  
22 say, this measure has been in use in Minnesota

1 for upwards of four or five years and this  
2 information is well documented in the medical  
3 record and validated through audit.

4 DR. NISHIMI: And, actually, I do want  
5 to speak to the question about -- rolling back my  
6 tape. There are obviously a whole body of  
7 measures on patient reported outcomes that NQF  
8 has looked at and there have been vaccination  
9 measures that rely on whether the patient reports  
10 they received the vaccination, for example, in  
11 the case of a pneumococcal vaccination.

12 MS. BAL: There was a question about if  
13 the measures are working well and Robin responded  
14 that they are currently endorsed, but we don't  
15 have more information than that. Just for the  
16 record. Okay. Were there any other questions?

17 MS. WEST: Thank you. I guess I'm just  
18 a little bit conflicted. So, the numerator  
19 indicates that it's looking to estimate the  
20 number of emergency room visits. Looking at the  
21 code list, without knowing all of the CPT codes,  
22 are the inpatient admissions assuming that the

1 patients are coming through the ED?

2 MS. LARSON: So this is Jasmine. I  
3 believe that question was directed towards me.

4 MS. WEST: Yes.

5 MS. LARSON: So, again, both of these  
6 components are patient reported, including the ED  
7 and inpatient events. In inpatient  
8 hospitalization -- I'm sorry, it's an ED visit  
9 without an admission and/or an inpatient  
10 hospitalization regardless of how they arrived  
11 there.

12 MS. WEST: But then it's going into the  
13 numerator estimating the number of emergency room  
14 visits.

15 MS. LARSON: It's not an estimate, it  
16 is the patient's report of the number of events  
17 in the previous 12 months.

18 MS. BAL: I think Stephen had his card  
19 up.

20 DR. GROSSBART: In the course of this  
21 debate, it struck me that since NQF measures are  
22 about being able to publically report performance

1 by a provider for a level of accountability, is  
2 there a potential unintended consequence of  
3 providers not asking the question, do you recall  
4 any visits, and not entering it? So, therefore,  
5 I mean, if you're going to be up on the website  
6 in Minnesota -- I mean I know that would be not  
7 typical, but it could happen, especially if  
8 you've known a patient's been in once, why ask  
9 again, and get the public dinging.

10           Whereas, if we used claims data, it  
11 would be -- with an admission or visit for a  
12 diagnosis of asthma, it would be much more  
13 reliable. And again, you did mention the results  
14 in Minnesota are audited, but what is the rate of  
15 patients who don't have -- whose number of visits  
16 to the ED or inpatient is inconsistent with what  
17 the claims record is? Have you tested that?

18           DR. SCHINDLER: And, Stephen, this I  
19 think dovetails with a question I had with the  
20 validity, is that -- Jasmine, this kind of goes  
21 with Stephen's question, but you had said there  
22 wasn't a problem with missing data, but there

1 weren't -- if you could talk about that a little  
2 bit more. It just wasn't further explicated and  
3 I think it gets to this exact point around data  
4 capture.

5 MS. LARSON: Sure, I'll do my best. So  
6 if the patient's response to the question is not  
7 documented in the medical record or if  
8 documentation of if the question was asked is not  
9 in the medical record, that counts as a numerator  
10 miss. So, the patient remains in the  
11 denominator, but does not meet the target of the  
12 measure. And upon validation audit, the auditor  
13 needs to be able to confirm the number that was  
14 reported in the data submission against the  
15 medical record itself.

16 So any missing data, including a  
17 missing assessment or the question not asked  
18 counts as a numerator miss, but as I stated, the  
19 patient remains in the denominator. And, I'm  
20 sorry, I think you had another question and now  
21 I've lost track of it in my mind.

22 DR. GROSSBART: Correlation between the



1 self-reported data and the claims.

2 MS. LARSON: Right. So in Minnesota we  
3 don't have an all-payer claims database, so we  
4 don't necessarily have a data source to be able  
5 to provide all of the complete claims history.  
6 And then the matching -- the patient-to-patient  
7 level matching of the data would also be  
8 problematic. And that's then also compounded by  
9 the timing of when that would be available.

10 Our reporting from the medical groups,  
11 from the practices themselves, has a data  
12 submission that occurs six to 12 weeks after  
13 completion of the measurement period dates of  
14 service. And, as I'm sure you are all well  
15 aware, claims data would not be ready for that  
16 kind of comparison or analysis for quite some  
17 time lag after that point.

18 CO-CHAIR LANG: Chana, Rich, did you  
19 have questions or comments? Anyone else?

20 MS. BAL: Okay. Thank you, everyone.  
21 So, now we're voting on reliability for 2852, the  
22 options are 1 high, 2 moderate, 3 low, 4

1 insufficient.

2 Again; 1 high, 2 moderate, 3 low, 4  
3 insufficient. And we are voting on precise  
4 specifications and that the testing is  
5 appropriate and has a scope with adequate  
6 results.

7 DR. NISHIMI: David, we're still  
8 waiting for your vote in the chat box. David?  
9 Okay, we got it.

10 (Voting.)

11 MS. BAL: So, the results for  
12 reliability for 2852 is zero percent high, 50  
13 percent moderate, 41 percent low, nine percent  
14 insufficient. That does put us in the grey zone,  
15 and as mentioned earlier, we will continue  
16 discussing this measure.

17 CO-CHAIR LANG: Validity, Christine,  
18 Steve?

19 DR. SCHINDLER: Jasmine, I think we  
20 touched on a little bit of the validity in terms  
21 of missing data. One of the other questions I  
22 had for you was in this section about exclusions.

1 You had documented that cystic fibrosis, COPD,  
2 emphysema, and acute respiratory failure were  
3 exclusions and then a couple bullets below -- as  
4 well as certain eligible populations that  
5 consistently less than one percent of the total  
6 population met these criteria, which just --  
7 there was some dissonance for me around that  
8 because we know that the incidence of those  
9 diseases are probably -- I would anticipate  
10 Minnesota is not different than the rest of the  
11 country -- if you could just touch on why it was  
12 consistently less than one percent that met those  
13 exclusion criteria.

14 MS. LARSON: Sure. This is Jasmine.  
15 I apologize for that lack of clarity. So, we do  
16 ask providers to share an exclusion file around  
17 the allowable exclusions. The required  
18 exclusions would include the other respiratory  
19 conditions, is not included in that one percent.

20 DR. SCHINDLER: So, in terms of  
21 validity then, how many or what percentage of the  
22 patients are excluded?

1 MS. LARSON: What percentage of  
2 patients are excluded due to the respiratory  
3 conditions?

4 DR. SCHINDLER: Yes.

5 MS. LARSON: We don't have that  
6 information.

7 DR. SCHINDLER: Okay.

8 MS. LARSON: They're generating a  
9 patient list based on query of their system with  
10 the inclusion criteria and then excluding these  
11 diagnoses up front. But the measure development  
12 work group felt pretty strongly about excluding  
13 these conditions given that the control tools  
14 were not validated on patients with those  
15 comorbid conditions and control of asthma  
16 symptoms, they felt it was difficult to assess  
17 the symptom burden and isolate asthma from these  
18 other respiratory conditions.

19 DR. SCHINDLER: Okay. Thank you.

20 DR. GROSSBART: At this juncture, we're  
21 also evaluating the risk adjustment model and the  
22 outcome is adjusted by the following measures:

1 gender, age, zip code, race, ethnicity, country  
2 of origin -- if I'm reading this correctly --  
3 primary language, and insurance product, as well  
4 as comorbidities of depression, tobacco use, and  
5 tobacco exposure. The risk adjustment model only  
6 shows that insurance product, Medicaid, Medicare,  
7 commercial status, et cetera, is statistically  
8 significant.

9 And then also, I have a question of  
10 why tobacco use is considered a risk adjuster?  
11 And this is more of a comment to the developer;  
12 tobacco use is part of the optimal diabetes care,  
13 are you using tobacco? Why wouldn't tobacco use  
14 be part of the optimal asthma care as a part of  
15 the composite measure as opposed to a control  
16 variable in the risk adjustment model? It just  
17 strikes me as incongruous. That's a comment.

18 CO-CHAIR LANG: Anything else on risk  
19 adjustment?

20 DR. GROSSBART: I think that covers our  
21 major comments on this section.

22 CO-CHAIR LANG: Thank you, Christine,

1 Steve. Any other comments, questions from other  
2 members of the committee? Going once, going  
3 twice. Thank you. Poonam?

4 MS. BAL: Okay. Voting for validity  
5 for 2852 is now open. The options are 1 high, 2  
6 moderate, 3 low, 4 insufficient. Again, the  
7 options are 1 high, 2 moderate, 3 low, 4  
8 insufficient.

9 You're voting on the specifications  
10 are consistent with evidence, that there's an  
11 appropriate method and scope with adequate  
12 results for the testing, and that the following  
13 threats are addressed: exclusions, risk  
14 adjustment, meaningful differences, compatibility  
15 with multiple specifications, and missing data.

16 (Voting.)

17 MS. BAL: Sorry, so the results are  
18 zero high, 14 moderate, eight low, zero  
19 insufficient. And percentage-wise, we do hit the  
20 requirement for a pass on this requirement. So,  
21 now, we'll vote on the composite portion.

22 DR. KAZEROONI: I'm sorry, can you

1 repeat the results of the voting?

2 MS. BAL: One second.

3 CO-CHAIR BRATZLER: It was 64 percent

4 --

5 MS. BAL: Yes.

6 CO-CHAIR BRATZLER: -- so it passed.

7 MS. BAL: Yes. And so, for numbers  
8 wise, 14 moderate, eight low. Okay. So we're  
9 now voting on scientific acceptability of the  
10 measure properties as a composite. And so the  
11 options are 1 high, 2 moderate, 3 low, 4  
12 insufficient. Again, 1 high, 2 moderate, 3 low,  
13 4 insufficient. And again, you don't have to  
14 wait for me to finish talking, just a way to give  
15 you the information, so we can continue to vote  
16 whenever you would like.

17 And the composite for this, we're  
18 looking that empirical analysis support composite  
19 construction and that composite measures fit  
20 quality, construct, add value, and so on.

21 (Voting.)

22 MS. BAL: Okay. So the number results

1 are zero high, 13 moderate, nine low, zero  
2 insufficient for the composite scientific  
3 acceptability for 2852. And for percentages, we  
4 are in the grey zone for this section, but we  
5 continue to move on to feasibility.

6 CO-CHAIR LANG: Discussion of  
7 feasibility; Steve, Christine?

8 DR. SCHINDLER: Jasmine, it looks like  
9 this has been really feasible in Minnesota,  
10 you've done a nice job collecting. All the data  
11 elements are in the EHR. I guess my question for  
12 you was: do you know are these measures,  
13 particularly the asthma control measures, being  
14 used nationally? If not, how hard would that be  
15 to implement? Just, are they the current  
16 standard of practice everywhere?

17 MS. LARSON: Thank you for the  
18 question. This measure, the composite measure,  
19 has been included in PQRS for this program year.  
20 This is the first time that it has been  
21 implemented nationally and I don't have any  
22 information about the feasibility of it beyond



1 its current implementation.

2 CO-CHAIR LANG: Jasmine, this is David  
3 Lang. I have a question. In the feasibility  
4 section, you state all data elements are in  
5 defined fields in electronic health records. Yet  
6 on the page 1 of the measure information, you  
7 state one of the data sources as being paper  
8 medical records. Could you please elaborate on  
9 that?

10 MS. LARSON: Certainly. So, our data  
11 collection and submission process in Minnesota is  
12 one that is supportive of medical groups at all  
13 stages of EHR implementation, including those  
14 that are on fully paper charts all the way  
15 through those that have a fully implemented EHR  
16 with discrete data capture. And so, we have  
17 specified it so that manual extraction can occur  
18 and those groups can participate in reporting for  
19 these measures, but we also know that the  
20 majority of practices in the state of Minnesota  
21 have done builds in their EHRs to be able to  
22 capture the data elements discretely so that they

1 can programmatically extract the information.

2 CO-CHAIR LANG: So, a brief follow-up.  
3 So then, if your health service utilization  
4 component of the measure is by patient self-  
5 reports, so then those data presumably are being  
6 entered into Smart Fields in the electronic  
7 medical record so they're retrievable?

8 MS. LARSON: That is correct.

9 CO-CHAIR BRATZLER: Jasmine, what --  
10 tell me about the Minnesota public reporting. I  
11 mean, what's the teeth that makes all the  
12 practices do this? I can see it being done in a  
13 health plan level or other things, but, I mean,  
14 do you have every practice in the state? What  
15 are the teeth that make people actually do this,  
16 to add these data fields to the electronic  
17 medical record or report this?

18 MS. LARSON: Sure. I mean, we are the  
19 first to admit that Minnesota is unique and we  
20 have had voluntary data reporting since 2004, but  
21 we also do have the benefit of, since 2004  
22 actually -- I'm sorry, effective 2008,

1 implemented in 2009, we had a Minnesota  
2 Department of Health state mandate for quality  
3 reporting for physician practices.

4 So, I hesitate to call that teeth  
5 because there isn't necessarily penalties or  
6 enforcement of that, but it is a state rule as  
7 well. But prior to that state rule, we still had  
8 70 percent of medical practices voluntarily  
9 submitting data to us.

10 MS. BAL: Okay. So we're now going to  
11 vote on feasibility for 2852. The options are 1  
12 high, 2 moderate, 3 low, 4 insufficient. Again,  
13 1 high, 2 moderate, 3 low, 4 insufficient. And  
14 for Feasibility, we're looking at that the data  
15 is generated during care, there are electronic  
16 sources, and that the data collection can be  
17 implemented.

18 (Voting.)

19 MS. BAL: Okay. The results for 2852  
20 feasibility are seven high, 12 moderate, three  
21 low, four insufficient. And with the  
22 percentages, we are actually passing this measure

1 and we can move forward to usability.

2 CO-CHAIR LANG: Usability is the extent  
3 to which consumers, purchasers, policymakers, use  
4 or could use the performance results for  
5 accountability and performance improvement  
6 activities and would include discussion of  
7 unintended consequences. Please; Steve,  
8 Christine?

9 DR. GROSSBART: So, this is currently  
10 in use, as noted, in Minnesota. It's available  
11 on their website, each practitioner, each group  
12 is -- sees their overall score. It has been  
13 shown to lead to improvement of care in Minnesota  
14 over time. The unintended consequences appear to  
15 be minimal.

16 It does not appear to be burdensome  
17 for clinicians to collect in Minnesota. And as  
18 noted, this has been incorporated in PQRS, so  
19 it's gaining traction as a quality measure  
20 nationally, or has the potential to gain traction  
21 as a quality measure nationally.

22 DR. SCHINDLER: I don't have much to

1 add. The Minnesota group is really using this  
2 quite extensively in both accountability,  
3 payment, quality measures within the state. They  
4 seem to -- yes, do a great job using it and  
5 publically reporting it and it's easy to find.

6 MS. BAL: Okay. So we're now voting on  
7 the usability and use of 2852. The options are 1  
8 high, 2 moderate, 3 low, 4 insufficient. And  
9 you're looking at if there's accountability and  
10 transparency, if there's been improvements seen,  
11 and if the benefits outweigh the evidence of  
12 unintended negative consequences. Again, the  
13 options are 1 high, 2 moderate, 3 low, 4  
14 insufficient.

15 (Pause.)

16 MS. BAL: Okay. So we're missing  
17 somebody in the room for one more vote. Did  
18 someone step out? Okay. You have two seconds.  
19 All right. So we're just going to go ahead and  
20 move forward.

21 (Voting.)

22 MS. BAL: Oh, we got the last vote in.

1 So, the results for usability for 2852 are nine  
2 high, 12 moderate, one low, zero insufficient.  
3 And for percentages wise, we can move forward.  
4 Okay. So now we're going to vote on the overall  
5 suitability for endorsement for the full  
6 composite measure. And your options are 1 yes, 2  
7 no. Again -- oh, I'm sorry, there's a question.  
8 Hold on one second.

9 DR. O'BRIEN: Just a quick question.  
10 I know this isn't part of the voting, but the  
11 comparison of related or competing measures and  
12 harmonization, the developers mention that there  
13 aren't relations to other NQF measures. I can't  
14 help but notice that we have multiple other  
15 measures looking at admission rate for asthma, ED  
16 visits for asthma, so I'm unsure why these  
17 weren't identified as potentially related  
18 measures by the developer.

19 MS. LARSON: This is Jasmine. I  
20 believe those are new candidate measures as well,  
21 are they not?

22 DR. O'BRIEN: I don't believe so.

1 Those are in maintenance.

2 MS. BAL: So if you look, we have  
3 identified some measures as related to the  
4 optimal asthma care, we do want to make sure that  
5 -- not all measures are considered related. If  
6 they don't have the same population or don't have  
7 the same focus, they wouldn't be considered  
8 related.

9 The reason that the two measures that  
10 were identified as related is because an aspect  
11 of this measure is already covered in those  
12 measures. So, those are more just kind of  
13 similar concepts, but not the same focus.

14 DR. O'BRIEN: Asthma in Younger Adults  
15 Admission Rates seems to be the same population,  
16 same outcome measure; so I'm just trying to  
17 figure out how those are harmonized, where the  
18 overlap might be. Certainly, it creates a lot of  
19 frustration, I find, for providers when they do  
20 really well on one measure and not the other one  
21 that seem to be the same construct.

22 MS. BAL: So if you feel that way, we

1 can definitely reevaluate that when we get to the  
2 related and competing. If you want to list  
3 additional measures for consideration underneath  
4 that, we can definitely do that.

5 But as I mentioned earlier, we do vote  
6 on the measure as-is and then speak about related  
7 and competing later. Were there any other  
8 questions before we vote?

9 (No response.)

10 MS. BAL: All right. So voting is  
11 open for overall suitability for endorsement.  
12 The options are 1 yes, 2 no. This is your  
13 initial recommendation to CSAC and the members.

14 (Voting.)

15 MS. BAL: Okay. So for the vote for  
16 overall suitability, we have ten yes, 12 no. So  
17 we actually are in the grey zone for overall  
18 suitability, so when we got out to comment, we  
19 write up the draft report, we'll make sure to  
20 mention and ask for comments specifically towards  
21 this. And since we were in the grey zone for  
22 overall suitability, we will revote for this



1 measure.

2 So, thank you, everyone. And it is  
3 break time. Since we did have that technical  
4 difficulty break, perhaps we could do ten minutes  
5 instead of five, would that be okay?

6 CO-CHAIR LANG: Yes.

7 MS. BAL: All right. Thank you. We'll  
8 take a ten minute break. Oh, never mind, we can  
9 just go ahead -- yes, we can do 11:00.

10 (Whereupon, the above-entitled matter  
11 went off the record at 10:46 a.m. and resumed at  
12 10:59 a.m.)

13 CO-CHAIR LANG: We're going to resume.  
14 Everyone, please take your seats. There's been a  
15 change from the agenda that was distributed in  
16 the sequence with which we will address measures  
17 in the next segment such that we will address  
18 measure 2856 now.

19 Measure 2856 is entitled  
20 Pharmacotherapy Management of COPD Exacerbation.  
21 This is an event-based measure that was  
22 previously endorsed as number 0549, but the

1 endorsement was removed in the last pulmonary  
2 project in July 2012 and the developer has  
3 resubmitted the measure for consideration. The  
4 measure -- actually, if the developer -- do we  
5 have -- Lindsey, Mary, do you wish to briefly  
6 summarize the measure in two to three minutes for  
7 us? Thank you.

8 MS. ROTH: Hello. I'm Lindsey Roth,  
9 Senior Healthcare Analyst at NCQA, and this is  
10 Mary Barton, Vice President for Performance  
11 Measurement. So, just to summarize the measure,  
12 this is an episode-based measure that assesses  
13 whether patients 40 years or older who appeared  
14 in the emergency department or the hospital for a  
15 COPD exacerbation are on or were dispensed  
16 corticosteroids and bronchodilators.

17 And two rates are reported. There's  
18 the percent that were dispensed a corticosteroid  
19 within 14 days of the event and also the percent  
20 who were dispensed a bronchodilator within 30  
21 days of the event, and the measure is based on  
22 clear guidelines and evidence that administering

1 corticosteroids and bronchodilators following an  
2 exacerbation reduces symptoms and shortens  
3 recovery time. And the measure is important to  
4 improving quality in this area.

5           So this is a health plan level measure  
6 and it uses administrative and pharmacy data to  
7 assess whether medication was dispensed to the  
8 patient. And we will be discussing several  
9 health plan level measures today that capture  
10 medication that was captured through  
11 administrative and pharmacy data, which is really  
12 the best approach we currently have for measuring  
13 medication management at the national health plan  
14 level at this point.

15           But over the past several years, we  
16 have had conversations both with the Pharmacy  
17 Quality Alliance and with health plan  
18 representatives about the potential for patients  
19 who may be dispensed medications outside of their  
20 pharmacy benefit or at pharmacies such as CVS or  
21 Walmart and how this may affect capturing  
22 dispensed data that's not paid for through the

1 patient's health plan. But what we have learned  
2 is that health plans are working hard to get this  
3 data from pharmacies and even going so far as to  
4 provide them incentives in order to get the data  
5 and that pharmacies are really willing to feed  
6 the data to plans because of their mission for  
7 improving quality.

8 So, because of this improved data  
9 exchange, there's been a lot of improvement in  
10 health plans' ability to capture prescriptions  
11 that were dispensed outside of their health plan.  
12 And we also had the opportunity to discuss this  
13 measure with the previous steering committee and  
14 we did bring the measure back to our expert panel  
15 after it lost endorsement to discuss some of the  
16 issues that were raised last time.

17 One of the issues that came up was  
18 related to capturing medication samples that are  
19 dispensed in the emergency department. And this  
20 is a practice that would actually affect all  
21 medication related quality measures and there are  
22 many NQF endorsed measures that currently do not

1 capture medication samples. But for this  
2 particular health plan level measures, we did  
3 survey several ED physicians and they confirmed  
4 that samples for the corticosteroids are rarely  
5 provided. Samples given in the ED for  
6 bronchodilators may be a little bit more likely.

7 But what we had done is that we  
8 specified the bronchodilator rate to account for  
9 situations like this; so we actually allow the  
10 patient to receive the bronchodilator within 30  
11 days following the event, and this is if they  
12 were given a sample or had their prescription  
13 filled in the ED that day. The typical day  
14 supply is 30 days, so this would allow them to  
15 have their prescription refilled in the  
16 outpatient setting within 30 days. And so,  
17 therefore, the patient would count toward the  
18 numerator.

19 So, we really tried to specify the  
20 measure to account for all situations where a  
21 patient was already on or received the medication  
22 following the event in a timely manner. And,

1 finally, I just wanted to mention that the  
2 measure is a health plan accountability measure  
3 that's used in national public reporting programs  
4 and that plans have demonstrated around a six  
5 percentage point improvement since 2008 on both  
6 measured rates and there is further room for  
7 improvement, particularly on the corticosteroid  
8 rate.

9 CO-CHAIR LANG: Thank you. And we have  
10 -- to discuss this, we have Crystal and Thomas.  
11 Take it away.

12 DR. RILEY: Thank you. I'll start with  
13 evidence, I think. So, this measure was based  
14 primarily on two clinical practice guidelines  
15 that seem to have pretty robust levels of  
16 evidence. So the practice guidelines that were  
17 utilized encompass well over 600 studies between  
18 the two of them, so there seems to be a pretty  
19 robust level of evidence that this measure is  
20 based on.

21 I think one of the primary questions  
22 that we had when we started reviewing this

1 measure was why the endorsement was initially  
2 pulled and why it's being brought back now? And  
3 I think Lindsey just touched on that a little  
4 bit, so just a question for the developer; given  
5 that there's a note in this guide that the  
6 specifications for the measure were largely  
7 unchanged from the initial measure that was found  
8 under a different NQF number and this current  
9 one, was looking at the administration of  
10 medication samples the only thing that was  
11 reviewed or revised or were there other  
12 components that were sort of adjusted that  
13 compelled you to bring this measure back under  
14 review?

15 MS. ROTH: Thanks. Thanks for that  
16 question. So, the reason the Measure did not  
17 pass last time was related to the validity  
18 component, which the main issue was discussion  
19 around the providing samples of the medications  
20 and also I think due to some confusion around how  
21 we were defining active medications. So, I think  
22 my comments earlier touched more on the ED sample

1 issue, but those were the two main reasons.

2 DR. RILEY: Okay. And just looking at  
3 the patient population, we're looking at acute  
4 inpatient discharge or ED encounter, was there  
5 any thought given to patients that might show up  
6 at an urgent care facility? Was that lumped into  
7 ED or was that looked at separately or just sort  
8 of disregarded as an option for patients to  
9 receive care?

10 MS. ROTH: So, we did not look at  
11 urgent care. We did separate -- we looked at  
12 emergency department and hospital admissions  
13 only.

14 DR. RILEY: Okay.

15 DR. BARTON: There's still a lot of  
16 improvement to happen --

17 DR. RILEY: Right.

18 DR. BARTON: -- at those more acute  
19 settings, but I agree that it would be  
20 interesting in the future, should these top out  
21 and everyone's doing great on the ED, then go  
22 down a level of acuity and look at what's



1       happening in urgent care centers.

2               DR. RILEY: Okay.

3               CO-CHAIR BRATZLER: So, it's been a  
4       while since I've looked at these particular  
5       guidelines. I guess what worries me about --  
6       particularly when we get to the gap, but talking  
7       about the need for the metric, is that you're  
8       looking at corticosteroids prescribed within 14  
9       days, or filled essentially because you're  
10      looking at pharmacy data, and bronchodilators  
11      within 30 days. So, I would be shocked that many  
12      patients with an acute exacerbation of COPD come  
13      through an ED and don't get one or both  
14      medications.

15              And so I guess the question is at what  
16      point in time, if the patient has a relatively  
17      quick and good response to the initial management  
18      in the emergency department, is it necessary to  
19      continue that? I don't like keeping patients on  
20      corticosteroids for any length of time after an  
21      acute exacerbation if they don't continue to need  
22      them.

1                   So, I guess we'll get more into  
2                   validity and other things, but how often -- I  
3                   mean, have we done reviews to look at the cases  
4                   that are failing the measure to see what's  
5                   actually happening to them in the emergency  
6                   department in terms of defining that gap?

7                   MS. ROTH: So, I think what I can say  
8                   is that we based the measure as close as possible  
9                   to the guidelines. And so we cited several, the  
10                  main ones being the GOLD guidelines, that clearly  
11                  state that the patient should be provided these  
12                  two medications within a timely manner. And so,  
13                  I think that's -- we just wanted to align with  
14                  those as closely as possible. I don't know,  
15                  Mary, if you want to add anything?

16                  DR. BARTON: I think I would just add  
17                  that our respiratory advisory panel includes a  
18                  lot of clinicians who do have direct experience  
19                  in practice and in health plans and at no time --  
20                  and as well as the fact that NCQA uses a feedback  
21                  loop where we ask people who implement our  
22                  measures to report to us any difficulty with

1 reporting the measures or any clinical  
2 uncertainty around the specification of the  
3 measures, and we have not heard that particular  
4 criticism from our user group, from our advisory  
5 panels, so while I can't give you a positive  
6 saying that I've heard your exact point negated,  
7 I've also not heard it brought up.

8 CO-CHAIR BRATZLER: I guess the other  
9 point I wanted to make is you alluded to getting  
10 pharmacy data from other sources. So I know what  
11 I'm seeing in our practice a lot is patients  
12 going and getting their \$4 medications, which is  
13 a lot less expensive than the co-pays for some of  
14 the pharmacy plans that they're dealing with.

15 So, how much of that data do you  
16 actually get? We find it to be very, very common  
17 for patients that don't show up in the pharmacy  
18 database, but we know the patient's getting the  
19 medication because they go pay \$4 for it.

20 DR. BARTON: And that's where the  
21 health plan has really better -- more leverage  
22 than a physician practice has, because the main

1 providers of the \$4 medicines are huge chains  
2 like Walgreens, Walmart, and health plans often  
3 work with them to get the data; that's the  
4 situation Lindsey spoke of where health plans  
5 actually provide incentives to pharmacies to  
6 report data to them because they want to have a  
7 complete record and the pharmacies are willing to  
8 do that. So, I think that's the answer of how we  
9 see the health plans performing at the level that  
10 we see.

11 DR. LAMPONE: I had one additional  
12 comment on that point. I think when you're  
13 dealing with the health plans, one of the  
14 challenges they have is being able to identify  
15 their membership going to that particular chain.  
16 So, if that member does not present their  
17 insurance card and they're getting a  
18 corticosteroid filled, which even off-plan is  
19 very, very cheap, for example, prednisone. Maybe  
20 some of the short-acting inhalers are a bit more  
21 expensive, but they may be able to get them  
22 cheaper at other chains or even the VA, a lot

1 less expensive.

2 So if they don't present their health  
3 card, the health plan doesn't know that they are  
4 there. And, as you look across the states,  
5 there's different levels of penetration, if you  
6 will, in engaging the national chains at the  
7 state level and at the plan level in those states  
8 to get that information back. And it does cause  
9 some burden of data collection on the plans, so  
10 they have to do a lot of work. But you're  
11 absolutely right, there is initiatives underway  
12 to close that data gap with the plans.

13 CO-CHAIR LANG: Are there any  
14 additional comments by members of the committee  
15 or on the phone? Questions for the developers?  
16 Okay. We're going to vote on the evidence.

17 MS. AMIRAULT: So, we're going to go  
18 ahead and vote on evidence for measure 2856.  
19 Your options are 1 high, 2 moderate, 3 low, and 4  
20 insufficient. Just one second, sorry about that.  
21 Okay, polling is open.

22 (Voting.)

1 DR. NISHIMI: David, we're still  
2 waiting for your vote. So, can everyone in the  
3 room please point to Janine again and vote. And  
4 David, we're still waiting for your vote.

5 (Voting.)

6 DR. NISHIMI: Okay, we got it, David.

7 MS. AMIRAULT: Okay. So there are nine  
8 votes for high, 12 moderate, one low, and zero  
9 for insufficient, for evidence for 2856. And  
10 based on the percentages, we can move along.

11 CO-CHAIR LANG: Thank you. Crystal,  
12 Tom, performance gap?

13 DR. RILEY: So, looking at performance  
14 gaps, the developer notes that COPD does have a  
15 rather high incidence, 15 million adults impacted  
16 each year, presumably high cost; and there's also  
17 a predicted rise in mortality rate over the next  
18 several years, about 30 percent. So there is an  
19 opportunity to engage early and sort of head the  
20 incidence off.

21 They've also indicated that there are  
22 disparities found across several aspects of the

1 patient population; looking at gender, racial,  
2 ethnic, area, socioeconomic status, looking at  
3 payers, and also patients with various  
4 comorbidities. So there is a high occurrence of  
5 disparities in COPD as well that should be looked  
6 at.

7 DR. LAMPONE: I would agree. I have no  
8 other additional comments to that. It's  
9 interesting that the data that they did develop  
10 -- that they did report out showed that  
11 Caucasians had a 45 percent higher mortality rate  
12 than other races or ethnicities, although African  
13 Americans had a higher ED visit, which brings up  
14 the issue of access to care and are there  
15 problems in that domain, either to medication or  
16 to proper follow-up and adherence?

17 DR. RILEY: As well as variance in the  
18 services that they actually do receive when they  
19 do present to the ER or inpatient setting.

20 CO-CHAIR LANG: Thank you. Is there  
21 any other additional discussion questions?

22 DR. DiGIOVINE: I just had a question

1 about the data that you show around use of  
2 systemic corticosteroids and bronchodilators from  
3 HEDIS. Is that data after an exacerbation or is  
4 that just data in patients with COPD? And the  
5 second is, I'm not sure I'm understanding, are  
6 there data that show there's a difference by  
7 socioeconomic background for this measure across  
8 populations?

9 MS. ROTH: So, I can speak to your  
10 first question. So, the data that we presented  
11 from HEDIS is based on patients who had an ED  
12 visit or a hospital admission with COPD as the  
13 primary diagnosis. So it's based on those who  
14 had an exacerbation and were hospitalized or went  
15 to the ED for that. And your second question was  
16 related to -- could you repeat that again?

17 DR. DiGIOVINE: Yes. Just the second  
18 part is -- so using that data or any other data,  
19 I didn't see a gap in performance across  
20 socioeconomic groups on this measure. So, you  
21 give like 77 percent of HEDIS patients have a  
22 corticosteroid prescribed, does that differ based



1 on race or socioeconomic status?

2 MS. ROTH: Okay. So for HEDIS, we  
3 actually -- we don't collect data on  
4 socioeconomic status. We can sort of get at that  
5 by looking at the rates for Medicaid plans  
6 compared to the commercial or Medicare plans, but  
7 -- Mary, do you want to say anything about the  
8 disparities?

9 DR. BARTON: Well, just that the  
10 Medicaid plans are somewhat lower on the  
11 corticosteroid rate, not necessarily on the  
12 bronchodilator rate, but on both, they actually  
13 have a wider variability, which means that the  
14 distance between the tenth percentile and the  
15 90th percentile plan is larger, which means that  
16 there's still a bunch of plans that are  
17 performing considerably lower than this median.

18 DR. DiGIOVINE: Can I -- I just wanted  
19 to follow up on that. Because this comes up, I  
20 think, for a number of measures and so I'm trying  
21 to understand how we assess what is normal  
22 variation across a population and what is

1       disparate care.

2                   So, we wouldn't expect that every plan  
3       is going to have 70 percent compliance if that's  
4       the mean, so what is variation that somehow  
5       statistically we decide is more than what we're  
6       going to see because we're humans and there's  
7       going to be a normal distribution?

8                   DR. BARTON: I think when there is a  
9       distribution around, say, the commercial rate for  
10      bronchodilators that shows that there's a 16  
11      point difference between the tenth percentile and  
12      the 90th percentile, then you have a sense of how  
13      closely grouped around their median performance,  
14      which is, I think, 75 or 81. Right? So you have  
15      roughly eight points on either side of 81 that  
16      includes everybody from the tenth to the 90th  
17      percentile. So that's a huge majority of plans.

18                   And for Medicaid plans, in contrast,  
19      around a rate of 66 for corticosteroids, they've  
20      got a 20 -- is that 20? 30 percent difference  
21      between the tenth and 90th. So you have a wider  
22      distribution, which means you have more people

1 further down, and I would suggest that a rate of  
2 40 percent on getting appropriate medications to  
3 someone with a COPD exacerbation should not be  
4 thought of as a random variation, we're all  
5 human, but as a quality problem.

6 DR. DORMAN: Point of clarification,  
7 since it's the 30 percent and it's on either side  
8 of the mean or the median, then it doesn't go  
9 down to 40 percent. It's only 15 below 75, so  
10 the range would be 60 to 90 for the 30 percent.

11 CO-CHAIR LANG: Are there additional  
12 questions for the developers or additional  
13 comments, members of the committee? All right.

14 MS. AMIRAULT: Okay. So we can go  
15 ahead and vote for performance gap for measure  
16 2856. And the options are 1 high, 2 moderate, 3  
17 low, and 4 insufficient. Again, for performance  
18 gap for 2856.

19 (Voting.)

20 MS. BAL: Could everybody in the room  
21 vote one more time? No, never mind, we're good.  
22 Thank you.

1 MS. AMIRAULT: Okay. So, 13 for high,  
2 seven moderate, two low, and zero insufficient.  
3 And based on the percentages, we can move along.

4 CO-CHAIR LANG: Thank you.  
5 Reliability?

6 DR. LAMPONE: A couple of things that  
7 came to light when looking at reliability; during  
8 this reliability testing and performing the beta-  
9 binomial measure scores, it looks as though that  
10 when they had updated data submission, the scores  
11 -- there was some dis correlation between the  
12 scores. And if you look at the bronchodilator  
13 indicator for 2015 in the commercial population  
14 -- and also the systemic corticosteroid  
15 correlations -- those went down in both the  
16 commercial populations.

17 So, I was wondering again whether that  
18 was a data issue? The correlations for Medicaid  
19 and Medicare were pretty much in line and I  
20 wonder if there's any -- had you had any  
21 discussion around that indicator and why the  
22 difference in results in the updated data set?

1 DR. BARTON: Thank you. The beta-  
2 binomial looks at data that's reported from plans  
3 to try and distinguish to what degree the  
4 differences between plans are legitimate  
5 reflections of quality problems. And I will say  
6 that the beta-binomial works the best when  
7 there's a wide spread of responses or of  
8 indications.

9 So when we have the relatively narrow  
10 band between the tenth and the 90th percentile,  
11 and so we have everybody performing relatively  
12 tight band around -- whatever it is, 77 or 80,  
13 then the beta-binomial doesn't have very much  
14 difference to base its -- to power the  
15 mathematical calculation. So, we often see when  
16 there's a relatively well grouped rate that the  
17 beta-binomial is not as high as when there's a  
18 more varied distribution. That's just kind of a  
19 mathematical consequence of using the beta-  
20 binomial.

21 DR. LAMPONE: The other scores seem to  
22 be in line and I have no further comments on the

1 reliability test.

2 CO-CHAIR LANG: Okay. Thank you.

3 DR. O'BRIEN: Just a question regarding  
4 the measure specification, how it's handled if a  
5 patient is on -- either has these medications at  
6 home and is increasing the dosage or has them on-  
7 hand and then just resumes taking them?

8 MS. ROTH: So, this is related to the  
9 measure counting patients who have an active  
10 prescription for the medication and so what a  
11 health plan does when they're calculating this  
12 measure is they identify the person in the  
13 denominator and then they look back to see if the  
14 patient had an active prescription for the  
15 bronchodilator, the date it was dispensed to  
16 them, and then the day supply.

17 And so, as I mentioned before, the  
18 typical day supply is around 30 days. So, it's  
19 not like the health plan is having to go all the  
20 way back a year ago. They're really looking a  
21 short period of time back to see, were they  
22 dispensed the medication on this date? And so,

1 if the day supply is 30 days and the patient was  
2 hospitalized 15 days after that, then they would  
3 be in the numerator because they had a  
4 prescription filled for that medication already  
5 and were already theoretically on -- taking the  
6 medication.

7 DR. O'BRIEN: So, just to clarify, the  
8 30 days is the cut point? If they filled that  
9 prescription 30 days prior to that, they would be  
10 considered then a patient that had a miss?

11 MS. ROTH: Yes. So if it's --

12 DR. O'BRIEN: Okay.

13 MS. ROTH: -- 30 days or more, then  
14 yes, they would not be in the numerator.

15 DR. DiGIOVINE: I just want to clarify  
16 a point as well. If the data is being used to  
17 compare health plans, so am I right in assuming  
18 that -- the majority of patients that are going  
19 to be in there are patients with commercial  
20 insurance where the reliability is the least well  
21 supported?

22 DR. BARTON: The HEDIS looks at

1 Medicare plans, commercial plans, and Medicaid  
2 plans. And it's true that the population is  
3 higher for this measure in the Medicare plans,  
4 but the commercial plans that report have met a  
5 threshold of number of patients who meet the  
6 criteria.

7 So, there are no plans that are  
8 reporting on very small numbers, but it's true  
9 that the average number of people in the measure  
10 is going to be higher in the Medicare plan than  
11 in the commercial plans.

12 CO-CHAIR LANG: Are there any  
13 additional comments, questions for the  
14 developers?

15 MS. AMIRAULT: You can go ahead and  
16 vote on reliability for measure 2856. And the  
17 options are 1, high, 2, moderate, 3, low, and 4,  
18 insufficient. Again, for reliability for measure  
19 2856.

20 MS. BAL: Ella and David, if you're  
21 still on the call, please vote. Operator, could  
22 you also check David's connection, he said he was



1       having difficulty. Oh, never mind. Never mind.

2               MS. AMIRAULT: So we have five for  
3       high, 16 moderate, one low, and zero  
4       insufficient. And we can move forward based on  
5       the percentages.

6               CO-CHAIR LANG: Thank you. Validity?

7               DR. LAMPONE: Okay. We'll move on to  
8       validity testing. They underwent construct  
9       validity testing and that was new since the prior  
10      submission. They also included in validity  
11      testing sensitivity and specificity, which was  
12      also new. We did have a question on the data  
13      elements for the validity testing using the  
14      sensitivity and specificity. It appears as  
15      though you only used four plans worth of data, is  
16      that right? And in the total, you had much  
17      higher participation in plans. When you look  
18      under construct validity, you quote 241  
19      commercial plans, 357 Medicare, and 157 Medicaid,  
20      was that just an added sample just to test to see  
21      the specificity and sensitivity?

22              MS. ROTH: So, there are two different

1 ways that we had tested the measure. There was  
2 the original field test data that we had  
3 conducted in 2004 and there's also more up-to-  
4 date HEDIS data that we had provided from, I  
5 believe, year 2014. And so, that's why you're  
6 seeing the differences in the numbers there.

7 DR. LAMPONE: Okay. And --

8 MS. ROTH: Right. And we, I just  
9 wanted to clarify one thing is, we actually did  
10 not conduct the sensitivity/specificity analysis  
11 that was on Page 7 of the worksheet. It was  
12 based on our field test data from 2004. But that  
13 was something that NQF had conducted --

14 DR. BARTON: Right. We took the field  
15 test data, as the PA indicates, and NQF Staff  
16 converted that to those values.

17 DR. LAMPONE: Okay. Now for me, the  
18 sensitivity was a little bit low, but the  
19 specificity being higher I think drove the 88 or  
20 85 percent positive predictive value, so that  
21 made me feel a little bit better. And then, on  
22 the Pearson correlation coefficients, they were a

1 wide range. Can you comment on that? Is that,  
2 the wide range, is that based on the different  
3 percentile performances? So, from the tenth to  
4 the 90th? That's on the bottom of Page 7.

5 MS. ROTH: So for the construct  
6 validity testing, the good thing is that we did  
7 look at the correlation between the two rates  
8 within the measure and those were highly  
9 correlated, which is --

10 DR. LAMPONE: Okay.

11 MS. ROTH: -- what we would expect. We  
12 also did conduct correlations between this  
13 measure and another related, similar measure for  
14 looking at spirometry testing following a COPD  
15 diagnosis, so it's not -- the connection between  
16 how those two measures are related is a little  
17 bit less than the correlation between the two  
18 rates within the measure, but it is something  
19 that we wanted to look at and provide a data for,  
20 so the correlations for that are not quite as  
21 strong.

22 DR. LAMPONE: Okay.

1 DR. DiGIOVINE: Sorry about that. I'm  
2 really struck by your field tests and I'm just  
3 trying to make sure I understand it right, what  
4 I'm understanding you to say, when you looked at  
5 all of these cases that about 50 percent of the  
6 time, your administrative data is saying the  
7 patient has a COPD exacerbation, there is no  
8 evidence in the medical record that that actually  
9 occurred. Is that correct?

10 DR. BARTON: So you're talking about  
11 the data about confirming exacerbations or data  
12 about filling medicines?

13 DR. DiGIOVINE: Yes, the first one is,  
14 I'll get to the medicine second, but the --

15 DR. BARTON: Okay.

16 DR. DiGIOVINE: -- first table that you  
17 have is the COPD exacerbation medical record  
18 validation by plan and product line. It's not  
19 numbered, it's the first one under the results of  
20 critical data element validity. It's on the  
21 bottom of Page 38, start of Page 39.

22 DR. BARTON: Okay.

1 DR. DiGIOVINE: At least in our final  
2 version, which may not be the one you have.

3 DR. BARTON: Yes. Well, so, I guess  
4 the generic point that I want to make about the  
5 2004 field test that used a -- where we asked a  
6 small number of health plans to use all the data  
7 that they had at their disposal. So,  
8 administrative data, pharmacy data, and pulling  
9 medical records. It does not surprise me that  
10 there are events that happen that patients have a  
11 claim for that don't get reflected in their  
12 medical record.

13 It could be that the health plan  
14 couldn't find the relevant provider who was  
15 taking care of that patient for that problem.  
16 Maybe they found, you know, a primary care chart  
17 and the patient had a pulmonologist, they didn't  
18 find the pulmonologist chart. I mean, I think  
19 that the completion of the data we can be sure  
20 about is much higher for the claims and the  
21 pharmacy claims. If you get in an emergency  
22 department, that hospital will bill your insurer

1 100 percent of the time.

2 And so, the data for looking at which  
3 data can we trust, there are places where the  
4 medical record either does not reflect something  
5 that we could say with a pretty high degree of  
6 confidence probably happened and then conversely,  
7 there are things that show up in the medical  
8 record, because I'm presaging the medicine  
9 points, there will be doctors who will write,  
10 patient got X and Y meds, but the patient never  
11 filled them.

12 And so, it appears in the medical  
13 record that they have been prescribed a medicine,  
14 but the effective result is apparent from the  
15 pharmacy claims that they never picked it up.  
16 So, there is -- we would not have presented the  
17 sensitivity and specificity data in the way that  
18 it was presented to the steering committee  
19 because we think that there, again, looking at  
20 that 2004 data, there are enough questions in my  
21 mind about the completion of the medical record  
22 data and the accuracy of the medical record data.

1 MS. ROTH: I would also add quickly  
2 that I think we did note in here as well that one  
3 of the limitations of this testing that we had  
4 done was that none of the four plans had access  
5 to any medical records on the hospital side. And  
6 so, that's another reason why the COPD diagnosis  
7 might be missing in the medical record in this  
8 data.

9 DR. DiGIOVINE: So, just to -- is it --  
10 I mean, I think it's possible that somebody could  
11 go to an emergency room, you could have record of  
12 that, but on a medical record review, you decide  
13 it's not a COPD exacerbation, it's a pneumonia,  
14 it's heart failure, and it somehow got coded as a  
15 COPD exacerbation. Do you have any sense of to  
16 what extent that was the issue?

17 DR. LAMPONE: How about your  
18 specificity data? Would that address that? You  
19 have --

20 DR. BARTON: I'm sorry --- so, you have  
21 to have COPD to be in the denominator of the  
22 measure, so I --

1 DR. DiGIOVINE: I understand that, but  
2 you can go to an emergency room for something  
3 other than a COPD exacerbation.

4 DR. BARTON: Of course. And so, you're  
5 saying that the percent of time that the ED is  
6 wrong in how they assign the diagnosis, it's not  
7 actually a COPD exacerbation, and I don't have  
8 data on that.

9 DR. DiGIOVINE: Okay. And then, so in  
10 terms of the second part, again, your data is  
11 saying that somewhere between 30 percent of the  
12 patients that you're saying do not get  
13 corticosteroid or a bronchodilator, in fact in  
14 the medical record there's evidence that they  
15 were prescribed those medications? Does that  
16 strike you as problematic in terms of the  
17 validity of this measure?

18 DR. BARTON: Not when so many plans  
19 have been able to show a rate of 80 percent  
20 compliance. So, it does not -- if the  
21 improvement went from 60 to 80 percent overnight  
22 even, you would say, okay, well, they figured out



1       how to capture the medications that are actually  
2       being given. So, if the providers somehow have a  
3       way that's not captured of giving medications,  
4       health plans have figured out how to capture  
5       that. So, I can't really speak to what was going  
6       on in 2004 at the time of the field test, I was  
7       not part of the organization at that time, and  
8       there's actually nobody who's still part of the  
9       organization I think who did this field test, so  
10      there's probably some unanswered questions that  
11      we all have.

12               DR. DiGIOVINE: Okay.

13               CO-CHAIR LANG: Thank you. In the  
14      interest of time, we're going to move on to vote  
15      on validity.

16               MS. AMIRALT: So, we'll be voting on  
17      validity for measure 2856. And the options are  
18      1, high, 2, moderate, 3, low, and 4,  
19      insufficient. Again, for validity for 2856. So  
20      for results, one high, 13 moderate, eight low,  
21      and zero insufficient. And we can move along.

22               CO-CHAIR LANG: We're running a few

1 minutes behind, so if you could comment briefly  
2 on feasibility, Crystal, Tom?

3 DR. LAMPONE: Okay, sure. Feasibility,  
4 really this is data obtained from the medical  
5 records. I think some of the threats to that is  
6 the ED access to medical records. And then also,  
7 where you have some impact on the data where you  
8 have patients, especially in the Medicare  
9 population, who may be on chronic corticosteroids  
10 or frequent corticosteroid dosing and certainly  
11 inhalers that may impact the feasibility in the  
12 sense that it may be overstating that they're  
13 already on a medication and then they're  
14 compliant and moving on that way. But, I think  
15 overall, those are the only concerns to  
16 feasibility and those getting prescriptions  
17 filled at other places.

18 CO-CHAIR LANG: Is there anyone else  
19 who has any comments, questions for the  
20 developers? If not, we will proceed to vote on  
21 feasibility.

22 MS. AMIRAULT: So, we'll be voting on

1 feasibility for 2856. And the options are 1,  
2 high, 2, moderate, 3, low, and 4, insufficient.  
3 Again, feasibility for 2856. So the results, two  
4 high, 17 moderate, three low, and zero  
5 insufficient. And we can move along.

6 CO-CHAIR LANG: Crystal, comments on  
7 usability and use? Tom?

8 DR. RILEY: Sure. I'll try and make it  
9 brief.

10 CO-CHAIR LANG: Thank you.

11 DR. RILEY: So, from a usability  
12 perspective, it looks as though this measure is  
13 already used pretty widely. It's been  
14 incorporated in public reporting for NCQA State  
15 of the Health Care Annual Report and Quality  
16 Compass, used in the Medicare Advantage Star  
17 Rating Program, et cetera, et cetera. So from a  
18 usability perspective, we didn't identify any  
19 issues.

20 DR. LAMPONE: I agree.

21 CO-CHAIR LANG: Other comments,  
22 questions for the developers? Thank you. We'll

1 proceed to the vote.

2 MS. AMIRAULT: For usability and use  
3 for 2856, the options are 1, high, 2, moderate,  
4 3, low, and 4, insufficient. Again, usability  
5 and use for 2856. So 16 high, six moderate, zero  
6 low, zero insufficient and based on the  
7 percentages, we can move along. Okay. So, now  
8 the overall suitability for endorsement, 1 is  
9 yes, and 0 no, for measure 2856. Okay.  
10 Seventeen yes and five no.

11 MS. BAL: Could everyone turn off their  
12 mics? Thank you. So, with that, this measure is  
13 recommended for endorsement and we can move on to  
14 the next measure.

15 CO-CHAIR LANG: Lindsey, Mary, thank  
16 you. So, now we will proceed to address two  
17 measures. The measure steward for each of these,  
18 they're similar measures, the measure steward is  
19 University Hospitals Cleveland Medical Center.  
20 And the first is 2794: Rate of Emergency  
21 Department Visit Use for Children Managed for  
22 Identifiable Asthma, a PQMP measure. The second

1 is Appropriateness of Emergency Department Visits  
2 for Children and Adolescents with Identifiable  
3 Asthma, a PQMP measure. We will address these  
4 individually, however. And, Larry, would you  
5 like to summarize the first measure, taking  
6 perhaps two to three minutes?

7 DR. KLEINMAN: It would be my pleasure.

8 CO-CHAIR LANG: This is Larry Kleinman,  
9 who is with us today.

10 DR. KLEINMAN: Good morning. I'm Larry  
11 Kleinman. I am the measure developer, which  
12 really was CAPQuaM, the Collaboration for  
13 Advancing Pediatric Quality Measures. What I'd  
14 like to do is very briefly give a history of the  
15 development of the measure and then say a couple  
16 of things about the measure, and partly in  
17 response to the call that took place. I'll try  
18 to get this all within two to three minutes.

19 First of all, CAPQuaM is one of seven  
20 Centers of Excellence that emerged from a peer  
21 review competition held by AHRQ and CMS to create  
22 the Pediatric Quality Measures Program, something

1 that was defined and created legislatively as a  
2 part of the CHIPRA, the Children's Health  
3 Insurance Program Reauthorization Act of 2009.  
4 Our tasks were to improve and strengthen  
5 children's healthcare quality measures, expand on  
6 existing pediatric quality measures, and advance  
7 their development in order to increase the  
8 portfolio of quality measures available to public  
9 and private purchasers of children's healthcare  
10 services, providers, and consumers. And that is  
11 directly from the legislative act.

12 For this work, we were guided by the  
13 Institute of Medicine definition of quality,  
14 which is the degree to which health services for  
15 individuals and populations increased the  
16 likelihood of desired health outcomes and are  
17 consistent with current professional knowledge.  
18 And as a part of that, I'd like to point out that  
19 this suggests that quality may be a continuum and  
20 not only a dichotomy of good and bad. And the  
21 various components of quality according to the  
22 IOM are timely, safe, effective, efficient,

1 patient-centered, and equitable care.

2 We had a very -- our process was peer  
3 reviewed as a part of the competition for the  
4 grant. It was a highly engaged and transparent  
5 process and the various definitions and  
6 parameters, I know there were questions of how we  
7 got age groupings and things, came from a  
8 national expert panel. Our partners in this work  
9 included the Academy of Pediatrics, the American  
10 Academy of Family Physicians, and NCQA was a  
11 partner, New York State Medicaid was a partner,  
12 there were a large national partnership. I'm  
13 happy to give more of that if there's questions.

14 The panel used a RAND style method.  
15 And the panel not only created the parameters,  
16 but once we created the measure, they, without  
17 objection, endorsed the measure. A couple of  
18 things that relate to the measure itself is the  
19 rate of emergency department visits for children  
20 with identifiable asthma, defined as visits per  
21 100 child years. We discussed -- so, I can stop  
22 there and we'll take it wherever you'd like it to

1 be.

2 CO-CHAIR LANG: Okay. Thank you,  
3 Larry. The discussants for this measure are Don  
4 and Kim. Please begin with a discussion of the  
5 evidence.

6 DR. ELLIOTT: I'm happy to. Don, I  
7 think, is on the phone, so he can add to anything  
8 that I miss. But the measure number was already  
9 talked about, 2794, and the measure title is Rate  
10 of Emergency Department Visit Use for Children  
11 Managed for Identifiable Asthma. It is a PQMP  
12 measure. The description of the measure  
13 estimates the emergency department visits for  
14 children ages two to 21 who are being managed for  
15 identifiable asthma. And it is a little bit  
16 different measure method than I'm used to seeing,  
17 which is the rate of visits per 100 child years.

18 The level of analysis was done at the  
19 health plan, the integrated delivery system  
20 population community and it can be broken down or  
21 stratified by county or city population and other  
22 various stratifications. The evidence for the



1 measure indicates that it's an accessible, high  
2 quality, primary care reduces the amount of ED  
3 visits or the frequency of ED visits related to  
4 asthma. And a systematic review of the body of  
5 evidence was not required because this is an  
6 outcomes measure. However, the developer did  
7 provide evidence that based on the NHLBI  
8 Guidelines from 2006, there is evidence to  
9 support the measure, as well as they did a pretty  
10 comprehensive literature review, anywhere from  
11 2004 through 2006, and they reviewed 4,747  
12 abstracts. So, the literature review was pretty  
13 comprehensive. Don, do you have anything to add?

14 CO-CHAIR LANG: Don unfortunately is  
15 not on the phone right now. Basically, the  
16 premise here is that ED visits can be avoided if  
17 asthma management is improved strictly in the  
18 primary care setting? Is that correct?

19 DR. KLEINMAN: Yes.

20 CO-CHAIR LANG: And there is a  
21 difference from an epidemiologic standpoint in  
22 terms of how you've set this up, if you could

1 please elaborate briefly on that for members of  
2 the committee?

3 DR. KLEINMAN: Sure. We were looking  
4 to enhance an existing measure that was a part of  
5 the CHIPRA Core Set. That measure looked at the  
6 percentage of children with an asthma ED visit,  
7 but you could qualify for that measure simply by  
8 having an asthma ED visit and never being known.  
9 We felt a more accurate measure would be  
10 represented by requiring identification of the  
11 child as asthma to proceed the ED visit in order  
12 to make it something that someone might be held  
13 accountable for.

14 In order to do this and appropriately  
15 weight the influence of any individual ED visit,  
16 we recognized it was more accurate to do so by  
17 having an actual rate and using a person timed  
18 denominator. So, if the child became  
19 identifiable according to the definition six  
20 months into the year, what happened in the first  
21 six months would not contribute to the numerator,  
22 only what happened in months seven through 12.

1 And so, we felt this was a more valid, more  
2 useful representation, and that because it was an  
3 epidemiological definition, it actually was  
4 pretty readily understood with just this basic  
5 explanation.

6 CO-CHAIR LANG: Thank you. Are there  
7 additional questions for the developer or  
8 comments from members of the committee?

9 DR. DiGIOVINE: Sorry, just a quick  
10 question. Are we measuring physicians in this or  
11 health plans or both?

12 DR. KLEINMAN: Not measuring  
13 physicians, not measuring the hospitals that  
14 they're going to, measuring health plans and up.

15 CO-CHAIR LANG: We'll proceed with the  
16 vote on the evidence.

17 MS. AMIRAULT: Okay. So voting on  
18 evidence, health outcome, 1 is yes and 2 is no  
19 for measure 2794.

20 DR. NISHIMI: Can everyone point again?  
21 We're only looking for 21.

22 MS. AMIRAULT: Okay. So 21 yes, zero

1 no, and we can move along.

2 CO-CHAIR LANG: Kim, performance gap?

3 DR. ELLIOTT: Yes. I think that they  
4 did a really good job, the measure developer did  
5 a pretty good job on performance gaps. It does  
6 clearly indicate that there are some disparities,  
7 particularly in two different age populations,  
8 the very young and the adolescent. It also  
9 showed a pretty good stratification in those age  
10 groups. I think some of the other things that  
11 they pointed out is that there are some  
12 disparities between rural and urban, so clearly  
13 there are some opportunities for improvement.  
14 And Hispanic and black, also those populations  
15 had some disparities. So, from an opportunity to  
16 really make a difference by measuring the  
17 outcomes, I think the developer did a good job  
18 identifying that there was opportunity for  
19 improvement.

20 CO-CHAIR LANG: Dale?

21 CO-CHAIR BRATZLER: So, I completely  
22 agree, there's opportunity for improvement, but

1 the question is, is that a true gap? I mean, so  
2 I'm not a pediatrician, so I don't know whether  
3 we expect asthma admission rates be different by  
4 different age groups, I don't know. So that may  
5 be one of the reasons that there's a quote,  
6 disparity by age group, and then we have all  
7 those issues around sociodemographics that  
8 clearly impact rural versus urban, black versus  
9 white. I mean, so definitely disparities, but is  
10 that a gap in the actual care or does that  
11 reflect the system that prevents supportive care?  
12 And then, were there differences by age group?

13 DR. KLEINMAN: In general, the disease  
14 is not considered to be biologically different by  
15 age group, but clearly there are utilization  
16 patterns that differ. I think regarding some of  
17 the other demographics and I'd done this in a  
18 number of areas, but I brought the data simply  
19 for black versus not black because I think that  
20 the black was the highest utilization rate so it  
21 allows it. If you look at black versus --

22 MS. AMIRAULT: Sorry. Larry, you're mic

1 needs to be on.

2 DR. KLEINMAN: Okay. It was lit there  
3 but not here. Sorry. So, what I'm saying is  
4 that there are not fundamental biological issues  
5 that are recognized by age, but there definitely  
6 are utilization issues. So, age is important  
7 probably to consider. In terms of black and  
8 white, I ran the data after the phone call by  
9 plan and race to look at the difference. And if  
10 you look at it, between black versus not black,  
11 there's a mean difference of about ten units, ten  
12 visits per 100 child years.

13 But there are plans for which that gap  
14 is 2, 2.2, 2.4, 2.8 on the low end and others at  
15 15, 18, 15.6 at the high end, suggesting that  
16 this is not determined solely by demographics,  
17 but that really plans seem to matter. And these  
18 differences were significant and meaningful and  
19 the distribution, it was pretty dramatic to see  
20 it on the little graph.

21 CO-CHAIR LANG: May I ask you a  
22 question, follow-up to that right away? You

1 said, not solely determined by demographics, your  
2 data implies that it's not determined solely by  
3 race? I mean --

4 DR. KLEINMAN: I'm sorry, yes.

5 CO-CHAIR LANG: -- in order to say  
6 that, you would need to adjust for other -- were  
7 other sociodemographics factors included in your  
8 analysis?

9 DR. KLEINMAN: I'm sorry, before I had  
10 the mic on, I had mentioned that I did it for  
11 others such as rural versus urban. I didn't  
12 bring those data with me. The differences were  
13 not as dramatic and, therefore, the data were not  
14 as dramatic, but the pattern was the same.

15 CO-CHAIR LANG: Let me rephrase the  
16 question. The other demographic factors that  
17 would be important in your analysis in addition  
18 to race would be, for instance, zip code of  
19 residence, income, educational attainment of  
20 parents, et cetera, which also as we all know can  
21 influence outcomes.

22 DR. KLEINMAN: What I would say is the

1 NHLBI Guideline says that this is attainable in  
2 all children. And if we're talking about at the  
3 plan level, as opposed to at the practice level,  
4 which is where this is, plans contract to manage  
5 with the populations that they have. So, we did  
6 look -- I did not do this same breakdown between  
7 the phone call and today, but I do have data  
8 looking at poverty at county of residence, I  
9 don't have individual level. These were all  
10 Medicaid patients, by the way. So, this was  
11 within already a difficult to manage population,  
12 but we see significant broad variation. And we  
13 also see across plans that there's a large range  
14 of performance rates and it's not solely  
15 dependent upon whether, you know, they're black  
16 or poor, it's determined by other things.

17 CO-CHAIR LANG: So then, again, to  
18 follow up, your data show that there's a  
19 difference by race, not -- so, you broadened it  
20 to demographics, which is a much broader  
21 category, as you know, that includes other  
22 factors. So, I'm just trying to be precise and



1 understand what you're saying.

2 DR. KLEINMAN: Race and urbanicity is  
3 what I have examined. And I would say that --  
4 well, I think that the data suggest that  
5 populations that are historically thought of as  
6 hard to manage, some plans do much better than  
7 others. And the ideal rate for this, I should  
8 say, because this also comes to the rural/urban  
9 consideration, is not zero. You would expect  
10 that there are some children who have had  
11 terrible deteriorations quickly in the past, they  
12 go to the ER rather than going to the doctor.

13 There are exacerbations, there are  
14 children who are well managed who have really bad  
15 asthma or who break through, who are exposed to  
16 something or the season changes or the weather  
17 changes. So this is not -- this is why it is  
18 really granted as a continuum. And if these data  
19 are interpreted with a good deal of thought, the  
20 higher numbers in urbanicity relate probably both  
21 to management and availability of emergency rooms  
22 in contrast to at least the rural areas. So

1       there is an access component that probably plays  
2       into this.

3               CO-CHAIR LANG: You just -- so we're  
4       going to be voting on performance gap  
5       momentarily, but again, some of these issues are  
6       crossing over more into validity as opposed to  
7       performance gap. So we need to vote on  
8       performance gap now. Thank you.

9               MS. AMIRAULT: Okay. So voting for  
10       performance gap for measure 2794, 1, high, 2,  
11       moderate, 3, low, and 4, insufficient. So for  
12       results, six high, 14 moderate, one low, and zero  
13       insufficient. And based on the percentages, we  
14       can move along.

15              CO-CHAIR LANG: Kim?

16              DR. ELLIOTT: Okay. Let me move into  
17       the reliability. And there was some concern from  
18       Don regarding the reliability that he sent me and  
19       that was basically that it really is hard to  
20       attribute the ED visits to really being an  
21       outcomes measure for what they're trying to  
22       represent it as. And that was really the only

1 comment that he wanted me to specifically make.  
2 But, as far as the information that the developer  
3 provided, the results are not risk adjusted, so  
4 it is a pretty straightforward measures.

5 One of the concerns that I had was  
6 related to the pharmacy data and possibly some of  
7 the pharmacy data not being available to really  
8 determine the outcomes for this particular  
9 measure and that the developer indicated that the  
10 pharmacy data really wasn't critical, yet asthma  
11 is clearly a pharmacy driven measure, even coming  
12 out of an ED. So, that was a little bit of  
13 something that I think the developer really needs  
14 to address with us as well.

15 DR. KLEINMAN: Okay. Thank you. One  
16 thing I want to say is in pediatrics, this is a  
17 pretty well accepted outcome measure for  
18 performance and it's used in various not  
19 consistently specified ways. But in terms of the  
20 pharmacy data, I would say that data is not  
21 fundamentally critical to the measure. And the  
22 reason I say that, and I regret I do not have the

1 data because the person who did the analysis at  
2 New York State is gone and we've not been able to  
3 find the analysis, but we found that use of the  
4 pharmacy data qualified a few more children into  
5 the measure, not a large percentage, something on  
6 the order of one to two percent more children  
7 were qualified as having identifiable asthma, but  
8 did not have impact on the rate.

9 The pharmacy data was included because  
10 we were looking to try to be as inclusive as  
11 possible and that was the judgment of the expert  
12 panel who felt that the pharmacy data ought to  
13 count as part of this. But I would say it is not  
14 fundamental to the measure, I think at the  
15 margins, it makes it a better measure.

16 CO-CHAIR LANG: Is there additional  
17 discussion? Questions?

18 DR. ELLIOTT: The only other thing I  
19 would point out is that the developer didn't do  
20 any additional testing for validity, it relied on  
21 previous evidence.

22 CO-CHAIR LANG: Larry?

1 DR. KLEINMAN: I believe, and we may  
2 not have put this in the application because  
3 we're still new at this to some extent, but I  
4 believe that the expert panel endorsement of the  
5 measure is considered to speak to its validity as  
6 well.

7 CO-CHAIR LANG: We're on reliability.

8 DR. KLEINMAN: Yes.

9 CO-CHAIR LANG: Okay. So, we're going  
10 to vote on reliability.

11 MS. AMIRAULT: So, for reliability for  
12 measure 2794, the options are 1, high, 2,  
13 moderate, 3, low, and 4, insufficient. Again,  
14 reliability for 2794.

15 DR. NISHIMI: And we need everyone to  
16 point their clicker again.

17 MS. AMIRAULT: Okay. For results, two  
18 high, 17 moderate, two low, and zero  
19 insufficient. And we can move along.

20 CO-CHAIR LANG: Validity, Kim?

21 DR. ELLIOTT: Validity specifications,  
22 the developer relied a lot on literature to

1 support its conclusion on the validity and they  
2 did use administrative data as a primary source.  
3 It is at the data element level. The developer  
4 did cite face validity, but did not specifically  
5 assess face validity at the computed measure  
6 score level, and that is something that NQF  
7 really does look for. They do have some threats  
8 to the validity as well that they talked about.

9           They did exclude COPD as a diagnosis,  
10 cystic fibrosis and emphysema, which is  
11 appropriate. And the exclusions are clinical and  
12 represent construct validity, rather than  
13 statistical validity and considerations. And  
14 they did not do any risk adjustment, so  
15 disparities are -- they really focus on the  
16 disparities rather than risk adjusting the  
17 population. And the specifications that they put  
18 into the measure did stratify by age group and  
19 race/ethnicity, which also seemed appropriate.  
20 And they didn't note that there is some  
21 variability when they did these stratifications  
22 by rural versus urban and at the county level.

1 Since they used administrative data for their  
2 research and their results, there really wasn't  
3 an issue with the completeness of the data set.  
4 And I believe that's all the comments I had.

5 DR. GLOMB: My comment, I guess, is  
6 this the right time to talk about validity? The  
7 comment was that there was not a difference,  
8 someone actually might have already said it, that  
9 there wasn't really a difference in asthma across  
10 the age spectra. And, that really kind of goes  
11 against one of the inherent built-ins in  
12 pediatric pulmonology. Fernando Martinez, back  
13 in the 1990s, published that there really are  
14 three different types of wheezers as children  
15 move from infancy through at least their first  
16 six plus years of life.

17 And my concern with using emergency  
18 department visit as a measure of whether or not  
19 the patient is overall being well controlled does  
20 in fact exclude viral seasons, et cetera, that  
21 are going to adversely affect particularly the  
22 young wheezer, the early transient wheezer who

1 won't turn out to have asthma, the non-atopic  
2 wheezer who is going to respond to every viral  
3 illness with wheezing. And I guess the  
4 expectation is, well, during the viral season,  
5 they should all be on ICS, but could you address  
6 that please?

7 DR. KLEINMAN: So, first of all, one of  
8 the things we did is that the specifications  
9 start from age two up, so the very early wheezers  
10 we're taking out of it, the tracheo-  
11 laryngomalacia, who are stridorous wheezing,  
12 whatever the heck it sounds like to people. So  
13 part of it is the definition of the population.  
14 The other thing is this notion of identifiable  
15 asthma puts a hurdle of prior diagnosis so that  
16 if they haven't been considered to be an  
17 asthmatic or haven't been managed for asthma  
18 within the previous, it could be anywhere from  
19 one year to two years, because other way we'd do  
20 the assessment on a month basis, I'm sorry, from  
21 12 to 23 months, then they wouldn't qualify. We  
22 tried to create enough of a hurdle to avoid at



1 least a good chunk of those that you're talking  
2 about. I share your concern otherwise.

3 DR. GLOMB: And I -- you know, not to  
4 disparage the ER docs, but a lot of times these  
5 running diagnoses of asthma come out of their ER  
6 visits rather than their routine PCP or other  
7 specialist visits. So, if we're relying on a  
8 previous ER visit where they were wheezing and  
9 the diagnosis of asthma was made to establish the  
10 underlying diagnosis of asthma, I --

11 DR. KLEINMAN: It would be at least two  
12 events, not just -- this has to be the third  
13 event if they're under six. Over six, it could  
14 be the second event.

15 DR. GLOMB: Thank you for clarifying.

16 DR. KLEINMAN: And so that's -- but I  
17 share your concern, I'm sure there's some noise  
18 from that, but I think we've mediated it and  
19 moderated that pretty well through the  
20 specifications.

21 CO-CHAIR LANG: Yes. I'm wondering  
22 whether this would be the area to discuss the

1 risk adjustment strategy here or the lack of risk  
2 adjustment.

3 DR. KLEINMAN: Our feeling was that  
4 you've got multiple players in this system and we  
5 have specifications for -- we ask for it to be  
6 stratified by age and race, we have  
7 specifications for rurality, we have  
8 specifications related to poverty of the home  
9 county. And we make all of them available. We  
10 didn't require them, because we were trying to  
11 balance between burden and precision.

12 But our -- the way we articulate this  
13 is that the accountability entity, the people who  
14 are asking for the measure to be used, who after  
15 all are theoretically the payers or the  
16 regulators, ought to be the ones who make the  
17 decisions how many slices into the stratification  
18 there is. This will be a more precise measure,  
19 assuming that there's adequate sample size, the  
20 more it is stratified.

21 And we tried to provide the tools to  
22 do that, but we don't want to exclude plans that

1 are a little bit smaller or accountability  
2 entities from saying, we're contracting with you  
3 to manage a population and then of course that  
4 ought to be figured into the cost and the way  
5 they pay. So, to us this is something that isn't  
6 for the measure developer to decide, but is  
7 actually a part of the relationship between the  
8 accountability entity and the accountable entity.

9 DR. DiGIOVINE: I'd just like to kind  
10 of follow up on that. So, is there a sense from  
11 the developer, from you, whether the differences  
12 -- to what extent the differences we see across  
13 race or urbanity are differences to the inherent  
14 quality of the primary care and how much of them  
15 are due to environmental factors and social  
16 factors that are not under the control of the  
17 health plan?

18 DR. KLEINMAN: What I can tell you, I  
19 can speculate to that. I think it's a mix of  
20 both. I will tell you, when I did work in  
21 Massachusetts Medicaid, I saw, you know,  
22 everybody was well above the national average, so

1 clearly there was something about the way they  
2 managed and I don't think the environment is good  
3 throughout Massachusetts.

4 I will also tell you that in this  
5 work, if I go back to the analysis I referred to  
6 earlier of just looking at black versus non-  
7 black, because I thought that was the most  
8 dramatic in terms of its potential impact, we see  
9 actually nine-fold differences, from 18 to 2  
10 absolute difference in rate between -- no, from  
11 one plan to the next, one plan had a gap of 2  
12 between blacks and whites or blacks and all  
13 others, and another had a difference of 18. And  
14 then if you look at the second one, to avoid the  
15 most dramatic, it's 2.2 and 15.6, still a seven-  
16 fold. And then, 2.4 and 15, still a six-fold  
17 difference. So, I don't think that's all  
18 environmental or all demographic, I think that  
19 reflects that there are real differences in  
20 management happening.

21 DR. LAMPONE: Across the plans, was the  
22 demographic distribution, race in this case,

1 about equal or did you have some plans that had a  
2 higher concentration of African Americans that  
3 they may have seen people, because they had a,  
4 you know, bigger cohort to follow up on and a  
5 more consistent application of their plan  
6 policies?

7 DR. KLEINMAN: I removed from this  
8 analysis all low numbers. I don't know exactly  
9 the answer. So this is not spurious because of a  
10 low number, whether -- so, I don't know. I have  
11 the data, I could probably answer that during the  
12 break if we needed to, but what I would say is  
13 that it's clear that there are skills and ways to  
14 manage the black population to make it closer to  
15 the non-black population, and in fact close to  
16 the non-black population, probably not equal, at  
17 least that I can demonstrate in the data. But,  
18 again, we provide for stratification because we  
19 think it's important that plans know. We also  
20 think that the gap itself is an intrinsic  
21 measure, the IOM asks equity as a part of it, if  
22 you risk adjust, it's much harder to see how

1 equity comes into play, if you stratify, it's in  
2 your face, frankly.

3 CO-CHAIR LANG: One final question and  
4 then we'll move to the vote.

5 CO-CHAIR BRATZLER: Okay. It's not  
6 really a question, it's just a point that David  
7 made earlier, that you've clearly shown  
8 stratification by race, but I can tell you that  
9 race varies dramatically, the impact of race, by  
10 location, site, all those other demographic  
11 factors that are very important that aren't  
12 addressed in this measure or the next one.

13 DR. KLEINMAN: If I could, we have  
14 specifications and we were advised during the  
15 process not to put them all in. For percentage  
16 of poverty in the county and the rurality, we  
17 don't have always easily available patient level  
18 data of this. And this was all within Medicaid  
19 that we did that, but we also looked at different  
20 categories within Medicaid and found actually  
21 surprising little differences there.

22 CO-CHAIR LANG: We will move to a vote

1 on validity and I want you to note that according  
2 to the NQF algorithm for validity, the highest  
3 eligible rating for this measure for validity is  
4 moderate. So, we're voting 2, 3, or 4, for  
5 moderate, low, or insufficient.

6 DR. NISHIMI: Just to make the reason  
7 clear is because to be eligible for the high, you  
8 have to provide empirical testing at the score  
9 level. And, obviously, moderate is a passing  
10 grade. So 2, 3, and 4.

11 DR. KLEINMAN: And just -- this is  
12 where I'll make that point I made earlier that I  
13 don't know that it was articulated, but this was  
14 approved without dissent by the expert panel as a  
15 measure, not only the components.

16 MS. AMIRALT: Okay. So, if you  
17 haven't voted for validity for 2794, the options  
18 are 2, moderate, 3, low, and 4, insufficient.  
19 So, zero for high, ten for moderate, 11 low, and  
20 zero insufficient. So this will be in the grey  
21 zone.

22 CO-CHAIR LANG: Feasibility, Kim?

1 DR. ELLIOTT: Yes. Feasibility, it is  
2 all administrative data. The fields that they  
3 would collect the data from are in the electronic  
4 as well as paper based. So, I didn't see any  
5 issues with feasibility for this particular  
6 measure.

7 CO-CHAIR LANG: So there are no  
8 concerns identified. Anyone else have any  
9 comments, questions? We will proceed then to  
10 vote on feasibility.

11 MS. AMIRALT: Okay. So, feasibility  
12 for 2794, 1, high, 2, moderate, 3, low, and 4,  
13 insufficient, for feasibility for 2794. Okay.  
14 So there are 15 high, six moderate, zero low, and  
15 zero insufficient. And we can go ahead and move  
16 on.

17 CO-CHAIR LANG: Excellent. Usability  
18 and use, this is a new measure not currently in  
19 use. Kim?

20 DR. ELLIOTT: That's correct. And  
21 currently it's not publically reported, it's not  
22 used as an accountability for any particular



1 program, as least as referenced by the developer.  
2 It is planned to be used, but there wasn't a lot  
3 of information as to who or what would use the  
4 measure. They did not indicate any potential  
5 harms and there was no additional feedback given  
6 on this particular measure.

7 CO-CHAIR LANG: So, ED visits are  
8 already commonly measured by a number of plans  
9 around dashboards, what does this add?

10 DR. KLEINMAN: This adds a number of  
11 things. First of all, it's the concept of  
12 identifiable asthma is a new construct that, when  
13 we validated it against things like prevalence,  
14 it was about half the prevalence, we validated it  
15 against something like persistent asthma, which  
16 was a much tighter diagnosis, the NCQA diagnosis  
17 was about two and a half times as many it  
18 identified, so it achieved that. We also  
19 recognize, we looked at New York State Medicaid  
20 data and also national data and found that when  
21 you look at emergency department visits through  
22 billing data, if the child is hospitalized, most

1 of the time those data are not actually  
2 forwarded.

3 So when we defined -- and we found  
4 that somewhere between 70 and 85 percent, in New  
5 York State it was 83 percent, of admissions for  
6 children with asthma come through the ED. So, if  
7 you actually want to accurately estimate the  
8 number of emergency department visits, the best  
9 way to do that is not simply with ED visits, if  
10 you're using this data, but with ED visits and  
11 hospitalizations, and then deduplicate. So,  
12 that's something else that we add. It's a more  
13 accurate assessment than other sorts of data.  
14 It's also specified for children and the rate,  
15 the fact that it uses a person timed denominator  
16 actually introduces a new construct into  
17 accountability measurement that I think will be  
18 valuable for other things as well.

19 DR. GLOMB: Just before we leave this,  
20 and under unintended consequences and I don't  
21 want to belabor the point any more than I have  
22 to, but I still am fairly concerned about lack of

1 stratification by risk here. I understand what  
2 you're saying, I understand what your panel felt,  
3 I'm going to take our real world experience  
4 across Texas, not doing some sort of risk  
5 adjustment on the patient base may give some  
6 very, very skewed results.

7 Health plans that are predominately in  
8 the urban areas, and I'll take Houston as an  
9 example, where their Medicaid plan, where their  
10 population might be 60 percent black in an urban  
11 area, which rates as the highest asthma risk  
12 category, versus a company that is in the  
13 predominately the rural areas of this state,  
14 where the black population may be only 15 to 20  
15 percent in Medicaid there and where,  
16 interestingly enough, the risk to the black  
17 patient in the rural area drops almost to the  
18 level of the Caucasian patient in those same  
19 areas. I think that then doing a cross  
20 comparison across the state without taking risk  
21 into account would adversely affect that  
22 predominately urban plan versus a plan with a

1 broader base of numbers.

2 DR. KLEINMAN: Well, we --

3 DR. NISHIMI: It's not at a point now  
4 where we need to discuss back and forth, we can  
5 just -- the committee has heard your view, the  
6 committee has heard the other views of the other  
7 committee members, we just need to vote.

8 DR. DiGIOVINE: Just as a quick -- this  
9 is not a new measure, so I'm just curious as to,  
10 have you approached groups to --

11 DR. NISHIMI: This is a new measure.

12 DR. DiGIOVINE: Oh, I'm sorry.

13 DR. NISHIMI: This is a new measure to  
14 NQF.

15 CO-CHAIR LANG: We will proceed to the  
16 vote then.

17 MS. AMIRALT: Okay. So --

18 CO-CHAIR LANG: This is -- please go  
19 ahead.

20 MS. AMIRALT: Oh, no, go ahead.

21 CO-CHAIR LANG: No, go ahead. Go  
22 ahead.

1 MS. AMIRAULT: Usability and use for  
2 measure 2794, the options are 1, high, 2,  
3 moderate, 3, low, and 4, insufficient. Again,  
4 usability and use for 2794.

5 MS. BAL: Ella, please vote, we're  
6 still waiting for yours.

7 MS. AMIRAULT: Okay. So, four high, 11  
8 moderate, five low, and one insufficient. And we  
9 can move along. So, now we'll look at overall  
10 suitability for endorsement, 1 for yes and 2 for  
11 no, for measure 2794.

12 MS. BAL: Ella, we're still waiting for  
13 your response to overall suitability, please.

14 MS. AMIRAULT: Okay. Eleven yes, 10  
15 no. And that will be in the grey zone.

16 MS. BAL: Yeah. So, as mentioned  
17 earlier, with the grey zone, we'll put this out  
18 to comment and then you'll reconsider this  
19 measure during your post-comment call.

20 CO-CHAIR LANG: This is open for public  
21 comment.

22 MS. BAL: Operator, could you please

1 open up public comment?

2 OPERATOR: Yes, ma'am. At this time,  
3 if you would like to make a comment, please press  
4 star then the number 1. Okay. And you do have a  
5 public comment from Elizabeth Herman.

6 DR. HERMAN: Yes. Should I limit it to  
7 this measure or can I also comment on the  
8 previous measure?

9 MS. BAL: You can comment on any of the  
10 measures that have been discussed so far.

11 DR. HERMAN: Great. So, my name is  
12 Elizabeth Herman. I'm a senior scientist with  
13 CDC's National Asthma Control Program. And these  
14 are my opinions and do not necessarily represent  
15 official CDC statements. On measure 2852,  
16 optimal asthma care, I'd like to note that this  
17 is a patient-centered and measures a proximal  
18 outcome of care, asthma control, which fills an  
19 important gap in the current set of asthma  
20 quality measures. It's also well-grounded in the  
21 evidence and aligns with the National Asthma  
22 Education and Prevention Program Guidelines. It

1 also has been shown to motivate providers to  
2 incorporate an important, but underutilized tool  
3 for asthma care, the assessment of asthma control  
4 using validated instruments. This measure is  
5 analogous to and as important as the measure of  
6 blood pressure for the control of hypertension.

7           Regarding measure 2794, this measure  
8 offers two significant improvements over existing  
9 measures of emergency department use for asthma.  
10 One, it focuses on children with previous  
11 documentation of asthma and, thus, children who  
12 should be integrated into a system of care. And  
13 it addresses issues of gaps in enrollment and  
14 change in health plans, or churning, which are of  
15 concern to providers and health plans. Thank you  
16 for the opportunity to comment.

17           OPERATOR: Okay. You have another  
18 comment from the line of John Schall.

19           MR. SCHALL: Hi, thank you. I just  
20 wanted to make a somewhat more general comment to  
21 urge that we're mindful of some material and  
22 systematic technical discontinuities caused by

1 the administrative data coding. The definition  
2 changes that occurred October 1 of last year,  
3 when we moved from ICD-9 to ICD-10, and  
4 essentially there was one code that was fairly  
5 common, it's the chronic obstructive asthma that  
6 in ICD-9, 493.2X was considered an asthma code,  
7 but under ICD-10, it's considered a COPD code.

8 And so, as long as there's consistency  
9 between time periods and baseline versus  
10 performance, there's not a problem, but if you  
11 have a baseline using ICD-9 data and a  
12 performance period using ICD-10 data, then there  
13 could be an issue unless there's some type of  
14 consistency adjustment. And, you can adjust by -  
15 - there's some measures that combine asthma and  
16 COPD, in which case it's not an issue. If you  
17 count the particular code range as if it's COPD  
18 even though it's an asthma numeric code, it'll be  
19 in both sides and would be consistent. If it's  
20 not consistent, asthma is defined by any of the  
21 493 codes. It may still be okay if it's not  
22 materially different.



1                   So, for example, that code really  
2                   represents both asthma and COPD and there's far  
3                   less of that in children so it probably is not an  
4                   issue on the pediatric measures, but could be  
5                   elsewhere. The problem is, it may be a 20  
6                   percent shift in rates for asthma or COPD  
7                   depending on whether it's consistent or not. And  
8                   that's a concern for perhaps a couple of the  
9                   measures that you're looking at over the next two  
10                  days and for the future, because this is a  
11                  standing committee, we're likely to see broad  
12                  based measures like morbidity rankings for COPD  
13                  rise because what used to be counted as asthma  
14                  now is coming in as COPD.

15                 It may also be an issue for other  
16                 measures indirectly because COPD and asthma are  
17                 currently both considered chronic conditions and  
18                 the risk adjustment in a number of measures  
19                 across various specialties include a count of  
20                 comorbidities. And someone that has both asthma  
21                 and COPD may have in ICD-9 two comorbidities and  
22                 in ICD-10 only one for the same patient, just

1 because of the coding difference. And being  
2 mindful of that will be helpful going forward.  
3 Thank you.

4 OPERATOR: Okay. And at this time,  
5 there are no comments.

6 CO-CHAIR LANG: Okay. Thank you for  
7 the public comment. Rather than, we have our  
8 next measure 2816, but rather than placing that  
9 measure in between us and lunch, what we'd like  
10 to do is to take a ten minute break and each of  
11 us can grab our lunch and bring it back and we  
12 can have a working lunch while we're addressing  
13 that measure. Thank you. So, we're going to  
14 take a ten minute break and we get to extend our  
15 time with you, Larry. Thank you.

16 (Whereupon, the above-entitled matter  
17 went off the record at 12:32 p.m. and resumed at  
18 12:44 a.m.)

19 CO-CHAIR LANG: We're going to start  
20 in a minute if everyone could please take their  
21 seats. The next measure, the next morsel for us  
22 is the measure 2816 entitled Appropriateness of

1       Emergency Department Visits for Children and  
2       Adolescents with Identifiable Asthma.

3               This is categorized as a process  
4       measure. Larry, would you like to go over this  
5       for two minutes for us please?

6               DR. KLEINMAN: Thank you. The first  
7       thing I want to say is we thought of this as a  
8       process measure because that's how I was trained  
9       to think. But it was raised by the committee  
10      that is this better thought of as an intermediate  
11      outcome measure.

12              And I would be prepared to accept that  
13      judgment if that were the case. I think there  
14      are, they are both there. I think this is an  
15      interesting measure. There are a paucity of  
16      appropriateness measures out there.

17              So it's been perceived as a need.  
18      This is again a Pediatric Quality Measures  
19      Program measure requested by, we were requested  
20      to look at overuse in ED asthma by AHRQ and CMS.

21              And it's a challenging thing to do.  
22      This is not a perfect measure. I think it's a

1 very good measure. It is, it's also important,  
2 there was a question about gaming that came up,  
3 the notion of gaming and false documenting or  
4 forcing documentation.

5 Yeah. Okay. Happy to do that later  
6 then. That's fine. Thank you very much. And  
7 this was developed for through same process and  
8 also endorsed by the expert panel.

9 CO-CHAIR LANG: Thank you. Dale, take  
10 it away.

11 CO-CHAIR BRATZLER: All right. So I  
12 strongly agree also that this is not a process of  
13 care measure. I embrace the argument that this  
14 is an outcome measure that focus on the  
15 appropriateness of emergency department visits  
16 for children and adolescents.

17 The denominator for the metric were  
18 those patients with an emergency department visit  
19 for asthma as a first or second diagnosis who  
20 meet other specified criteria for having  
21 identifiable asthma. The numerator for the  
22 measure is appropriateness as defined by one of

1 eight consensus appropriate use criteria that the  
2 expert panel defined.

3           They include hospitalization directly  
4 from the ED, documented physical exam findings  
5 consisting of respiratory distress including  
6 labored breathing retractions, accessory muscle  
7 use or markedly decreased breath sounds, O2  
8 saturation less than 90 percent and ABG obtained,  
9 a consultation ordered and obtained with a  
10 pulmonary asthma specialist and order for an  
11 arterial blood gas or consult with pulmonary  
12 asthma, patient caregiver referral to an ED after  
13 evaluation from the PCP, patient or caregiver  
14 report of administering two or more doses of an  
15 inhaled rescue medication or parent or caregiver  
16 report that the child was in a pre-defined red  
17 zone on their peak flow measurement as a part of  
18 asthma.

19           So that's the numerator, denominator  
20 are again are those patients diagnosed, seen in  
21 the emergency department for asthma with that in  
22 the first or second diagnosis. Because this, I

1 believe, is an outcome measure it's an  
2 appropriateness measure, then the question on  
3 evidence becomes simply are there processes,  
4 structures, changes in care that could  
5 potentially impact the outcome for the measure  
6 which I believe there are. So that's my evidence  
7 discussion.

8 CO-CHAIR LANG: Are there additional,  
9 or are there comments, questions, yes, please.

10 DR. DIGIOVINE: So I'm understanding  
11 this measure as sort of we're asking whether  
12 patients are going to the emergency department  
13 when they should not be going to the emergency  
14 department based on their level of severity.  
15 What is the evidence that educating patients or  
16 giving them action plans or any of those things  
17 prevents those kinds of ED visits?

18 DR. KLEINMAN: The way that question  
19 was, just to be absolutely explicit, was posed to  
20 the expert panel was is the emergency department  
21 an appropriate level of care for a patient blah,  
22 blah, blah. So just not to put, to overstate it

1 in one way or another.

2 There is evidence that levels of  
3 appropriateness of a variety of things have  
4 changed, are changeable. There is evidence that  
5 more robust primary care systems have fewer kids  
6 go to the emergency department and when they do  
7 they are sicker.

8 But I would say that this measure is  
9 best interpreted in combination with that rate  
10 measure because a high level of inappropriateness  
11 may suggest that asthma outcomes are better than  
12 expected or they were thought based simply on  
13 that, but that the efficiency and the capacity of  
14 primary care, capacity and/or skill of primary  
15 care to manage the patients is not sufficient.

16 A very low level suggests that the  
17 primary care system may be working well, but that  
18 most of those visits are actually because the  
19 kids are sick and that maybe it's not actually  
20 specifically managing the asthma as well. So  
21 this is a -- it's somewhat of a nuance measure  
22 and I think it works better with the other one to

1 tell a story.

2 CO-CHAIR BRATZLER: Yes. So again, I  
3 think we were okay that a structural issue, if  
4 you had better access to primary care you might  
5 have fewer admissions to the emergency  
6 department. Access has been linked to rates.

7 So when we talked about this before  
8 that was our feeling that as an outcome measure  
9 the question is are there structures, processes,  
10 interventions that could impact the outcome. Our  
11 answer to that was, yes.

12 DR. DIGIOVINE: So let me start maybe  
13 asking a science question. So I have no doubt  
14 that there's lots of research on access to care  
15 decreases ER visits. Is there lots of science  
16 that says access to care decreases inappropriate  
17 ER visits where they actually look at down at  
18 this kind of detail was this an appropriate ER  
19 visit?

20 DR. KLEINMAN: I can answer that  
21 question. There is evidence limited that kids,  
22 that access impacts the severity of care with



1 which kids present to the emergency room in the  
2 way you would expect with this.

3 This particular measure and these  
4 details have not been studied. This is a new  
5 measure. It's a new formulation that came from  
6 the expert panel. Each of these was approved by  
7 the expert panel.

8 DR. GLOMB: Thank you. And following  
9 up on that this, I mean I loved everything about  
10 this. I intellectually agree with this approach.  
11 I think it sounds like a good measure.

12 But that last statement that you made  
13 is, at least my primary concern that I want to  
14 extrapolate in that, you know, we have three  
15 years ago we killed some measures because one  
16 facet of the components just you couldn't draw a  
17 bold straight line from Point A to Point Z.

18 And here I am concerned that this list  
19 of eight things, most of which I agree with, is  
20 arbitrary. It might be an indicator of  
21 appropriateness or it might not give a larger,  
22 you know, a step back.

1                   And if we can't prove that all eight  
2                   or seven of the eight or five of the eight are  
3                   not valid measures of appropriateness can we then  
4                   hold someone to the measure?

5                   DR. KLEINMAN: I appreciate your  
6                   concern. What I would say is this was designed  
7                   to be an index at a population level, not to  
8                   grade the care of any individual.

9                   Again, these are system-level measures  
10                  not even a hospital level measure. And as such I  
11                  think the signal-to-noise is high and the  
12                  validity comes from the fact that this was  
13                  proceeded, that the expert panel was proceeded by  
14                  a literature review, interviews with front line  
15                  patients --

16                  MS. BAL: We're on evidence. Please  
17                  focus on evidence.

18                  DR. KLEINMAN: Okay.

19                  CO-CHAIR LANG: I have one more  
20                  question for you, Larry, on number, I need to ask  
21                  you this. Number five, consultation are obtained  
22                  with a pulmonologist asthma specialist. Isn't an

1 allergist, immunologist a pulmonologist asthma  
2 specialist?

3 DR. KLEINMAN: I would consider you  
4 would be an asthma specialist, yes.

5 CO-CHAIR LANG: With that thank you,  
6 with that clarification we will proceed to vote  
7 on the evidence. According to the NQF algorithm  
8 for evidence this is eligible for insufficient  
9 with exception. So we must achieve more than 60  
10 percent insufficient on an initial vote on  
11 evidence.

12 MS. BAL: So just a little additional  
13 clarity, if you are to vote and you vote low then  
14 the measure does not move forward. But if you  
15 vote insufficient then we would vote insufficient  
16 if you would like to pass it with insufficient  
17 with exception. Could you put your mic on?

18 CO-CHAIR BRATZLER: I need a point of  
19 clarity. If this is, if we're going to call this  
20 an outcome measure where does that show up as  
21 insufficient?

22 MS. BAL: So actually it wouldn't be

1 considered an outcome measure because we have to  
2 review the measure as it was presented. And  
3 since the developer presented it as a process  
4 measure we do have to vote on it as a process  
5 measure.

6 And if we don't move this measure  
7 forward there is opportunity for the developer to  
8 bring it back and make alterations as necessary.  
9 But since they did not provide us the evidence  
10 based off of it being an outcome there's no way  
11 for us to really evaluate it in that manner.

12 MS. GORHAM: And just a reminder, you  
13 have the algorithm at your seat if you would like  
14 to take a look at that.

15 MS. AMIRAUULT: Okay. So polling will  
16 be open for the first evidence part for Measure  
17 2816. Again --

18 DR. GROSSBART: Can you repeat what  
19 you said at the start of how, what each vote  
20 would mean to the measures, the result of the  
21 measure? Is that possible? I couldn't follow  
22 it.

1 MS. GORHAM: Could your question  
2 please, can you speak into the mic?

3 DR. GROSSBART: Can you repeat what  
4 you had said at the, as you introduced the  
5 voting?

6 MS. BAL: Yes. So if we vote high or  
7 moderate you are passing this measure on moderate  
8 saying that this has enough evidence to move this  
9 process measure forward.

10 If you vote low you're saying that the  
11 evidence provided is not applicable or it's not  
12 enough evidence or it was just insufficient  
13 indicates that you feel that there is not, the,  
14 basically there is not enough information to move  
15 forward, that whatever has been provided to you  
16 is not sufficient enough.

17 And so that, only if we have 60  
18 percent or more on just insufficient shall we  
19 move on to an additional vote for insufficient  
20 with exception. However, if you wish to not go  
21 towards that you would vote low. Based on our  
22 algorithm it would not be eligible for high or

1 moderate.

2 MS. AMIRAULT: So we go ahead. For  
3 evidence for 2816 one high, two moderate, three  
4 low or four insufficient. Again, evidence for  
5 2816.

6 (Voting.)

7 MS. AMIRAULT: Okay. Zero high, five  
8 moderate, seven low and eight insufficient.

9 MS. BAL: So since we did not get 60  
10 percent on, sorry, insignificant we actually,  
11 this measure would go down because we would need  
12 at least 60 percent or more for it to move  
13 forward for insufficient with exception. So this  
14 measure does end with evidence.

15 DR. KLEINMAN: Is there an opportunity  
16 potentially for the Committee to revote because  
17 those who provided moderate might like, obviously  
18 there's more than 60 percent who wanted it to  
19 move on and if they move to insufficient that  
20 would allow the measure to move on?

21 MS. BAL: I will leave it up to the  
22 Co-Chairs on the Committee if they would like to

1 revote.

2 CO-CHAIR BRATZLER: I can only speak  
3 for what happened at our pre-meeting which was we  
4 didn't have this conversation that we had to  
5 evaluate this based on it being a process  
6 measure. Our feeling as a Subcommittee meeting  
7 beforehand was that this was clearly an outcome  
8 measure.

9 So we never had any of this  
10 conversation at all. That's what surprised me a  
11 bit here. We had the, our conversation based on  
12 this is an outcome measure, not a process  
13 measure. So I'm not trying to make the decision  
14 one way or the other. I just was a bit surprised  
15 by this.

16 CO-CHAIR LANG: I think if there's  
17 some misunderstanding regarding, I would say if  
18 there some misunderstanding regarding those who  
19 vote moderate we should, you know, have clarity.  
20 So I would agree that we can revote.

21 MS. BAL: Okay. So we're going to go  
22 ahead and revote on this evidence for this

1 measure. Again, with the algorithm your options  
2 really are just low or insufficient.

3 If we do not receive at least 60  
4 percent insufficient votes than the measure will  
5 go down at this point. So give us one second to  
6 reset the voting and then we'll let you know when  
7 it's ready.

8 MS. AMIRAULT: You can go ahead and  
9 put your votes in, in the meantime. Sorry for  
10 the delay. Give us just one more second.

11 MS. BAL: Still having some technical  
12 difficulty. For everybody on the phone, we'll be  
13 starting in just a second with the vote.

14 CO-CHAIR LANG: Sorry for the delay.  
15 The battleground state of Ohio it's voting day  
16 today. I just got a, sorry, I just got a text  
17 from my wife saying that we just got a call from  
18 Arnold Schwarzenegger asking us to vote for John  
19 Kasich.

20 MS. BAL: With that we are now ready  
21 to vote. So please, as mentioned, the options  
22 are three low, four insufficient. If we have 60



1 percent or more for low than we will not continue  
2 discussing this measure.

3 But if we get 60 percent or more for  
4 insufficient, I'm sorry, more than 60 percent for  
5 insufficient we will do a secondary vote.

6 DR. DORMAN: Did Arnold have  
7 recommendation for us?

8 (Voting.)

9 MS. AMIRAULT: So zero high, two  
10 moderate, nine low and nine insufficient. And so  
11 we're at 45 percent insufficient.

12 MS. BAL: So with that on our second  
13 vote this measure does still go down and we can  
14 move on to the next measure.

15 CO-CHAIR LANG: Thank you. So at this  
16 point prior to moving on to the next measure we  
17 have the opportunity to discuss related measures,  
18 to discuss the three asthma measures that we've  
19 addressed this morning and into this afternoon  
20 including the Minnesota Community Measure,  
21 Optimal Asthma Control and the two measures  
22 pertaining to emergency department visit use and

1       appropriateness of emergency department visit  
2       use.

3                       We're discussing this in terms of  
4       harmonization, yes?

5                       MS. BAL: Yes, I just wanted to  
6       provide some clarification.

7                       CO-CHAIR LANG: Please.

8                       MS. BAL: That the 2816 since it  
9       didn't pass we wouldn't review it for related and  
10      competing. So at this point we're only looking  
11      at 2852 and 2794 as related measures. So if you  
12      could just bring up the decision logic.

13                      So we had some questions earlier about  
14      what is the logic behind creating the related and  
15      competing. So this is what NQF considers when we  
16      make that determination comparing all the  
17      different measures. So first we really begin to  
18      look at does the measure address the same target  
19      population or the same measure focus.

20                      If the answer is, no, then we consider  
21      the measures not related or competing. If the  
22      answer is, yes, we move on to the next aspect

1 which is does measure address both the same  
2 target population and the same measure focus?

3 If the answer is, no, we would start  
4 considering this measure for just related. And  
5 if the answer is, yes, then we would start  
6 considering it for competing. Then moving from  
7 there for the related measures I'll focus on that  
8 since we do not have any competing measures.

9 We would address with, if either of  
10 the same target population or the same measure  
11 and if they do then we would consider them  
12 related. And if they don't then we would not  
13 consider them related.

14 So I hope that brings a little more  
15 clarity about the process that we took to  
16 determine what measures were related and which  
17 were not. So with that we can open us  
18 discussion. Yes, go ahead.

19 DR. O'BRIEN: Just a question. It  
20 appears that we're only considering new measures  
21 in this. Is there a reason we don't consider  
22 existing measures also as far as the

1 harmonization?

2 MS. BAL: So we do consider existing  
3 measures as part of the harmonization. At this  
4 point when staff reviewed all the measures we  
5 felt that only these three were related.

6 However, if you think that there is an  
7 endorsed measure or a measure in our portfolio  
8 that would also be related or competing you are  
9 free to mention that now and we can open up the  
10 discussion to the Committee.

11 DR. O'BRIEN: So I think the optimal  
12 asthma control, one of those measures related to  
13 admissions and there's a PQI measure that is  
14 admissions for asthma.

15 MS. BAL: Could you provide the number  
16 please?

17 DR. O'BRIEN: Sure. It's 0283 and  
18 then 0728 are both asthma admission rates.

19 MS. BAL: Okay. We can definitely add  
20 that to the list of discussion points if the  
21 Committee as a whole agrees. So just to confirm  
22 you said 0283 and 0275?

1 DR. O'BRIEN: 0728 was the second one,  
2 asthma admission rates. They are PQI 15 and PDI  
3 14. And we've got those tomorrow as a discussion  
4 related to competing measures to other, that  
5 we're discussing tomorrow.

6 MS. BAL: So since those measure those  
7 developers are, were not notified that the  
8 discussion would happen we should focus  
9 discussion on measures and we can do that  
10 discussion during the meeting tomorrow. Would  
11 that be okay?

12 Okay, perfect. Thank you. So then  
13 let's focus the discussion on the two measures in  
14 front of us which is 2852 and 2794. What we're  
15 asking of the Committee is do you feel that these  
16 measures need to be further harmonized or are  
17 they efficient the way that they are?

18 Is the developer, Jasmine from  
19 Minnesota still on the line?

20 CO-CHAIR BRATZLER: So I'll just make  
21 a comment that the data source for these two  
22 separate are very, very different. One focused

1 exclusively on the medical record, one  
2 exclusively based on claims analysis.

3 So the, their use would be very  
4 different. I mean Minnesota made it very clear  
5 that they did not have a unified, all paired,  
6 discharged data set to actually collect this data  
7 from so they relied on medical record review for  
8 2852 versus 2794 which is based entirely on  
9 claims.

10 MS. BAL: Okay. So based on that I  
11 would say that you're saying that you don't feel  
12 that these need to be harmonized further,  
13 correct?

14 CO-CHAIR BRATZLER: I think it would  
15 be difficult to harmonize them further.

16 DR. GLOMB: The person who called in  
17 from, was it CDC also talked about how the  
18 Minnesota method was a patient-centered measure.  
19 So their claims base would be potentially outside  
20 that. So again, a little bit of a skewed look at  
21 the data.

22 DR. O'BRIEN: Looking at this

1 framework where is the data source? Which step  
2 is the data source?

3 MS. BAL: Okay, so we're getting the  
4 feeling that everyone is fine with these measures  
5 as is and we can move forward.

6 DR. O'BRIEN: Well I was actually  
7 asking for a walk through this step by step  
8 because I don't see the data source as one of the  
9 steps. These look to me, I mean they're  
10 addressing the same target population, the kids  
11 with asthma.

12 CO-CHAIR BRATZLER: The same target  
13 population although I know this issue has come up  
14 before for a whole host of measures where the  
15 condition or the patient population, so take  
16 nursing home versus hospitalized patients or  
17 others where the population of patients may be  
18 very much the same but the source of care or the  
19 site of care or the source of the data that  
20 actually used to populate the measures is very  
21 different. So I don't have strong feelings about  
22 it.

1 DR. NISHIMI: The, whatever you want  
2 to call it, it's not really an algorithm but the  
3 guidance does not, as you indicate focus on data  
4 source. That is one of the reasons that the  
5 Committee can cite as to why they feel that two  
6 measures are appropriate.

7 Different data source and then  
8 different foci. One was more patient directed as  
9 Dr. Glomb indicated and, you know, one is at the  
10 claims integrated healthcare system. One is  
11 focused on the providers, i.e. the front line  
12 docs. That's sort of what that other one was or  
13 groups.

14 The other is focused on integrated  
15 health systems and plans. So those are the  
16 reasons you can justify for differences. This  
17 helps staff sort the initial. But then your  
18 discussion is broader.

19 DR. DIGIOVINE: I guess I would just  
20 like to add my voice to saying I think these  
21 should be harmonized. I see them as relating to  
22 the same thing.



1 I don't think anyone brought up the  
2 idea that asking a patient whether or not they  
3 had an exacerbation was somehow a more valid  
4 measure than claims data. It was just brought up  
5 that it was probably as good or it might be as  
6 good.

7 And so I have my concerns that and I  
8 think the comments from the CDC were really about  
9 using an asthma control questionnaire which I  
10 don't think anyone disagreed with. I think that  
11 all of the disagreement was around the emergency  
12 room visit measurement.

13 And I think these two measures would  
14 work better if the first one stuck only to  
15 assessing control and we used the latter to  
16 measure ER visits.

17 DR. GLOMB: I second that. I really,  
18 that was my big problem with Minnesota as it sat  
19 today was it's just putting so much credence in  
20 the memory of the patient.

21 DR. NISHIMI: Any other comments?

22 DR. KLEINMAN: First of all I

1 appreciate the confidence in our rate measure. I  
2 just would note that there are different age  
3 populations. We go up to age 21. They go up to  
4 age 50.

5 And we do have that prior requirement  
6 which is in terms of identifiable asthma which I  
7 don't think is a problem. But it would well, it  
8 could conceivably and likely be defined  
9 differently at an older age.

10 DR. GROSSBART: I had a comment on the  
11 patient-centeredness discussion. The measurement  
12 developer didn't bring that up. So they weren't,  
13 and I don't believe that, they didn't bring that  
14 up.

15 And I know we worked with the  
16 Minnesota group and Cincinnati on aligning forces  
17 for quality. And the big appeal and pitch was  
18 that providers had more confidence in their own  
19 data than the insurance companies data.

20 And that's how the debate was. So I  
21 don't know that, you know, this is using the  
22 claims is patient-centered or using the ED self-

1 reported makes this more patient-centered. It's,  
2 and I don't know if that's what this comment --

3 DR. NISHIMI: That's fair. It's in  
4 the NQF rubric a patient-reported outcome is  
5 viewed so, but that's absolutely a fair comment.  
6 You're right. The developer themselves did not  
7 raise that.

8 MS. BAL: Okay. Were there any other  
9 comments? As always we recommend that the  
10 developer take back this feedback and when they  
11 do, you know, once you get this all processed if  
12 you bring it back to take it into consideration.

13 DR. NISHIMI: So what unfolds is that  
14 the developers are given this feedback. We ask  
15 them to have discussions and then report back as  
16 to why they feel they should or should not, you  
17 know, harmonize these.

18 The developers are under no  
19 obligation, obviously to do so. These are the  
20 Committee's recommendations. But they should be  
21 taken to heart because the measures have to come  
22 back for measure maintenance.

1 CO-CHAIR BRATZLER: So I just want to  
2 summarize that I think what I've heard though is  
3 fairly consistently for the Minnesota measure  
4 there is still concern about the self-reported ED  
5 inpatient and that if there's any way they can  
6 incorporate the claims-based approach to  
7 identifying those that would be recommended or  
8 certainly harmonization with what you've done  
9 with the pediatric population.

10 DR. KLEINMAN: We're not being asked  
11 to do anything at this point from our end. Is  
12 that, thank you, okay.

13 CO-CHAIR LANG: At this point I will  
14 pass the baton to Dale to proceed with additional  
15 review of measures pertaining to asthma. Thank  
16 you.

17 CO-CHAIR BRATZLER: All right.  
18 Thanks, David. So we're going to move ahead with  
19 Measure Number 0047, asthma, I'm sorry.

20 MS. GORHAM: Before we actually do  
21 that let us go over the differences between the  
22 maintenance measures and the new measures because

1 now we're about to begin maintenance measure  
2 review.

3 Okay. So now that we have our slides  
4 up, so as you know NQF reviews maintenance  
5 measures every three years or so. And this is to  
6 ensure that the endorsed measures reflect the  
7 current science and are reliable and valid and  
8 still meet NQF's criterion.

9 We do have a new maintenance process.  
10 And that process began, was effective October 1,  
11 2015. So of course this project is included in  
12 the new maintenance process.

13 The maintenance measures use the same  
14 criteria as the new measures. But the emphasis  
15 is slightly different. So as you see on your  
16 screen for evidence there is a decreased emphasis  
17 for maintenance measures.

18 So if the developers have attested  
19 that the evidence is the same and you agree that  
20 there is no new evidence then we can say that we  
21 do not have to read this in the conversation or  
22 the vote for that. However, for a gap there is

1 an increased emphasis for maintenance measures  
2 and so we definitely want to look at gap.

3 So for scientific acceptability there  
4 is no difference for specifications. We still  
5 want to look at specifications for maintenance  
6 measures. However, for reliability and validity  
7 testing again if that is the same and you all,  
8 the developers have attested that is the same we  
9 do not have to revisit that conversation or vote  
10 for that.

11 However, we do want to address the  
12 questions of SDS for our trial period. So again,  
13 feasibility there is no difference. For  
14 usability and use there is an increased emphasis  
15 because the maintenance measures have been in use  
16 and so we do want to look at that data and there  
17 is increased emphasis on that.

18 Okay. And so now, Dale, we can move  
19 to our first maintenance measure.

20 CO-CHAIR BRATZLER: All right, very  
21 good. Thank you. So our first measure is 0047,  
22 Asthma: Pharmacologic Therapy for Persistent

1 Asthma from the American Academy of Asthma,  
2 Allergy and Immunology. And, Rebecca, I'll let  
3 you give it a brief overview of the measure.

4 MS. SWAIN-ENG: Thank you very much.  
5 So I'm here on behalf of the American Academy of  
6 Asthma, Allergy, and Immunology or AAAAI. Just  
7 to give you a little background the AAAAI just  
8 recently overtook this measure from the American  
9 or excuse me the American Medical Association's  
10 Physician Consortium for Performance Improvement  
11 in late 2015.

12 So AAAAI took over stewardship just  
13 the end of last year and is kind of new to this  
14 process. So we are just kind of getting our feet  
15 wet on the ground really learning what does NQF  
16 endorsement mean? How do we maintain  
17 endorsement?

18 What do we need to do to do a little  
19 bit of testing to make sure that we're up to date  
20 with the new NQF endorsement process? Since as  
21 Shaconna just mentioned it's really been updated  
22 here recently just at the end of last year.

1           So we're really happy to be able to  
2       present this measure for your review today for  
3       maintenance. This measure is currently part of  
4       the 2016 CMS PQRS program. It has been used in  
5       the PQRS program for the past several years.

6           It is one of the only asthma measures  
7       in the asthma measures group reporting option and  
8       is one of only two asthma quality measures in the  
9       program. It has been used in several AAAAI  
10      programs for quality improvement, maintenance of  
11      certification and as an AAAAI Qualified Clinical  
12      Data Registry or QCDR.

13          AAAI is also aware that several other  
14      organizations have incorporated this measure into  
15      their internal quality improvement program. So  
16      it's definitely in use, which is one of the big  
17      criteria that you'll be reviewing today.

18          This measure has been previously  
19      endorsed by the National Quality Forum most  
20      recently in 2014. And this measure was recently  
21      updated. The specifications were updated. So  
22      the denominator was updated to take out the upper



1 limit of the age range.

2 So previously it had an upper age  
3 range limitation of 64 years old. So now it's  
4 just five years and older. And this was done to  
5 be able to be used in the PQRS program to include  
6 the Medicare population.

7 And also the numerator was recently  
8 updated just to be able to include more generic  
9 drug names and to better reflect what's going on  
10 in practice. So we're just really looking  
11 forward to hearing your input today and if you do  
12 have any questions please let me know.

13 CO-CHAIR BRATZLER: Okay. Thank you,  
14 Rebecca. So our two discussants are Curtis and  
15 Steve who is, take the lead.

16 DR. GROSSBART: I'll just, you just  
17 want to flip-flop back and forth?

18 DR. COLLINS: Well, I had that it's  
19 Christine and Crystal on the, it changed.

20 MS. BAL: That was a typo.

21 DR. COLLINS: Will you take the lead  
22 please?

1 DR. GROSSBART: Easy enough. So  
2 starting with the evidence the measure developer  
3 reports that there's no evidence changes and no  
4 evidence to call into question the measure.

5 And just, this is just to reiterate  
6 this is a process measure and the developer  
7 already made some nice comments on what minor  
8 changes have been made. And the evidence still  
9 seems valid.

10 CO-CHAIR BRATZLER: Okay. So any  
11 questions or comments about evidence?

12 DR. NISHIMI: So can I see a show of  
13 hands if people feel that we should revote and  
14 further discuss this, if you feel we should do  
15 that? Okay.

16 (Off microphone comment.)

17 DR. NISHIMI: Well based on what Steve  
18 has indicated and what you find in the --

19 DR. O'BRIEN: Do you mean revote on  
20 just this item, just Item 1A?

21 DR. NISHIMI: Just this item. We're  
22 just talking about evidence and the summary

1       that's in the preliminary analysis and what  
2       Steven just summarized indicates that the  
3       evidence hasn't changed. Developer attests it  
4       hasn't changed.

5                   CO-CHAIR BRATZLER: So I guess the  
6       question, raise your hand if you think we need to  
7       revote evidence?

8                   DR. NISHIMI: We're just talking about  
9       evidence.

10                  CO-CHAIR BRATZLER: Seeing none we'll  
11       move on.

12                  DR. NISHIMI: Right. So we'll move on  
13       to performance gap.

14                  DR. GROSSBART: Performance gap. The  
15       developer shows that there is a gap and the Work  
16       Group discussion focused a lot on whether the  
17       measure has approached being topped off. So the  
18       developer's standpoint is that there is  
19       opportunity to continue to close the gap.

20                  There's variation. There's still, as  
21       in the data presented, there's still variation  
22       particularly race, ethnicity and socioeconomic

1 status continue to have a disparate care. And so  
2 again, there still is a gap.

3 This measure probably in the near  
4 future will top out if the progress continues.  
5 But I know it was my feeling that there was still  
6 opportunity given, you know, given a still  
7 significant band between disparate groups.

8 CO-CHAIR BRATZLER: So, Bruno, did you  
9 have a comment?

10 DR. DIGIOVINE: I'm sorry.

11 CO-CHAIR BRATZLER: Okay. So, Steve,  
12 I just wanted to clarify. Is the total  
13 performance metric reported 99.3 percent? I saw  
14 that number quoted.

15 DR. GROSSBART: I would have to get  
16 into the data.

17 DR. COLLINS: Yes, that would be a  
18 question I would have for the developer as well.  
19 They have 88 percent for one measure, 71 and then  
20 a combined measure of 99.3, which that is getting  
21 very close, in my opinion.

22 And I expressed this in the Work Group

1 as well as being topped out or close to that  
2 discussion point.

3 MS. SWAIN-ENG: So that's just from  
4 one of the recent testing that we did just  
5 looking at one sample looking at one clinical,  
6 one large health group. And that's right.

7 When we looked at the combined. We  
8 looked at one thing I didn't mention in my  
9 introduction. We looked at three different rates  
10 and that was the combined for any of the long-  
11 term control medications was the 99.3 percent  
12 within all of those different clinics.

13 However, we haven't had a chance to  
14 really get a lot of data from the PQRS program  
15 yet. So we just updated the metrics in 2014 to  
16 go up to the 50 year old age range and then in  
17 2015 it included up to the 64 year old age range  
18 and now into 2016 there is no upper age range.

19 So we expect to still see a lot of  
20 variation. And so we think there is still going  
21 to be a lot of gap that is going to come from  
22 that. And one thing that we did note, I don't

1 know if you all had a chance to see this, is that  
2 when we looked at the data even from 2010 to  
3 2013, the PQRS data from those age ranges only  
4 38.7 percent of those physicians had at least 90  
5 percent of a, a 90 percent performance rate or  
6 higher.

7 So there still is a significant  
8 portion of physicians that are, at least  
9 according to that PQRS data that aren't at that  
10 really high performance rate. So there still is  
11 room for improvement with this measure, we  
12 believe.

13 CO-CHAIR BRATZLER: So I guess has  
14 there ever been any discussion because, you know,  
15 I've actually looked at this metric before and  
16 there's a long list of controller medications.  
17 It's not that hard to pass this performance  
18 measure with the long list of, you know.

19 But when you get down to inhaled  
20 corticosteroids then the rates drop off. So has  
21 there been any conversation with the Work Group  
22 about whether, you know, you need or whether the

1 focus should be on some type of corticosteroids  
2 in these patients or inhaled versus just the  
3 long, it's a very long list of medications that  
4 you could pass this measure with?

5 MS. SWAIN-ENG: I wasn't privy to  
6 those specific conversations. That's something I  
7 could ask the Work Group and kind of come back to  
8 you all with that.

9 I know they wanted to try to be more  
10 inclusive to be able to meet the different  
11 individual patients that would be needing  
12 different medications based on comorbid  
13 conditions or patient preferences or, you know,  
14 what does their insurer cover to be able to meet  
15 the broadest range of medications that would be  
16 applicable for this patient population. That's a  
17 good question.

18 DR. JIMENEZ: Thanks. Would this be  
19 something that we would, should see in  
20 utilization or utilization on this one? I mean  
21 how is the measure being utilized right now?

22 MS. SWAIN-ENG: Do you want me to

1 answer that now or wait to --

2 DR. NISHIMI: Under use and usability.

3 DR. GLOMB: To follow on what you're  
4 saying, Dale, I wonder if we couldn't make a  
5 recommendation at some point that perhaps there  
6 needs to be a couple of numerators with this  
7 particular measure. For instance, all  
8 controllers versus ICS or whatever option it  
9 might be.

10 DR. NISHIMI: Sure, that's something  
11 that we can include in the report.

12 CO-CHAIR BRATZLER: Other comments?  
13 Okay. So I think we're ready to vote on gap.

14 MS. AMIRAULT: Okay. So we'll vote on  
15 gap for Measure 0047 and the options are one  
16 high, two moderate, three low and four  
17 insufficient. Again, for gap for Measure 0047.

18 (Voting.)

19 MS. AMIRAULT: Okay. Four high, 16  
20 moderate, zero low and zero insufficient. And  
21 based on the percentage we can move along.

22 CO-CHAIR BRATZLER: Okay. We'll move



1 on to scientific acceptable.

2 DR. COLLINS: So for reliability  
3 testing the developers raised the age limit above  
4 65. They tested for reliability with their beta-  
5 binomial analysis and reported reliability rates  
6 greater than 0.97 in all three categories.

7 The Work Group did not have any  
8 concerns with the reliability or the updated  
9 testing.

10 CO-CHAIR BRATZLER: Anything else,  
11 Steve? So any other comments about reliability?  
12 Okay. I think we're ready to vote.

13 MS. GORHAM: Before we continue with  
14 the vote just for record purposes I want to state  
15 that David Lang, one of the Co-Chairs is recusing  
16 himself from the discussion and the vote of this  
17 measure.

18 MS. AMIRAULT: Okay. So for  
19 reliability for Measure 0047 the options are one  
20 high, two moderate, three low and four  
21 insufficient. Again, reliability for 0047.

22 (Voting.)

1 MS. BAL: Ella, if you could please  
2 vote. Sorry, never mind. We've received.

3 MS. AMIRAULT: Okay, 12 high, 8  
4 moderate, zero low and zero insufficient. You  
5 can move along.

6 CO-CHAIR BRATZLER: Okay, to validity.

7 DR. GROSSBART: So the, excuse me,  
8 validity testing phase exclusions appear  
9 appropriate. Risk adjustments not applicable.  
10 The biggest, the validity of the measure was, I  
11 think Curtis already touched on this, the beta-  
12 binomial analysis some concern of the strength of  
13 that relationship.

14 Developer argues that .7 indicates  
15 sufficient reliability to distinguish among  
16 physicians. So there's, so those are the main  
17 points that I recall from the conversation,  
18 Curtis.

19 DR. COLLINS: Yes, the Work Group  
20 really didn't have, discussed reliability.  
21 Validity was the same way. I think that the  
22 developers, we thought that they had done

1 appropriate testing on the updated age groups  
2 methodology. And we really didn't have concerns  
3 with validity either.

4 DR. NISHIMI: I just want to remind  
5 the Committee that they did data element level  
6 validity testing not score level and face  
7 validity. So the highest eligible vote, based on  
8 the NQF algorithm would be moderate. So your  
9 options are moderate, low and insufficient.

10 MS. AMIRAULT: Okay, so for validity  
11 for Measure 0047 the options are two moderate,  
12 three low and four insufficient. Again, for  
13 validity for 0047.

14 (Voting.)

15 MS. AMIRAULT: Okay, so zero high, 17  
16 moderate, three low and zero insufficient. And  
17 based on that percentage we can move along.

18 CO-CHAIR BRATZLER: Okay, feasibility.

19 DR. COLLINS: From a feasibility  
20 standpoint it's electronic data currently being  
21 captured in, you know, quite a few sources. We  
22 did not have concerns with feasibility. Pretty

1 straightforward. I don't know if anything has  
2 changed since the last review.

3 CO-CHAIR BRATZLER: I would assume  
4 this is a metric that can be reported via codes  
5 also.

6 MS. SWAIN-ENG: Yes.

7 CO-CHAIR BRATZLER: Some physicians  
8 may report this using claims, not using  
9 electronic health record data. Some physicians  
10 may report this metric as a PQRS measure using  
11 their claims data rather than using electronic  
12 health record data to actually report it.

13 So any other questions or comments  
14 about feasibility? All right. We can vote.

15 MS. AMIRAULT: Okay. So feasibility  
16 for Measure 0047. The options are one high, two  
17 moderate, three low and four insufficient.  
18 Again, feasibility for 0047.

19 (Voting.)

20 MS. AMIRAULT: Okay, 17 high, 3  
21 moderate zero low and zero insufficient. And  
22 based on the percentage we can move along.

1 CO-CHAIR BRATZLER: Okay, usability  
2 and use.

3 DR. GROSSBART: In the area of  
4 usability and use this is already a public  
5 reported measure, part of the PQRS measure set.  
6 It's been used in some payment programs, public  
7 reporting and the Work Group did not see any  
8 unintended consequences of continued use.

9 DR. COLLINS: I'll add too that there  
10 was improvement in performance from 2011 to 2013.  
11 There was nearly a 20 percent improvement in  
12 performance on this measure reported by the  
13 developer. So it seems to be usable.

14 CO-CHAIR BRATZLER: So I'm curious  
15 what data source is used to demonstrate that  
16 improvement?

17 MS. SWAIN-ENG: I think the one he is  
18 referring to is the Maintenance and Certification  
19 Program through ABMS. So using data from eCITY  
20 who is one of the vendors that works with a lot  
21 of the medical specialty societies to be able to  
22 report back which is a dashboard where you are

1     able to really see individualized physician  
2     reports. This is also seen in an aggregate  
3     report on your membership.

4             CO-CHAIR BRATZLER: And I make that  
5     point so that's very helpful just as you see with  
6     that program Maintenance and Certification and as  
7     you see with PQRS right now selection to the  
8     measures is left at the level of the individual  
9     practitioner or the group.

10            And so I will tell you as a group  
11     quality director that we pick the measures we  
12     look good on to report and we don't necessarily  
13     report the ones we don't look good on and I think  
14     that's probably consistent across most plans. So  
15     there's probably greater opportunity for  
16     improvement if everybody had to report the same  
17     metric than the pure voluntary reporting or it's  
18     not voluntary but you pick the measures because  
19     you get the option of choosing performance  
20     metrics that you choose to report.

21            Any other comments about use,  
22     usability? And if not we'll go ahead and vote.

1 MS. AMIRAULT: Okay, so usability and  
2 use for Measure 0047. The options are one high,  
3 two moderate, three low and four insufficient  
4 information. Again, usability and use 0047.

5 (Voting.)

6 MS. BAL: Susan and Ella, could you  
7 please send in your votes via the chat? We  
8 haven't received them yet. Thank you.

9 DR. KAZEROONI: I already sent mine.  
10 I'll send it again.

11 DR. POLLART: Yes, I did the same, but  
12 I just resent.

13 MS. BAL: Thank you.

14 MS. AMIRAULT: Okay, 15 high, five  
15 moderate, zero low and zero insufficient. And  
16 based on the percentage we can move along.

17 CO-CHAIR BRATZLER: And the last vote  
18 then would be just on overall suitability for  
19 endorsement. So is there any discussion?

20 MS. AMIRAULT: So for 0047 the overall

21 --

22 CO-CHAIR BRATZLER: And I guess the

1       only thing we, I think we have the recommendation  
2       that the developer consider whether there should  
3       be two separate numerators for this particular  
4       metric based on the very high overall rate of the  
5       combined. So just at least as a consideration.

6               But any other conversation or comments  
7       back for the developer? Two or more, yes, right.  
8       Any other comments? Okay.

9               MS. AMIRAULT: So for the overall  
10       suitability for Measure 0047, one for yes and two  
11       for no.

12               (Voting.)

13               MS. AMIRAULT: Did anyone in the room  
14       not vote yet? Okay. So we have 20 yes and zero  
15       no for 100 percent.

16               CO-CHAIR BRATZLER: All right. Thank  
17       you, Rebecca.

18               MS. SWAIN-ENG: Thank you very much.

19               CO-CHAIR BRATZLER: All right. So the  
20       next measure that we're going to consider is  
21       Number 1800: Asthma Medication Ratio (AMR) from  
22       the National Committee for Quality Assurance.



1                   And I'll repeat the announcement. Dr.  
2                   Lang also is conflicted on this measure and will  
3                   be recusing himself from the conversation or  
4                   vote. So we have Lindsey Roth and Ben Hamlin as  
5                   developers to present the measure.

6                   MS. ROTH: If it's okay I'm actually  
7                   going to provide an overview for the two asthma  
8                   measures right now instead of separating those  
9                   out. So we have two health plan level asthma  
10                  medication measures.

11                  And these improve upon an older  
12                  measure of ours that had assessed whether  
13                  patients were only dispensing controller  
14                  medication at least once during the measurement  
15                  year. But these two asthma measures that we will  
16                  discuss today are higher bar than the older  
17                  measure that we found had really high  
18                  performance.

19                  And they each focus on slightly  
20                  different aspects of asthma care. So the first  
21                  is the asthma medication ratio measure. And this  
22                  looks at the percent of patients with persistent

1       asthma who have a ratio of controller medications  
2       to total asthma medications of .5 or higher.

3               The measure is an intermediate outcome  
4       measure that identifies people with persistent  
5       asthma who are well controlled and are not  
6       relying on rescue medications to control their  
7       symptoms but rather are following the recommended  
8       daily use of controller medications.

9               There are at least three studies that  
10       found that patients with a medication ratio above  
11       .5 are less likely to have a subsequent ED or  
12       hospitalization for an asthma exacerbation. And  
13       the summary wasn't included in your materials.  
14       But I did want to just point out that there are  
15       existing studies and we can provide more  
16       information about them if you would like.

17              The second measure is the medication  
18       management for people with asthma. And this  
19       measure looks at the percent of people with  
20       persistent asthma who were dispensed controller  
21       medications that they remained on throughout the  
22       measurement year.

1           So patients need to be on a controller  
2 medication in order to be in this measure. And  
3 the, what we're really assessing here is  
4 adherence to their controller medication to see  
5 who is really taking it as recommended.

6           And to assess adherence we used a  
7 proportion of days covered method which means  
8 calculating the percent of days that the patient  
9 was covered by at least one asthma controller  
10 medication during the treatment period. And we  
11 define the treatment period as the first day  
12 during the year that an asthma controller  
13 medication was dispensed through the end of the  
14 measurement year.

15           And this measure has two rates. One  
16 for the percent of patients who were on the  
17 asthma controller medication for at least 50  
18 percent of their treatment period and the other  
19 rate is looking at those who were on it for at  
20 least 75 percent of their treatment period.

21           And I also just wanted to point out  
22 that we did provide a summary of studies that

1 have examined the link between the 75 percent and  
2 the 50 percent adherence rates in outcomes. And  
3 this was to show that there is some mixed  
4 evidence in this area.

5 So for example, a study came out last  
6 year. The primary researcher was Yoon. And they  
7 did not find a link between the 75 percent  
8 adherence rate and outcomes. They did however,  
9 find a link between the 50 percent adherence rate  
10 and ED visits.

11 But there have been several other  
12 studies that have validated the link between the  
13 75 percent and 50 percent adherence rates and  
14 outcomes. So I just wanted to mention that we  
15 did have the opportunity to meet several times  
16 with the researchers on the Yoon study to discuss  
17 their analytical methods.

18 And they received our recommendations  
19 very well and they're actually conducting further  
20 analyses. So we're looking forward to seeing the  
21 results as well as any new emerging evidence that  
22 might come out in this area.

1           So just again, both measures are  
2 health plan level that use administrative and  
3 pharmacy data. And they are both stratified by  
4 four different age groups. And this is for  
5 several reasons.

6           The first is that we wanted to align  
7 with the asthma medication management guidelines  
8 which are separate for children and adults. And  
9 then the second reason is that the measures are  
10 used in programs specific to children and adults.  
11 And so for that reason we also wanted to see the  
12 rate separated by age.

13           CO-CHAIR BRATZLER: Thank you. So I  
14 have as the leads for the discussion Christine  
15 and Crystal.

16           DR. RILEY: Okay. I'll start with the  
17 evidence. The developer indicated that the  
18 updates to the evidence were that the 2007  
19 guidelines cited updates for those that were  
20 published in 2004.

21           The guidelines being those created by  
22 the National Heart, Lung and Blood Institutes,

1       graded Category A where the guidelines reference  
2       a little over 550 studies that are related to  
3       pharmacologic therapy for asthma. So that seems  
4       to be the only change indicated for the evidence.

5               CO-CHAIR BRATZLER: So since this is  
6       a maintenance measure again we'll have that  
7       conversation about do we need to revote on the  
8       evidence and raise your hand if you think we need  
9       to revote on the evidence.

10              (Off microphone comment.)

11             CO-CHAIR BRATZLER: We're talking  
12       about 1800 only. We'll take the second measure.  
13       We're just going to talk about 1800 only for now.  
14       So anyone think we need to revote the evidence at  
15       this point? Okay, we'll move on then.

16             DR. SCHINDLER: Thanks, Lindsey. So  
17       in terms of the performance gap, as Lindsey  
18       stated this is a health plan level. So the only  
19       gap that really is identified is between the  
20       different types of products, so commercial  
21       product versus Medicaid, Medicare.

22             And certainly like we'll back up to

1 the raw numbers there are gaps that have been  
2 consistent throughout 2012, '13 and '14. There's  
3 not been a lot of movement on those. It's a  
4 pretty steady gap.

5           Unfortunately because it is a health  
6 plan level measure there really aren't additional  
7 data looking at demographic information. I think  
8 it would be really helpful if we could see  
9 something stratified by race, ethnicity, urban  
10 versus rural, age.

11           But it was really clear from them that  
12 this evidence is really hard or these data are  
13 really hard to extract given it's a plan data.  
14 It's just not reasonable to collect at that  
15 level. So disparity is macro but we don't really  
16 have the, you know, really specifics.

17           CO-CHAIR BRATZLER: Lindsey, any  
18 questions, comments? Anybody else have any  
19 questions? Yes, Bill.

20           DR. GLOMB: Just on the plan level if  
21 it's a Medicaid plan it's required that we have,  
22 that we collect that data. So at least a subset

1 of the plan data could be broken down  
2 demographically.

3 DR. DIGIOVINE: I guess to harmonize  
4 a little with the one we just talked about is  
5 there a reason that this ends at 65 and doesn't  
6 extend beyond 65?

7 MS. ROTH: So when we originally  
8 developed the measure we did make the decision to  
9 end at 65. And this was mainly due to some  
10 concerns we had heard about the older population  
11 and possibly, you know, misdiagnosis with COPD  
12 versus asthma.

13 And this measure is, you know,  
14 narrowly focused on asthma. So at the time we  
15 had made the decision to cap it although we are,  
16 we do have some data looking at the possibility  
17 of expanding it to not have an upper age limit  
18 and in the future we may decide to do that.

19 DR. DIGIOVINE: I just, 65 is a funny  
20 cut off. If that's the concern I would use 40.  
21 I think we typically use 40 if that's the  
22 concern.



1 MR. HAMLIN: So the original version  
2 of this measured population did actually cut off  
3 at 40 and several years ago we retested to look  
4 the kind of diagnosis between the asthma and COPD  
5 and found out that those disparities in the  
6 diagnosis really didn't exist.

7 And so we wanted to align the age  
8 stratification as much as possible to the product  
9 line that we report on as we mentioned before for  
10 the reporting programs. We do have an age strata  
11 from 50 to 64 I still believe in the measure that  
12 kind of addresses the potential differences in  
13 that population.

14 And that still is existing because we  
15 believe there may be some. But it hasn't born  
16 out right now. We do actually exclude anyone  
17 with COPD or any kind of chronic obstructive  
18 disease, so, yes.

19 CO-CHAIR BRATZLER: The only other  
20 question, I don't know if this is, it's not a  
21 gap. But, you know, the question does anybody  
22 ever graduate out of the measure or the

1 denominator?

2           So a patient has a diagnosis of asthma  
3 but, you know, gets better. I mean it doesn't  
4 become clinically relevant or they get where they  
5 move to get rid of their cap. They do something  
6 that's their triggers that, you know, don't  
7 require them to be on therapy. Does anybody ever  
8 graduate out?

9           MR. HAMLIN: Well according to our  
10 chair who is a pulmonologist generally they  
11 graduate into obstructive disease not generally,  
12 you know. So we do is, the number of exclusions  
13 for COPD does increase as the, as the age  
14 increases and it gets fairly significant I think  
15 over 65.

16           DR. DIGIOVINE: And I'm assuming the  
17 denominator is based on some set period of time  
18 with the diagnosis of asthma.

19           MR. HAMLIN: It's a two year  
20 denominator. So we work over multiple years.

21           CO-CHAIR BRATZLER: So any other  
22 comments, questions about gaps? Okay.

1 MS. AMIRAULT: Okay, so voting for  
2 performance for Measure 1800. The options are  
3 one high, two moderate, three low and four  
4 insufficient. Again, performance gap for Measure  
5 1800.

6 (Voting.)

7 MS. AMIRAULT: Just to double-check,  
8 did everybody in the room vote? If you could  
9 just send again?

10 DR. NISHIMI: Please repress.

11 MS. AMIRAULT: Okay, six high, 14  
12 moderate, zero low and zero insufficient. And  
13 based on the percentage we can move along.

14 CO-CHAIR BRATZLER: Okay, move to  
15 reliability.

16 DR. RILEY: Sure. So looking at  
17 reliability the developer noted that the  
18 specifications have not changed since the last  
19 endorsement submission. Reliability testing has  
20 been updated slightly to reflect new data from  
21 HEDIS from 2014.

22 But the developer also notes that the

1 reliability results still range from .93 to .97  
2 indicating strong reliability.

3 CO-CHAIR BRATZLER: Any questions or  
4 comments about reliability? Seeing none, let's  
5 vote.

6 MS. AMIRAULT: Okay. So voting for  
7 reliability for Measure 1800. The options are  
8 one high, two moderate, three low and four  
9 insufficient. Again, reliability for 1800.

10 (Voting.)

11 MS. AMIRAULT: Okay. We have 15 high,  
12 five moderate, zero low and zero insufficient.  
13 And based on the percentage we'll move along.

14 CO-CHAIR BRATZLER: Okay. And so  
15 we'll move to validity.

16 DR. SCHINDLER: Probably the biggest  
17 threat to validity is the percentage of people  
18 excluded. So in the commercial plans they said  
19 about 25 percent of individuals are excluded  
20 while on Medicaid about 18 percent.

21 And interestingly it seems like a  
22 disproportion of those were in that older age

1 group of 51 to 64 versus the five to 50 year old  
2 population. I think it's important just to look  
3 at that, you know, up to a quarter of the  
4 patients are excluded. Otherwise there was no  
5 big change in the validity from the first go  
6 around.

7 CO-CHAIR BRATZLER: Lindsey, did you  
8 have any comments? Any other comments about  
9 validity, questions? Yes, sir.

10 DR. LAMPONE: Yes, I did have a  
11 question about the medication adherence ratio  
12 that you had used. And I think in Yoon there  
13 were some questions regarding when patients are  
14 prescribed either at the beginning of the period  
15 of end of the period and what that does to the  
16 measurements.

17 And in fact that study, that Yoon  
18 study had a lot of concern about that measure.  
19 Can you comment on that and what your  
20 interaction, what, you had mentioned that you  
21 have spoken to some of those investigators?

22 MS. ROTH: So actually the Yoon study

1 was more related to the measure that's coming up  
2 next, the adherence measure. So I mean I can  
3 comment on it now.

4 DR. LAMPONE: No, I got confused then  
5 on the measurement ratio that you were using.

6 MS. ROTH: On the ratio, yes, so it's  
7 a ratio of controller medications to total asthma  
8 medications, so controller and reliever.

9 DR. LAMPONE: And actually Yoon  
10 supported that as a much more accurate study  
11 across populations.

12 MS. ROTH: Right, yes. There have  
13 been a few studies that have found the validity  
14 of that.

15 CO-CHAIR BRATZLER: Other comments or  
16 questions about validity? Seeing none, let's  
17 vote.

18 MS. AMIRAULT: Okay. So for validity  
19 for Measure 1800 your options are one high, two  
20 moderate, three low and four insufficient.  
21 Again, validity for 1800.

22 (Voting.)

1 MS. AMIRAULT: Okay, eight high, 12  
2 moderate, zero low and zero insufficient. And  
3 based on the percentage we'll move along.

4 DR. RILEY: For feasibility the  
5 developer notes that all of the data is generated  
6 during care processes and are currently included  
7 in defined fields in electronic claims. They  
8 also utilize independent audits to verify the  
9 HEDIS specifications are being met and that they  
10 do receive real time feedback from users of the  
11 measure.

12 So it doesn't seem like there are any  
13 concerns there with obtaining the data.

14 CO-CHAIR BRATZLER: So I'll raise the  
15 one issue that we talked about fairly extensively  
16 this morning and that's meds that may not show up  
17 in claims. It sounded like there are some  
18 periodic audits.

19 So I'm just curious, have you ever  
20 looked to see whether there's evidence patients  
21 were on meds that don't show up in your claims  
22 data files?

1 MR. HAMLIN: We've been increasingly  
2 interested actually for the next measure about  
3 those patients who don't meet the 50 percent  
4 adherence rate and finding out whether that's a  
5 data issue or a management issue. We haven't  
6 identified the perfect way to do that yet.

7 We're still looking. That's all I can  
8 really at this point. The consensus panel we  
9 used, the advisory panel is not convinced that  
10 the majority of asthma medications are, you know,  
11 sort of freebies or giveaways or low cost things.  
12 But that's just their highly respected opinion,  
13 professional opinion at this point.

14 CO-CHAIR BRATZLER: So other questions  
15 about feasibility? Okay.

16 MS. AMIRAULT: Okay. So voting for  
17 feasibility for Measure 1800. Your options are  
18 one high, two moderate, three low and four  
19 insufficient. Again, feasibility for Measure  
20 1800.

21 (Voting.)

22 MS. AMIRAULT: Okay, 15 high, five



1 moderate, zero low and zero insufficient.

2 CO-CHAIR BRATZLER: Okay. To  
3 usability and use.

4 DR. SCHINDLER: So this is a  
5 maintenance measure there's a higher emphasis on  
6 this. And this current measure is being used  
7 widely and publicly report. It's being used at  
8 the health plan rating annual state of the health  
9 care quality health plan accreditation and  
10 quality compass.

11 The developers included lots of links,  
12 very easy to find, easy to identify. It's a  
13 really pretty straightforward process measure.  
14 There's been, they cited a little bit of movement  
15 in the Medicaid population not so much in the  
16 commercial.

17 But it's small. But certainly it  
18 seems like it's being widely used.

19 CO-CHAIR BRATZLER: I'm sorry. I just  
20 want to ask quickly, clarify something you said  
21 about not much movement in the metric, any  
22 concerns about why it's not moving at all?

1 DR. SCHINDLER: I don't really know  
2 why it's not moving. I think, I don't know that  
3 it's particularly problematic. I think the hope  
4 that would be by measuring it we're going to  
5 start addressing the gaps.

6 There still remains a very wide gap  
7 between commercial product and Medicaid,  
8 Medicare. And they cite that there's no movement  
9 but that the numbers, I didn't run a statistical  
10 analysis on it.

11 But they clinically didn't feel  
12 different, 57, 65 back to 59 percent.

13 CO-CHAIR BRATZLER: Bill, I'll go to  
14 you and then we'll ask the developers.

15 DR. GLOMB: With reflecting the  
16 Medicaid there's been a push in the Medicaid  
17 managed care programs to use this measure. And  
18 we're certainly using it as an indicator with, in  
19 quality care.

20 And now that payment models are  
21 beginning to evolve and preferred provider  
22 networks we've actually set this as one of our

1 measures to be a preferred provider of asthma  
2 care in our network. It's a very young measure  
3 and we've been rolling it out and people are  
4 starting to pick it up I think.

5 It is for the last couple of years  
6 been relatively stabilized. As it gains traction  
7 I think we'll see better improvement as it gets  
8 more traction, more programs.

9 CO-CHAIR BRATZLER: Any other  
10 questions or comments? Okay, let's vote on use.

11 MS. AMIRAULT: Okay. Voting for  
12 usability and use for Measure 1800. Your options  
13 are one high, two moderate, three low and four  
14 insufficient. Again, usability and use for  
15 Measure 1800.

16 (Voting.)

17 MS. AMIRAULT: Okay, for results we  
18 have 13 high, six moderate, one low and zero  
19 insufficient and based on the percentage can move  
20 along.

21 CO-CHAIR BRATZLER: Okay. And then  
22 overall rating, suitability. Any other comments

1 or questions, concerns or anything else to relay  
2 to the developer? All right. You guys are  
3 quiet. So we'll move on with the vote.

4 MS. AMIRAULT: Okay. So voting for  
5 overall suitability for Measure 1800. One for  
6 yes and two for no.

7 (Voting.)

8 MS. BAL: Ella, we have not received  
9 your vote. Please vote.

10 DR. KAZEROONI: I already did that  
11 one. I'll do that again.

12 MS. BAL: Thank you. We received it,  
13 thank you.

14 MS. AMIRAULT: Okay, 20 for yes and  
15 zero for no, making it 100 percent.

16 CO-CHAIR BRATZLER: All right, very  
17 good. Thank you. So we'll move on to the  
18 discussion for the next measure which is 1799.  
19 You've already given us a nice overview of the  
20 measure.

21 Anything to add to that? Okay. So  
22 our discussants are Thomas and Curtis and we'll

1 start off with evidence.

2 DR. COLLINS: So, you know, I think  
3 this is one that potentially we could explore  
4 again based on the Yoon study that was mentioned  
5 here previously. For those familiar with the  
6 measure they look at the numerator at the 50th  
7 and 75th percentile compliance measure.

8 This is a maintenance measure and it  
9 sounds like when it was approved before the level  
10 of evidence was questioned on those markers  
11 previous but was ultimately approved. So the  
12 Yoon study, correct me if I'm wrong, looked at  
13 this exact measure in over 30,000 patients.

14 And looked at whether the process  
15 related measure can be tied to really any sort of  
16 outcome. And the developer lists that at the  
17 75th percent mark there was no difference in  
18 hospitalizations. At the 50 percent mark there  
19 was no difference in hospitalizations.

20 But there were fewer ED visits. That  
21 may or may not be clinically significant. The  
22 differences in ED visit rates was 3.7 and 4.2

1       percent.   So just a half a percent difference.

2               And as far as what the authors of this  
3       very large paper say, they say there's no  
4       meaningful clinical outcome.   If you read into it  
5       a little bit more some of my concerns are that  
6       this measure could actually increase costs and  
7       resource utilization and then potentially adverse  
8       events by actually increasing therapy or  
9       increasing medication use.

10              And the authors, while they don't  
11       provide a lot of great data for that do allude to  
12       that.   So I think the level of evidence has  
13       certainly changed since the last review.

14              The developers had mentioned some  
15       follow-up or some additional studies, although I  
16       didn't see those in my review here.   So we have a  
17       very large study and I think it certainly is  
18       noteworthy.

19              CO-CHAIR BRATZLER:   Did you have  
20       anything different, Tom, or anything else?

21              DR. LAMPONE:   I would agree with  
22       Curtis.   Also the basic tenant of the study cited

1       that the measure doesn't take into account other  
2       triggers of asthma such as viral illness or other  
3       environmental issues that may trigger an event  
4       and does not take into account the treatment of  
5       mild asthma where daily controller use may not  
6       always be appropriate.

7               And that's where I think they came to  
8       some of the conclusions that this may drive  
9       utilization in some asthma populations that would  
10      be inappropriate.

11             CO-CHAIR BRATZLER:   And so any other  
12      Committee Members have questions and then I'll  
13      ask the developers to respond to some of those  
14      comments.   Go ahead, Lindsey.

15             MS. ROTH:   Sure.   So first I just  
16      wanted to point out that I believe it's on Page 3  
17      of your measure worksheet is a summary of some  
18      other evidence looking at the links between the  
19      adherence rates and outcomes.

20             But going back to the Yoon study so  
21      one of the reasons that we are glad that we had  
22      the opportunity to meet with the researchers is

1 because we thought that there were a few  
2 limitations of the study. So the first one was  
3 that they were using an older version of the  
4 specification that had an error in how you  
5 calculate the denominator for the measure.

6 And it actually we thought was, could  
7 potentially be a, you know, a pretty big flaw  
8 because it was looking at how asthma or inhaler,  
9 canisters for inhaled medications were dispensed  
10 which is an important part of how you decide or  
11 calculate whether patients have persistent asthma  
12 versus the more, you know, mild intermittent  
13 asthma.

14 And the other, I think one of the  
15 other issues was they didn't control for disease  
16 severity which some of the other studies that did  
17 find a link to outcomes had done. And so they  
18 were also interested in going back and rerunning  
19 some data and looking at more recent data and  
20 addressing these two methods. So I think, do you  
21 want to add anything?

22 DR. DIGIOVINE: Can I ask, given



1 obviously there's a lot of questions about these  
2 cutoffs, why did you choose to make this a binary  
3 outcome instead of just saying it's a continuous  
4 measure of compliance and we would measure it  
5 like any outcome or any process we measure rather  
6 than a sort of yes/no?

7 MR. HAMLIN: So that's actually a  
8 great question because one of the things during  
9 the development process when we were looking at  
10 whether a medication adherence measure is  
11 appropriate for asthma as a condition,  
12 particularly persistent asthma, the group felt  
13 very strongly that just setting a single  
14 threshold like an 80 percent as you may see for  
15 diabetes adherence was really not appropriate.

16 And what they really wanted was a  
17 quality measure that essentially stratified the  
18 population into those who met a high level of  
19 adherence, those who sort of met the threshold  
20 for questionable whether it was adherent or not  
21 and those, the 50 and 75 percent were completely  
22 set as potential thresholds based on their own

1 judgments.

2 And we then have proceeded to look at  
3 the data as it comes in year over year. But  
4 again, it's a very young measure. So there's not  
5 a lot of studies that have been able to be  
6 completed in this short period of time.

7 The way I like to think about the  
8 measure is a 75 percent threshold tends to act as  
9 a performance rate and that's the one we use for  
10 the HEDIS accreditation scoring and the other  
11 programs where we're comparing plans. The 50  
12 percent rate, and this is what we've been talking  
13 about with the Yoon researchers is actually it's  
14 those who are under 50 percent you probably want  
15 to spend more of your time focusing on whether  
16 it's because they're not taking their meds or  
17 they shouldn't be taking their meds.

18 And that's sort of the population of  
19 interest, if you will. And so that rate remains  
20 in the measure and is popular with some people  
21 and not with others. And so we wanted to leave  
22 the measure until we had some good data and some

1 good evidence to show that those rates were  
2 either inappropriate or should be adjusted up or  
3 down one way or the other. And that's basically  
4 where we are in full transparency.

5 DR. DIGIOVINE: Okay. Just to follow  
6 up just because I'm, this number, I understand  
7 you're measuring sort of days covered with a  
8 controller medication. Are you assuming that  
9 everyone has a prescription or how do you know  
10 this is, is it a compliance or is it a physician  
11 ordering issue?

12 MR. HAMLIN: It's based on dispensed  
13 events. So it's only if they pick it up. And we  
14 start the clock at the first dispensing event.  
15 So the date they pick it up, the first date they  
16 pick up their medication in the measurement year  
17 is when we start the count effectively.

18 It's admin claims so we have no way of  
19 understanding the orders unfortunately at this  
20 time.

21 DR. LAMPONE: So for clarification the  
22 adherence rate is calculated if a patient is

1 given an index prescription in October, October 1  
2 they and they get that filled there's then three  
3 months in the treatment period and three months  
4 of active medication. And so they would be  
5 deemed compliant?

6 MR. HAMLIN: They would be. And we  
7 actually, we were very curious about that when we  
8 tested this measure with nine health plans when  
9 we first developed it. And we actually, we are  
10 sort of looking at when the index events occurs  
11 for most of the, majority of plan members and  
12 they actually happen the first quarter of the  
13 year.

14 So there are a few members who do meet  
15 the criteria. Remember we have a two year  
16 denominator for this measure. So you have to  
17 have two years of diagnosis or medications or  
18 combinations of events that get you as a  
19 persistent asthmatic.

20 And then so for that population  
21 really, I don't remember what the percentage? I  
22 don't remember the percentage numbers were. But

1 a very high percentage picked them. Their index  
2 prescription is the first quarter of the year,  
3 the first three months of the year tapering very  
4 rapidly into the second quarter and very few  
5 actually hit the fourth quarter.

6 DR. LAMPONE: So to be compliant in  
7 that example I used would the patient have to  
8 fill three prescriptions or if one was filled but  
9 the other two missed did you measure consistency  
10 or compliance with adherence?

11 MR. HAMLIN: So the measure requires  
12 a proportion of dates covered from the index  
13 prescription through the end of the measurement  
14 period. And we use the data supply field or the  
15 definitions that are in the measure because some  
16 of the data supply fields for canisters are a  
17 little wonky.

18 And so we use those calculations to  
19 determine the days covered, if you will, for each  
20 prescription. And many of them are not on any  
21 prescription. So in many cases for someone who  
22 is in the fourth quarter would get one

1 prescription and probably make it through the end  
2 of the year.

3 We don't count overlap. So if they  
4 get multiple prescriptions they're only allowed  
5 one controller per day, if you will, depending on  
6 which one that is in case of the medication  
7 switching issue and other things like that.

8 DR. LAMPONE: Okay. So I was having  
9 a little problem hearing you. So they have to  
10 have one prescription filled and it doesn't  
11 necessarily have to be for 30 or 90 days. You  
12 just count it across the board.

13 MR. HAMLIN: They just have to have  
14 one canister coverage per day of that period  
15 between the index prescription and the end of the  
16 measurement period.

17 DR. LAMPONE: Okay. So they would  
18 have to have, well three then, three canisters,  
19 okay.

20 DR. DIGIOVINE: Other comments or  
21 questions about evidence? So I think this one we  
22 want to revote because of the change. And I

1       assume, do you have any sense of your time line  
2       with Yoon in terms of the reanalysis of the data?  
3       I know it's not your data.

4               MS. ROTH: We're hoping soon. But,  
5       yes, we don't have a specific time line.

6               DR. DIGIOVINE: Okay. All right. So  
7       everybody agree I think we should revote the  
8       evidence on this particular metric. I'm seeing  
9       lots of heads nodding so I'm going to take that  
10      as a, yes.

11              MS. AMIRAULT: Okay. So voting for  
12      evidence for Measure 1799. Your options are one  
13      high, two moderate, three low and four  
14      insufficient. Again, evidence for 1799.

15              (Voting.)

16              MS. AMIRAULT: Okay. One high, 11  
17      moderate, five low and three insufficient. And  
18      this will be a grey zone.

19              MS. GORHAM: Just for record purposes  
20      again David Lang has recused himself from  
21      discussion and vote of this measure as well.

22              DR. COLLINS: All right. So we'll

1 move on to, yes, performance gaps. As the  
2 developer has said on one of their previous  
3 measures, they have commercial data and Medicaid  
4 or Medicare, Medicaid data looking at differences  
5 and trying to account for performance gaps or  
6 opportunities for improvement.

7 It looks like between the commercial  
8 and the government payer there is, you know,  
9 differences both at 50 percent and 75 percent  
10 compliance ratios. And it looks like there's  
11 opportunities for improvement.

12 But there's no reports on disparities  
13 other than what's listed and what was listed  
14 before. And please correct me if I'm wrong.

15 DR. LAMPONE: I have nothing else to  
16 add to that.

17 CO-CHAIR BRATZLER: So any other  
18 questions or comments about gaps, performance  
19 gaps? Similar to the previous measure  
20 differences by plan but no other stratification  
21 data.

22 MS. AMIRAULT: Okay, voting for



1 performance gap for Measure 1799. Your options  
2 are one high, two moderate, three low and four  
3 insufficient. Again, performance gap for 1799.

4 (Voting.)

5 MS. AMIRAULT: We have five high, 12  
6 moderate, three low and zero insufficient. And  
7 based on the percentage we can move along.

8 CO-CHAIR BRATZLER: Okay. We'll move  
9 along to reliability. Tom or Curtis, we're ready  
10 for reliability.

11 DR. LAMPONE: You ready to go? Okay.  
12 All right. Next section is reliability and I'll  
13 also after that discuss validity. And we touched  
14 upon this a little bit with the measure cut offs  
15 for the numerators at 50 and 75 percent of  
16 proportion of days covered.

17 There were no changes in this since  
18 the last endorsement. The denominator criteria  
19 had not changed. There's been some updates since  
20 the last submission but no big changes. I didn't  
21 have really anything else to add to this unless  
22 you do, Curtis.

1 DR. COLLINS: No, and the Work Group  
2 I don't believe did either.

3 CO-CHAIR BRATZLER: Any other  
4 questions or comments about reliability? Any  
5 other questions, comments? Okay. Go ahead and  
6 vote.

7 MS. AMIRAUT: Okay. For voting for  
8 reliability for Measure 1799. Your options are  
9 one high, two moderate, three low and four  
10 insufficient. Again, reliability for 1799.

11 (Voting.)

12 MS. AMIRAUT: Okay. Five high, 14  
13 moderate, one low and zero insufficient. And  
14 based on the percentage we can move on.

15 CO-CHAIR BRATZLER: Okay, validity.

16 DR. LAMPONE: Okay. So moving on to  
17 validity. We touched upon this a little bit as  
18 well looking at the thresholds of the 50 percent  
19 and 75 percent.

20 There was note made that the field  
21 test examined ED visits for the populations above  
22 and below 50 percent and then there was two new

1 studies reported by the developer that looked at  
2 the proportion of days covered based on the index  
3 prescription.

4 When you look at the testing for this  
5 I was drawn to the, first to the Pearson  
6 correlation coefficients in which you look at the  
7 medication adherence and asthma medication ratio  
8 and the asthma medication ratio, you know, drops  
9 below the .3 percent threshold. And partly the  
10 other reason why that caught my eye is that the  
11 asthma medication ratio has been looked at in  
12 other studies as well.

13 And in the Yoon study they cite other  
14 particular studies that have looked at this. And  
15 particularly those studies address race and  
16 ethnicity through over a gamut of asthma patients  
17 and also had comorbidity index, the Charlson  
18 Comorbidity Index as well put it into that  
19 analysis.

20 So I had the sense that when you look  
21 at, at least the asthma medication ratio by  
22 itself it may be a more reflective measure of

1 actual compliance as opposed to the proportion of  
2 covered days.

3 And when you further look at that data  
4 where you have it somewhat risk adjusted and I  
5 know that wasn't part of the particular measure,  
6 it puts another level on information and outcome  
7 data, in this case exacerbations in ER visits or  
8 hospitalizations into a, I think a more tangible  
9 type of a perspective.

10 So I think just that nuance in that  
11 measurement kind of, in my mind puts a question  
12 to the validity. And also when you look at the  
13 outcome data, again as Curtis mentioned, there  
14 was no difference between the adherent and  
15 nonadherent groups as far as outcomes.

16 So you look at that and that kind of  
17 gives you another reason to pause and say is  
18 there something in the measure or is it something  
19 that is confounding the population and the added  
20 factors in there that is not taken into account.

21 CO-CHAIR BRATZLER: Curtis, did you  
22 have anything? So I'll turn it over to you in

1 just a moment. But other comments about  
2 validity?

3 So I mean I think this is a really  
4 important conversation about are we actually  
5 measuring something that will predict outcomes  
6 for the patients. And you would certainly think,  
7 I think if I heard you correctly, I was looking  
8 at it, I haven't looked at the risk adjustment.

9 Is there risk adjustment, any at all  
10 and so from a claims perspective things like ED  
11 and inpatient visits would be something  
12 relatively well available to most health plans as  
13 a predictor of risk. So do you have any  
14 comments?

15 MR. HAMLIN: Yes, so I mean it's not  
16 risk adjusted other than the fact that it's  
17 heavily stratified by both product line and age  
18 group which I call the poor man's risk adjustment  
19 for the health plan because really when you  
20 understand without going into the whole NCQA  
21 submission process that on the plan's report  
22 they're done on an enormous, usually a state base

1 because of the confines of the health plan  
2 contracts.

3 And so each health plan may have a  
4 submission for each state and that's the level of  
5 data in the aggregate we're getting. And so, you  
6 know, we have, we do risk it as other measures of  
7 resource use for asthma population.

8 But for the things like when we're  
9 looking at adherence we really try and focus in  
10 on the proxies, if you will, for the, you know,  
11 for the quality of care being delivered and there  
12 probably is some data noise in there and there  
13 probably are some other places to do.

14 But we, our current philosophy is that  
15 the plans are well positioned to further  
16 investigate as I mentioned on the 50 percent rate  
17 of the patients that are not. And without us  
18 sort dictating at the point of care what the  
19 physicians should be doing we kind of try and use  
20 these proxies, if you will.

21 So the asthma ratio is a proxy of  
22 asthma control using claims data that's the best

1 data we have for this kind of condition. And the  
2 same with this adherence. You know, I would love  
3 to have a much better measure using much more  
4 distributed data.

5 But in the admin claims this is really  
6 the best approximation we can get to as far as  
7 measuring the kind of care processes that we  
8 think lead to better asthma care. And I think  
9 there was an earlier comment about the last round  
10 and it was not a fan favorite.

11 But it was filling a huge gap and a  
12 need of people felt there weren't any other  
13 asthma measures out there that were doing  
14 anything similar. And so it was an important  
15 thing to just sort of, you know, get out there  
16 and they thought it was, met the level to be  
17 endorsed, if you will, because it was, there's  
18 really nothing else out there really that does  
19 the same thing.

20 It was an improvement over the measure  
21 that just said do you have asthma, do you have  
22 one medication, which is the prior measure that

1 had topped out basically for us. So we replaced  
2 it with this one setting the bar a little higher.

3 MS. ROTH: I also did want to add too  
4 that so for the Pearson correlations, so as you  
5 noted we looked at the measures are stratified by  
6 age but we did the correlations looking at the  
7 total rate between the medication ratio and  
8 medication adherence measure.

9 But after we had submitted the forms  
10 we did go back and look at the correlations  
11 between the two measures within each age strata.  
12 And what we actually have found was that the  
13 correlations were much higher for the children,  
14 the adolescents and the younger adults.

15 So the correlations were closer to .4  
16 and .5 within those age groups. And it was  
17 really the older adults where the correlations  
18 were not as strong.

19 DR. DIGIOVINE: I had a question sort  
20 of, I guess it bridges this in usability. But  
21 what you're saying is that this is data that  
22 would be useful to health plans.



1                   Do you have, do you know of any health  
2                   plan that's gone out and looked at 100 of their  
3                   patients who have a ratio that's less than .5 and  
4                   could find a meaning in those, what those  
5                   patients, was going on with those patients and  
6                   could intervene and could actually improve  
7                   compliance?

8                   MR. HAMLIN: Not that I could name any  
9                   names, no. But, no, again we have heard that  
10                  they have been looking seriously at this measure  
11                  because it has again been starting to be  
12                  introduced in different programs for quality  
13                  reporting as a replacement for what was existing.

14                 And we're effectively waiting for  
15                 those studies to be done and be published, if you  
16                 will. And we do hear, and the lack of any other  
17                 information we have not heard or hate mail for  
18                 open lines that we get about measures when people  
19                 are not happy with them.

20                 So in the absence of any hate mail I'm  
21                 assuming that people are still interested or  
22                 intrigued and are still looking at this issue and

1       they're not going to just stay away because, you  
2       know, they don't think it's a valid measure.

3               DR. LAMPONE: Yes, in the information  
4       I've seen in reviewing this measure mainly what  
5       some of the plans looked at is when they had  
6       their members fall below that ratio threshold it  
7       would trigger an event of education to their  
8       membership and they would have programs with  
9       their providers to do this.

10              So it would help the provider target  
11       some of those members who are at risk for  
12       exacerbation based on that measure and try to get  
13       to a root cause of whether they were noncompliant  
14       or whether they were having other problems with  
15       meeting that measure.

16              They also made note that it also opens  
17       the conversation for the provider with that  
18       member to maybe explore other controlling  
19       medications that are easily administered, less  
20       multiple doses during the day and there was some  
21       data that looked at higher compliance rates when  
22       patients were able to be transitioned over to

1 more convenient controller medications.

2 So that's where I see the utility in  
3 some of those alternate measures that were not in  
4 this.

5 MR. HAMLIN: And I think we're  
6 perfectly in line with your vision.

7 CO-CHAIR BRATZLER: So other comments  
8 about validity? All right, we can go ahead and  
9 vote.

10 MS. AMIRAULT: Okay. Voting for  
11 validity for Measure 1799. Your options are one  
12 high, two moderate, three low and four  
13 insufficient. Again, validity for 1799.

14 (Voting.)

15 MS. AMIRAULT: Okay. Zero high, 15  
16 moderate, five low and zero insufficient. And  
17 based on this we can move along.

18 CO-CHAIR BRATZLER: All right. We'll  
19 go to feasibility.

20 DR. COLLINS: Yes, as far as we know  
21 nothing has changed since the last approval. It  
22 seems highly feasible electronic data which is

1 already, you know, collected in mass as the Yoon  
2 study would show.

3 CO-CHAIR BRATZLER: Any questions or  
4 comments about feasibility? Okay, we'll go ahead  
5 and vote.

6 MS. AMIRAULT: Okay. Feasibility for  
7 1799. Your options are one high, two moderate,  
8 three low and four insufficient. Again,  
9 feasibility for 1799.

10 (Voting.)

11 MS. AMIRAULT: Okay, 19 high, one  
12 moderate, zero low and zero insufficient. And  
13 based on the percentage we can move along.

14 CO-CHAIR BRATZLER: Usability and use.

15 DR. COLLINS: As far as usability it's  
16 publicly reported already in a number of places  
17 including consumer reports. I think the  
18 developers and we've had some nice discussions  
19 here already about the usability of this measure  
20 where the result means including some of the  
21 controversies around it. And I really don't have  
22 anything more to add.

1 CO-CHAIR BRATZLER: So I know you  
2 raised it earlier. But I do have concerns  
3 anytime we hold people accountable for a measure  
4 where there's a question in the evidence about  
5 the impact on outcome about unintended  
6 consequences of driving costs, use of medications  
7 just because we have a measure not because we're  
8 improving patient outcome.

9 So you've highlighted that before.  
10 But I just wanted to raise that one more time  
11 that does concern me some. Any other comments  
12 from the group, questions about usability? And  
13 this is a new measure so you haven't had time to  
14 see a lot of change over time. Okay. All right.  
15 I think no other comments we can vote.

16 MS. AMIRAULT: Okay. Usability and  
17 use for Measure 1799. One high, two moderate,  
18 three low and four insufficient. Again,  
19 usability and use for 1799.

20 (Voting.)

21 MS. AMIRAULT: Okay. Two high, 11  
22 moderate, six low, and one insufficient. And

1 based on the percentage we can move along.

2 CO-CHAIR BRATZLER: And then the last  
3 vote will be on usefulness, what's the term just  
4 overall suitability, okay. So any other  
5 comments? Obviously we've highlighted, I think  
6 the developers have made it clear they are aware  
7 of the controversy around one study and are  
8 looking at that.

9 And the issue about questions of  
10 unintended consequences has been raised and some  
11 of the questions about validity. Anything else  
12 that we need to raise with the developers? Go  
13 ahead.

14 MR. HAMLIN: To address your comment  
15 about unintended consequences, these two measures  
16 are paired with the risk-adjusted relative  
17 resource use for asthma which do include specific  
18 subcategories for medication use and use of  
19 syncopation and outpatient services among 37  
20 other things. So there is a way that we could  
21 track changes and resource use driven by these  
22 measures as a valued measure of this paired

1 quality.

2 CO-CHAIR BRATZLER: Almost a balancing  
3 measure. All right. Any other comments? So  
4 we'll take our final vote on this measure.

5 MS. AMIRAULT: Voting for overall  
6 suitability for Measure 1799. One for yes and  
7 two for no.

8 (Voting.)

9 MS. AMIRAULT: Okay, 12 yes and eight  
10 no, grey zone.

11 CO-CHAIR BRATZLER: All right, thank  
12 you. So we'll let our friends from NCQA give us  
13 one more introduction to the next measure which  
14 is 0577. This is Spirometry Testing and  
15 Assessment and Diagnosis of COPD. And Dr. Lang  
16 is back at the table now to be a participant in  
17 the conversation.

18 MS. ROTH: So again, this is a health  
19 plan level measure. It assesses whether patients  
20 40 and older with a new or newly active diagnosis  
21 of COPD had spirometry testing to confirm their  
22 diagnosis.

1           And plans calculate this measure by  
2     identifying people with a COPD diagnosis during  
3     the measurement year and then excluding those  
4     people who had a COPD diagnosis any time in the  
5     two years prior to that. So then they arrive at  
6     a population who has new COPD.

7           And we did test different options for  
8     this time interval including looking one year  
9     back, looking only six months back for the COPD  
10    diagnosis history. But we found that the two  
11    years was the most specific at getting to the  
12    newly diagnosed patients.

13          The measure is based on guidelines and  
14    evidence that spirometry should be performed to  
15    diagnose airflow obstruction in patients with  
16    respiratory symptoms in order to make a clinical  
17    diagnosis of COPD and to determine appropriate  
18    therapy. We did cite several studies from AHRQ  
19    evidence review that found that spirometry to  
20    confirm diagnosis helps providers identify those  
21    patients who might benefit from medication that  
22    would lessen their risk of COPD exacerbations.



1           But there is some more research needed  
2     to assess the link to outcomes. And then we did  
3     also provide some data following the Work Group  
4     call showing that the measure rates have improved  
5     six percentage points since 2008. And this was  
6     across all the plan types, commercial, Medicaid  
7     and Medicare.

8           But although there has been some  
9     improvement rates do continue to be low. So  
10    there's still opportunity for improvement going  
11    forward.

12           CO-CHAIR BRATZLER: Thank you. So our  
13    discussants are James and Todd.

14           DR. DORMAN: I think that leaves me.

15           CO-CHAIR BRATZLER: Okay.

16           DR. HARRIS: I'm on the line.

17           DR. DORMAN: Okay, wonderful. Do you  
18    want me to start or --

19           DR. HARRIS: Go ahead.

20           DR. DORMAN: Okay. It might be easier  
21    that way. So this is a, I think thank you for  
22    the explanation and I think that sets the stage

1 well. This is really about the use of spirometry  
2 testing in the diagnosis of COPD.

3 It's a process measure at the level of  
4 analysis of the health plan first endorsed in '09  
5 and then endorsed in 2012 and now up as a  
6 maintenance measure again. Under the level of  
7 evidence, new evidence updated evidence was  
8 provided.

9 This included from the GOLD Guidelines  
10 which references over 600 studies, a  
11 recommendation additional work through ACP\ATS  
12 and European Respiratory Society which also made  
13 the same basic recommendation that spirometry  
14 should be obtained to diagnose air flow  
15 obstruction in patients with symptoms and cites  
16 additional references of controlled trials meta-  
17 analysis and systematic reviews.

18 And then there's a third guideline  
19 that is also listed. And these are all updated  
20 so there is new evidence. I think the discussion  
21 we had centered around the six month to two years  
22 and did not see hard evidence of this but felt

1       that there was face validity and appreciated the  
2       explanation and felt that the vector of the  
3       evidence was not impacted by the new data.

4               And in fact we thought it was enhanced  
5       and merely the magnitude of that vector was even  
6       stronger so that the evidence base grew for this  
7       recommendation.

8               CO-CHAIR BRATZLER:   So this is a  
9       maintenance measure.   James, did you have any  
10      other comments about that?

11              DR. HARRIS:   No, I think, you know,  
12      again one of the things that the, in the initial  
13      endorsement there was some question about sort of  
14      the link between the process and the outcome.  
15      But some of the additional studies are providing  
16      a little bit more of that link.

17              So again, I think it's a little bit  
18      stronger than it was previously.

19              CO-CHAIR BRATZLER:   So based on that  
20      conversation, there is new evidence but it just  
21      seems to make the, strengthen the argument from  
22      the previously endorsed measure.   So raise your

1 hands if you think we need to revote the evidence  
2 at this time.

3 Okay. Seeing none we'll go on then  
4 with our discussion of --

5 DR. DORMAN: Thank you, James. You  
6 want me to continue or --

7 DR. HARRIS: I'll take this one if you  
8 want. So this is the gap, performance gap study.  
9 Again this was one of the things I think that we  
10 had some questions about in terms of looking at  
11 some of the numbers that were provided initially  
12 from HEDIS in terms of looking at the breakouts  
13 from commercial plans and Medicare and Medicaid.

14 And didn't see, there certainly are  
15 sort of differences between the lowest being the  
16 Medicaid plan and the highest being commercial,  
17 you know, with 42 percent Medicaid being 31. So  
18 it certainly does look there's some difference in  
19 terms of entities, opportunities to improve  
20 there.

21 There was no information on  
22 demographics, race and ethnicity provided. But

1 again, you know, because of the difficulty in  
2 breaking that information out in terms of the  
3 data that's actually collected in this measure.

4 CO-CHAIR BRATZLER: Todd, anything  
5 else?

6 DR. DORMAN: Nothing to add.

7 CO-CHAIR BRATZLER: Any other  
8 questions or comments about gaps? Okay, we can  
9 go ahead and vote.

10 MS. AMIRAULT: Okay. Performance gap  
11 for Measure 0577. Options are one high, two  
12 moderate, three low and four insufficient.  
13 Again, performance gap for 0577.

14 (Voting.)

15 MS. BAL: Could everyone vote one more  
16 time in the room? We're missing a few more  
17 people. Thank you.

18 MS. AMIRAULT: Okay, nine high, 12  
19 moderate, zero low and zero insufficient.

20 DR. DORMAN: So, James, I'll do  
21 reliability and let you do validity. Is that  
22 okay?

1 DR. HARRIS: Sure.

2 DR. DORMAN: Give me one second. So  
3 electronic clinical data, claims data  
4 specifications were not updated since the last  
5 review. This is a measures score. Beta-binomial  
6 method was used for signal-to-noise and they were  
7 quite high across multiple populations, .92 to  
8 .97.

9 And give me one second. Let me get to  
10 the other part of my notes. So I think the  
11 discussion centered mostly around again the six  
12 month to two year period of time. And there was  
13 some discussion around and maybe it's worth  
14 reiterating a piece here or having the developers  
15 respond on the contrasting evidence between  
16 spirometry reading to improve care and confirming  
17 diagnosis.

18 And I just want to add I think this  
19 comes about in part related not only to trying to  
20 drive towards quality but by the title of this  
21 particular one which says in assessment and  
22 diagnosis when the evidence is all about the

1 diagnosis. And the word assessment I think leads  
2 some people to believe ongoing management.

3 James, do you want to add anything on  
4 reliability?

5 DR. HARRIS: No, nothing outside that.

6 CO-CHAIR BRATZLER: So NQF staff tell  
7 me the specifications really have not changed,  
8 that we don't have to vote on this unless you  
9 want to. So how many think we need to vote on  
10 reliability?

11 Okay. We'll move on to validity. And  
12 I guess Mitch is, you prefer Mitch?

13 DR. HARRIS: Yes, James, Mitch is  
14 fine. I answer to both. My parents played a  
15 cruel trick on me when they named me one thing  
16 and called me the other. So substitute teachers  
17 were always fun at school.

18 So in terms of validity there is some  
19 change here in terms of when the measure was  
20 initially examined and endorsed. Initially it  
21 was just face validity was provided. Since then  
22 sort of there have been some updated validity

1 testing using some other and comparing to other  
2 measures.

3 So this is a place where before the  
4 validity could have only been rated medium and  
5 now it's eligible for high. But I think again  
6 you do see, I think some strong metrics here in  
7 terms of the comparisons to some of the other  
8 measures and the appropriate direction or the  
9 direction that they hypothesized them being.

10 There are no exclusions for this  
11 measure and there is no risk adjustment. So that  
12 maybe something to think about and then in terms  
13 of missing data as well they just cite sort of  
14 the audit processes that are in place currently  
15 to look at those, to look at the measure that  
16 would sort of help alleviate any of the concerns  
17 that might be around missing data.

18 CO-CHAIR BRATZLER: Todd, anything  
19 else?

20 DR. DORMAN: Nothing to add.

21 CO-CHAIR BRATZLER: All right. And in  
22 conversations about validity, questions about



1 validity? So we do need to vote on validity. So  
2 we'll go ahead.

3 MS. AMIRAULT: So validity for Measure  
4 0577. Options are one high, two moderate, three  
5 low and four insufficient. Again, validity for  
6 0577.

7 (Voting.)

8 MS. BAL: Could everybody just vote,  
9 never mind. We got it. Thank you.

10 MS. AMIRAULT: Eight high, 13  
11 moderate, zero low and zero insufficient. And  
12 based on the percent we can move on.

13 DR. DORMAN: Mitch, in the spirit of  
14 alternating I'll do feasibility and you've got  
15 the last part usability, okay?

16 DR. HARRIS: Sure.

17 DR. DORMAN: So feasibility all the  
18 fields are defined in electronic claims with  
19 differing individuals that obtain the data and  
20 code the data the NCCU conducts independent  
21 audits. And I don't know that there's much else  
22 to say.

1 CO-CHAIR BRATZLER: Any other  
2 questions, concerns about feasibility? Hearing  
3 none we'll go ahead and vote.

4 MS. AMIRAULT: Feasibility for Measure  
5 0577. One high, two moderate, three low and four  
6 insufficient.

7 (Voting.)

8 DR. NISHIMI: Can, point there, got  
9 it, okay.

10 MS. AMIRAULT: Sixteen high, five  
11 moderate, zero low and zero insufficient. With  
12 this percentage we can move along.

13 DR. DORMAN: Okay, Mitch, go talk  
14 about usability.

15 DR. HARRIS: Sure, thanks. So I think  
16 usability again a couple of things to look at.  
17 It is currently being used and the NCQA's Data  
18 Health Care Annual Report and also through  
19 reporting consumer reports used in Quality  
20 Compass.

21 So there are a couple of places where  
22 it's already being examined and used for

1 benchmarking and quality improvement. I do think  
2 one of the things, again some additional  
3 information was provided but initial data sort  
4 of, you know, there was some concern about is  
5 there actually improvement being shown.

6 The rates broken out by the plans were  
7 pretty stationary. But some of the additional  
8 data provided went back I think into 2008 you  
9 could see that there's, you know, in some cases  
10 five to ten percent sort of increases between the  
11 years the data that they provide.

12 So there is some change going on over  
13 time. But as we mentioned in the gaps also there  
14 is a lot of room for improvement as well.

15 DR. DORMAN: I wouldn't, nothing to  
16 add.

17 CO-CHAIR BRATZLER: All right. Thank  
18 you. So any other discussion about usability?  
19 All right. Seeing none, let's vote.

20 MS. AMIRAULT: So for usability and  
21 use for Measure 0577, one high, two moderate,  
22 three low and four insufficient.

1 (Voting.)

2 MS. AMIRAULT: Okay, seven high, 13  
3 moderate, one low and zero insufficient. And  
4 based on the percentage we can move on.

5 CO-CHAIR BRATZLER: All right. And  
6 our last vote will be on overall suitability.  
7 Any other conversation, comments for the  
8 developer that we want to send back?

9 Everybody is quiet. They're waiting  
10 for the break. So we'll go ahead and vote on  
11 suitability.

12 MS. AMIRAULT: Okay. Overall  
13 suitability for Measure 0577, one for yes and two  
14 for no.

15 (Voting.)

16 MS. AMIRAULT: Twenty-one yes and zero  
17 no for 100 percent.

18 CO-CHAIR BRATZLER: All right. Thank  
19 you very much. So I think the last thing we have  
20 to do before the break is we've just covered  
21 three metrics that look at pharmacotherapy for  
22 asthma.

1                   Two by NCQA and one by the American  
2                   Academy of Allergy and, Asthma, Allergy and  
3                   Immunology. So --

4                   DR. NISHIMI: So in this case the  
5                   Committee can encourage harmonization. They may  
6                   decide that they prefer one over the other. I  
7                   would note that or one is over the other.

8                   I would note that they are at  
9                   different levels of analyses. So that's often a  
10                  justification provided by the Committee and they  
11                  do use different data sources. The AAAAI is a  
12                  clinician level measure and obviously the two  
13                  NCQA measures are plan level.

14                  CO-CHAIR BRATZLER: And the one  
15                  comment I would make and we talked about this  
16                  extensively I think our major developer heard  
17                  that was that for the AAAAI measure the  
18                  performance rate combined control medications is  
19                  very, very high on the metric.

20                  And we made the recommendation to  
21                  consider reporting this in different ways. And  
22                  the ratio measure actually that NCQA has

1 potentially could be, it would be more difficult  
2 but there may be some way to report a ratio  
3 measure as a part of that or have as we discussed  
4 multiple numerators for the AAAAI measure also.

5 DR. NISHIMI: So the instruction would  
6 be to the developers in that regard is to have  
7 that kind of discussion. Is there anything else  
8 that the Committee wants to have them discuss?

9 DR. O'BRIEN: So I appreciate the fact  
10 that the ones at a clinician level and the other  
11 at the health plan levels. It would be great  
12 from an alignment standpoint of actually  
13 improving patient care.

14 There was alignment in those two  
15 measures so that you could go to the provider and  
16 say this is what you need to do for the health  
17 care plan to be successful as opposed to the  
18 possibility of them being disparate measures.

19 DR. OHTAKE: I just have a question  
20 about the count you made about 0047. It sounds  
21 like and well what we read is in the numerator  
22 it's just all controller medication, not

1 separating out corticosteroids.

2 But yet in the very first preamble in  
3 the brief description it says that three rates  
4 are reported where they do inhaled  
5 corticosteroids non-ICS and then everyone. I was  
6 wondering if the --

7 MS. SWAIN-ENG: Yes, there are three  
8 separate reads that they do report out. I think  
9 his comment though was to actually report out on  
10 because the list was so long perhaps you would  
11 want to make a smaller list. I think that was  
12 the comment if I'm correct.

13 CO-CHAIR BRATZLER: Well and the other  
14 thing though is the metric that actually gets  
15 used for public reporting, the value modifier and  
16 everything else is the combined rate which is  
17 very, very high rates of performance.

18 And I'm not convinced that is the most  
19 appropriate metric that we want to drive. So  
20 that's what gets used for all of these payment  
21 and reporting programs for 0047. So and that's  
22 where I think the ratio is an interesting concept

1 of looking what you're considering controller  
2 medications to all other asthma medications.

3 DR. NISHIMI: Anything else? Okay.

4 So the staff writes that up and then the  
5 developers will discuss and when it comes back  
6 for maintenance we'll see what happens.

7 CO-CHAIR BRATZLER: So you guys were  
8 incredibly efficient. It looks like we either  
9 gained five minutes of break or we can come back  
10 at ten after. What do you prefer? What's that?  
11 All right, 3:10 we're starting again.

12 (Whereupon, the above-entitled matter  
13 went off the record at 2:55 p.m. and resumed at  
14 3:11 p.m.)

15 CO-CHAIR BRATZLER: All right, very  
16 good. We did good, so let's keep moving forward.  
17 We have three more measures to discuss this  
18 afternoon.

19 The first one is 0091, COPD Spirometry  
20 Evaluation from the American Thoracic Society.  
21 With us here in person is Sue Frechette and Bela  
22 Patel is on the phone, and they'll give us the



1       brief introduction to the measure.

2                   MS. FRECHETTE:  Thank you.  I'm going  
3       to try to make myself heard.  Bela, are you on  
4       the call at this point?

5                   (No response.)

6                   MS. BAL:  Operator, could you make  
7       sure that Bela Patel has access, has a speaking  
8       line?  Thank you.

9                   MS. FRECHETTE:  So Dr. Bela Patel who  
10      is our COPD  expert who will be joining us  
11      shortly, if she's not on the call yet.  So let me  
12      just give you a brief introduction.

13                   First of all, the ATS spirometry  
14      measure was originally developed by the ATS in  
15      conjunction with the AMA-PCPI and has been in use  
16      in the PQRS program since 2007.

17                   It was initially endorsed by the NQF  
18      2009, and was recently reendorsed in 2012.  It's  
19      also been in use for the ABIM MOC program for the  
20      past three years.  In late 2014, stewardship was  
21      transferred from the AMA-PCPI to the ATS.  So we  
22      have recently taken over stewardship of this

1 measure.

2 Performance since 2008 shows a  
3 favorable trend, and that trend is well-aligned  
4 with the literature. Just as a side note, in  
5 your work sheet the numbers from 2008 were  
6 reported. I think they're approximately 50  
7 percent performance. There was some additional  
8 information. It's on page 16 of the full  
9 application.

10 But just to quickly summarize, the  
11 trend since 2010, 2010 performance was up to 56  
12 percent. The most recent numbers were from 2014,  
13 and performance was at 67 percent. So  
14 performance is definitely moving in the right  
15 direction on this measure.

16 We believe strongly that accurate  
17 diagnosis of COPD is essential to provide high  
18 quality COPD management, and as you know that  
19 will improve quality of life, reduce  
20 exacerbations and ultimately reduce the cost of  
21 care. I won't repeat the details. We have a  
22 large amount of information in our application so

1       that information's all there.

2               But I'd just like to point out that  
3       it's critical that patients who are undiagnosed  
4       with COPD may not benefit from medication that  
5       could improve their lives, reduce costs,  
6       etcetera.

7               But there are also many patients who  
8       do not have COPD, that when they receive COPD  
9       medication have negative consequences, and that  
10      also may not benefit from medication that could  
11      ultimately improve whatever condition,  
12      respiratory condition they may have if it's not  
13      COPD.

14              So that's why we think spirometry is  
15      absolutely critical for diagnosis, for treatment.  
16      So based on trend, the literature, our belief in  
17      the importance of accurate diagnosis, we believe  
18      that this measure continues to be a good measure,  
19      and we would seek reendorsement if you're in  
20      agreement.

21              There was a brief discussion at the  
22      workshop meeting about the clarity of the

1 numerator for this measure. We believe we can  
2 add a little bit of clarity and are glad to  
3 discuss it further in the numerator details,  
4 which is Question No. S-6 in the full application  
5 that ought to help with this discussion.

6 So with that said, Dr. Patel and I  
7 welcome the discussion and are available to  
8 answer any questions you may have on this  
9 measure. So thank you.

10 CO-CHAIR BRATZLER: And it's my  
11 understanding Dr. Patel is on the line. Can you  
12 hear us now or can we hear you?

13 DR. PATEL: Yes, I can hear you now.  
14 Hopefully you can hear me.

15 CO-CHAIR BRATZLER: Yes, we can. Did  
16 you have anything to add to that brief  
17 introduction?

18 DR. PATEL: No, I do not.

19 CO-CHAIR BRATZLER: Very good. All  
20 right. So our discussants are Gerene and Edgar.

21 DR. BAULDOFF: Okay. The COPD  
22 spirometry evaluation measure is a -- the

1 description is the percent of patients at 18 or  
2 greater years of age with a diagnosis of COPD or  
3 who have had spirometry documented. It's a  
4 process measure that is in consideration for  
5 maintenance endorsement, and it's at -- the level  
6 of analysis is at the clinician group or  
7 clinician team.

8 The developer has provided systematic  
9 review of the evidence, including quality,  
10 quantity and consistency, as well as grading of  
11 the evidence. There's been no change in the  
12 evidence since the prior approval.

13 The evidence algorithm indicates a  
14 high rating, and that the work group had reported  
15 that we thought there was no need to discuss the  
16 evidence, even though there has been an  
17 improvement in the gap. But the gap still is at  
18 greater than 30 percent.

19 CO-CHAIR BRATZLER: Any --

20 DR. JIMENEZ: No, nothing.

21 CO-CHAIR BRATZLER: All right. So we  
22 have a previously endorsed measure, strengthening

1 of the evidence but otherwise no real change  
2 since the original endorsement in '09 and '12.  
3 James, did you have a comment?

4 DR. O'BRIEN: Yeah. Just a quick  
5 question for the developers. I was unclear if  
6 this is patients who -- with a diagnosis of COPD  
7 who have ever had spirometry or that they  
8 repeatedly get spirometry documented?

9 MS. FRECHETTE: It's ever had  
10 spirometry. Ever.

11 DR. O'BRIEN: Ever.

12 CO-CHAIR BRATZLER: Any other  
13 questions or comments? So I'm going to ask  
14 anyone to raise your hand if you think we need to  
15 vote on the evidence.

16 (Pause.)

17 CO-CHAIR BRATZLER: Seeing none, we'll  
18 go on with the conversation about performance  
19 gaps.

20 DR. BAULDOFF: Do we need to vote on  
21 gap? Is that what we're discussing. Okay. The  
22 gap was reported at 67 percent. It is improved

1 from about 50 percent over the last four or five  
2 years.

3 Those were from PQRS scores, and that  
4 it's reported that the gap remains limited by  
5 current literature. There's just really nothing  
6 new. There's a paucity in the literature.

7 DR. JIMENEZ: There will be a slowdown  
8 in the gap also because MOC has been put on hold.  
9 I don't know if you are aware of that too, right,  
10 for at least a couple of years now that we  
11 understand.

12 DR. BAULDOFF: There were a couple of  
13 things that came out of the work group, that  
14 there was a couple of articles that were  
15 mentioned out of the work group. One was that  
16 dealt with individual FEV1 trajectories, the  
17 differential trajectories and other was clinical  
18 inertia in the management of chronic COPD. These  
19 would just supportive of the measure.

20 CO-CHAIR BRATZLER: So I'm curious.  
21 The data that the gap is reported on, is that  
22 strictly from the ABIM or is that national?

1 MS. FRECHETTE: I'm sorry. The data  
2 is from CMS. It's from 2010 through 2014.

3 CO-CHAIR BRATZLER: Okay. So that's  
4 reported at the level of the practitioner. So  
5 there really isn't any ethnicity, racial, you  
6 know, other stratification data out of that that  
7 you can --

8 MS. FRECHETTE: That's correct. We've  
9 requested it, but they don't stratify the data at  
10 that level.

11 CO-CHAIR BRATZLER: Okay. Any other  
12 questions then or comments about gaps?

13 (No response.)

14 CO-CHAIR BRATZLER: If none, we'll go  
15 ahead and vote.

16 MS. AMIRAUULT: Voting for performance  
17 gap for Measure 0091, 1 for high, 2 for moderate,  
18 3 for low and 4 for insufficient.

19 (Voting.)

20 MS. AMIRAUULT: Okay. 10 for high, 9  
21 moderate, 1 low and 0 insufficient, and based on  
22 the percentage, we can move along.



1 CO-CHAIR BRATZLER: All right. We'll  
2 discuss reliability.

3 DR. BAULDOFF: Okay. From a  
4 reliability standpoint, the specifications have  
5 not been updated since the previous review, and  
6 the reliability testing algorithm rated as high.  
7 There is some confusion, which you mentioned Sue,  
8 on the work group all around the time window on  
9 spirometry.

10 Is it one year, within the past one  
11 year or any time, and how do we manage multiple  
12 measurements were the questions that had come up.

13 MS. FRECHETTE: I forgot to turn this  
14 on. The clarification is during, and this is --  
15 it's probably written better than I can express  
16 it on the response to S-6 in the specifications.  
17 But the intent is that once a year look back to  
18 confirm that the patient has had at least one  
19 spirometry test confirming that the patient has  
20 COPD.

21 So it is possible that there could be  
22 an additional test that's done that perhaps is

1 not necessary. But based on the literature and  
2 based on the research that we've done on these  
3 measures or this measure, under-use of spirometry  
4 is a much greater issue than over-use at this  
5 point.

6 So we realize it could be a couple of  
7 over-use data elements sneaking into the overall  
8 performance, but we don't think that's a big  
9 issue at this point.

10 DR. JIMENEZ: The time limit was done  
11 on initial part of the measure, right? I mean it  
12 was any time. It was spirometry at any point in  
13 time.

14 MS. FRECHETTE: Spirometry at any  
15 point in time. The intent is that COPD is  
16 confirmed before a patient starts getting COPD-  
17 specific medication.

18 CO-CHAIR BRATZLER: Any other  
19 questions? Yes, Bruno.

20 DR. DiGIOVINE: Just in terms of data  
21 capture, what are the instructions around if this  
22 is being abstracted on -- is the intent that the

1 physician should always at least once a year  
2 mention PFTs that were done in the past? Is that  
3 the sort of the baseline request?

4 MS. FRECHETTE: The intention is that  
5 once a year, the physician just notes that yes,  
6 the COPD has been confirmed before I treat or  
7 change treatment or make adjustments to therapy.

8 DR. DiGIOVINE: Can you clarify that,  
9 because maybe I read it wrong? It said that the  
10 note has to have the FEV1 and the FEV1 VIFs, the  
11 FVC ratio in it unless I read it wrong. So that  
12 would not be merely writing a note that confirms  
13 that I previously had tested the patient and they  
14 were confirmed to have the diagnosis of COPD.  
15 That would be having to recite the results of  
16 that previous test. Am I misinterpreting?

17 MS. FRECHETTE: I can go back to the  
18 details, but I believe it's to confirm that  
19 somewhere in the chart it's noted that the  
20 spirometry testing was done and what the results  
21 were, which includes the ratio and the FVC1.  
22 Does that clarify?

1 CO-CHAIR LANG: So let me follow up on  
2 that. So then if Bruno sees a patient at Henry  
3 Ford Hospital in Detroit with mild COPD, and that  
4 patient relocates to Cleveland and sees me at the  
5 Cleveland Clinic, and I mention that the patient  
6 has had a spirometry in the past done in Detroit,  
7 what is the attribution, if this is at the  
8 clinician level?

9 MS. FRECHETTE: Well, that's one of  
10 those things where it depends. It's a complex  
11 situation. Very often a physician or a patient  
12 will be diagnosed with COPD by one physician,  
13 treated by another physician. The intent is not  
14 to repeat the spirometry; it's to confirm the  
15 spirometry was done and what the results were.  
16 There's always going to be patients that are  
17 going to move from one doc to another.

18 CO-CHAIR LANG: So I mean the age is  
19 another issue that I'll raise, but I mean your  
20 age is 18. So if that patient has had a  
21 spirometry, then that patient, wherever he or she  
22 goes for the rest of his or her life has

1 fulfilled this measure? I mean is that -- am I  
2 interpreting this correctly?

3 MS. FRECHETTE: That's the intent at  
4 this point.

5 DR. DiGIOVINE: I guess just to follow  
6 up on Todd's point, I guess -- I think it sounds  
7 like we would agree it would be more in line with  
8 what you're trying to get at, if the clinician  
9 states the patient had a spirometry which was  
10 consistent with the diagnosis of COPD, without  
11 actually adding the actual FEV1 or the ratio,  
12 that that would meet your GOLDS as a quality  
13 measure?

14 MS. FRECHETTE: Yes.

15 CO-CHAIR BRATZLER: Richard.

16 DR. MURRAY: Just to follow on with--  
17 just to follow on, if once at age 18 is enough  
18 for the rest of your life, then the intention  
19 must be for accuracy in the diagnosis and in no  
20 way for a medical assessment over time; is that  
21 right?

22 MS. FRECHETTE: I'm sorry. I didn't

1 hear the second half of your question.

2 DR. MURRAY: The intent of the measure  
3 is to drive accuracy in diagnosis at the origin,  
4 not for assessment over time?

5 MS. FRECHETTE: Correct. It's to  
6 confirm COPD as opposed to confirm or to check  
7 whether or not it's changing.

8 DR. MURRAY: Okay.

9 TL So I just had a clarification. On  
10 the cohort of patients you're following, they're  
11 enrolled in a registry; is that correct?

12 MS. FRECHETTE: This measure is set up  
13 to be reported either for a registry or through  
14 claims.

15 TL Or through claims. So when  
16 patients get this spirometry done 18, 19, 20, and  
17 they move and they go out of state or maybe even  
18 on an exchange plan, how do you -- how do you  
19 follow that trail and has that been problematic?

20 MS. FRECHETTE: I don't know if Bela  
21 has a more definitive response. My response  
22 would be that when a patient moves somewhere far

1 away or to a completely different treatment area,  
2 some tests will be repeated. That's just a  
3 reality of how we practice medicine in the U.S.

4 But the intent is if they've had a  
5 test, they wouldn't have to repeat the test or  
6 regular repeat the test.

7 DR. LAMPONE: So how does a provider  
8 wind up participating in the registry if you have  
9 a patient that started out in Texas and winds up  
10 in Iowa?

11 MS. FRECHETTE: Well, the intent --  
12 again the intent is that a physician would not  
13 treat somebody for COPD without confirming that  
14 they do have COPD with spirometry. So that does  
15 not require retesting a patient. What it  
16 requires is confirming that the test was done.

17 So hopefully in this age of electronic  
18 medical records, we can share those documents.  
19 Again, that's a little bit futuristic. They  
20 should be sharing documentation and sharing test  
21 results.

22 DR. PATEL: This is Bela. Now if you

1       were a physician treating this patient, either  
2       you would be able to get ahold of those prior  
3       spirometry results and review and confirm in your  
4       medical record, or like a lot of -- like  
5       infrequently, it doesn't happen infrequently in  
6       which the practitioner's unable to get the  
7       results and they would repeat the spirometry.

8                   CO-CHAIR BRATZLER:   So this is a PQRS  
9       measure that can currently be used.   I can tell  
10      you that we've run the report before.   We have a  
11      structured field documentation of the FEV1 and  
12      the FEV to F for spiral capacity ratio.

13                   Once that's in there, I can run a  
14      report for any doctor at any point and see  
15      whether there's structured field documentation of  
16      those numbers or not, and it lives in perpetuity  
17      in those structured fields.

18                   MS. WEST:   I guess I'm just trying to  
19      better understand how you basically keep that  
20      patient from being counted multiple times over  
21      multiple years, if they're already getting credit  
22      18 years ago when this patient was initially



1 diagnosed.

2 Are you now counting that patient  
3 every single year that you're submitting the PQRS  
4 data and getting credit for doing something that  
5 you did years ago? Like I guess I'm just trying  
6 to wrap my head around how you're doing  
7 accountability.

8 MS. FRECHETTE: Well, I think my  
9 perspective is what you call credit is doing the  
10 right thing, and so yes, year after year you can  
11 report that yes, I can confirm that I'm treating  
12 this patient with COPD medication, and I've  
13 confirmed that they have COPD.

14 DR. DiGIOVINE: I just want to -- just  
15 wanted to sort of echo in support. This is why  
16 we -- this is sort of a point of how bad we are,  
17 is that despite all of these sort of easy ways to  
18 be compliant, our compliance rates are still 40  
19 percent or 50 percent. I mean we -- we do a  
20 lousy job at this, which is I think the  
21 importance of having some measure of this.

22 MS. FRECHETTE: And that's 100 percent

1 aligned with the research literature as well.

2 CO-CHAIR BRATZLER: So I'm going to --  
3 unless anyone else has a burning comment,  
4 recommend we go ahead and vote on reliability.

5 MS. AMIRAULT: Okay. Reliability for  
6 Measure 0091, 1 for high, 2 for moderate, 3 for  
7 low and 4 for insufficient.

8 (Voting.)

9 MS. AMIRAULT: Okay. 4 high, 15  
10 moderate, 3 low and 0 insufficient, and based on  
11 the percentage we can move forward.

12 CO-CHAIR BRATZLER: Validity.

13 DR. BAULDOFF: Okay, validity. There  
14 was a new face validity that was conducted by the  
15 ATS Clinical Practice Group. It was a 91.7  
16 percent agreement, at agreed or strongly agreed,  
17 that the measure can distinguish good from poor  
18 quality. Both measure score and data element  
19 testing against the gold standard were reported.

20 The meaningful difference is reported  
21 to be 45.6 percent to 47.1 percent by the group  
22 size, the provider group size. There's -- it was

1 still unclear the work group regarded reported  
2 usage in gap is the spirometry to confirm  
3 diagnosis or does this focus on routine  
4 spirometry use?

5 Clearly, it focuses on routine  
6 spirometry use. This was not specific to just  
7 finding people being diagnosed, correct? It  
8 could be, but it wasn't limited to that.

9 MS. FRECHETTE: Correct. The intent  
10 is not routine spirometry use; it's a onetime  
11 confirmation.

12 DR. BAULDOFF: Okay, thank you.

13 CO-CHAIR BRATZLER: Any other  
14 questions or comments about validity?

15 DR. BAULDOFF: The validity algorithm  
16 came up as moderate.

17 CO-CHAIR BRATZLER: Other questions or  
18 comments?

19 (No response.)

20 CO-CHAIR BRATZLER: All right. We'll  
21 go ahead and vote on validity.

22 MS. AMIRAULT: Okay. Validity for

1 0091. The options are 2 moderate, 3 low and 4  
2 insufficient.

3 (Voting.)

4 DR. NISHIMI: Okay. Everyone point  
5 again.

6 (Voting.)

7 MS. AMIRALT: Okay. 0 high, 18  
8 moderate, 3 low and 0 insufficient, and based on  
9 the percentage we can move forward.

10 CO-CHAIR BRATZLER: Okay.  
11 Feasibility.

12 DR. BAULDOFF: From a feasibility  
13 standpoint, the work group and the reviewers,  
14 this appears a reasonable measure, as the  
15 information is collected and generated during  
16 routine care and it's available electronically.

17 DR. JIMENEZ: This is just to  
18 emphasize in what Bruno was saying a while ago,  
19 is as a comment, you know, that how -- what we  
20 generally do, if we have 1 in 3 physicians, I  
21 mean, they'll never use this and being so simple  
22 to apply. It's really feasible.

1                   So it is something that, you know, it  
2                   is alarming. If we have this the aviation  
3                   industry, we would have airplanes dropping in the  
4                   street every day.

5                   CO-CHAIR BRATZLER: We're not high  
6                   reliability you're saying? Any other comments  
7                   about feasibility?

8                   (No response.)

9                   CO-CHAIR BRATZLER: If not, we'll go  
10                  ahead and vote.

11                  MS. AMIRAULT: Okay. For Feasibility  
12                  for 0091, 1 high, 2 moderate, 3 low and 4  
13                  insufficient.

14                  (Voting.)

15                  MS. AMIRAULT: Okay. 12 for high, 9  
16                  moderate, 0 low and 0 insufficient, and based on  
17                  the percentage we can move along.

18                  CO-CHAIR BRATZLER: Use and Usability.

19                  DR. BAULDOFF: Usability, this data is  
20                  publicly reported. According to the application,  
21                  the plan is to include in the CMS Physician  
22                  Compare Program. It wasn't included as of

1 December 14th, 2015. It is in the PQRS. Has it  
2 shown up in the CMS Physician Compare yet? I  
3 don't think that's changed again yet, has it?

4 MS. FRECHETTE: I have not checked  
5 yet.

6 CO-CHAIR BRATZLER: Okay. Physician  
7 Compare currently I think only has the metrics  
8 that are reported via the web interface for PQRS.  
9 Therefore, this is not one of the web interface  
10 measures. But moving forward, it could show up  
11 you would think. Any comments about use or  
12 usability?

13 (No response.)

14 CO-CHAIR BRATZLER: If no, we'll go  
15 ahead and vote.

16 MS. AMIRALT: Okay. Usability and  
17 use for Measure 0091, 1 high, 2 moderate, 3 low  
18 and 4 insufficient.

19 (Voting.)

20 MS. AMIRALT: If everyone could just  
21 point one more time? Sorry.

22 (Voting.)

1 MS. AMIRAULT: Okay. 8 high, 12  
2 moderate, 1 low and 0 insufficient, and based on  
3 the percentage we can move along.

4 CO-CHAIR BRATZLER: All right, and our  
5 last discussion will be on overall suitability.  
6 So I think the primary issue I heard discussed  
7 frequently is that the bar is pretty low on this  
8 metric. Has spirometry ever been done and  
9 documented in the electronic -- in the record.

10 I think there was a general consensus  
11 that that's probably too low of a bar, but  
12 there's still a big gap in performance. Other  
13 than that, are there other issues that we need to  
14 raise with the developer?

15 DR. BAULDOFF: The only other one is  
16 probably outside of this, and that's around  
17 related and competing measures, and we can  
18 discuss that later.

19 CO-CHAIR BRATZLER: Okay, very good.  
20 Yes.

21 MS. WEST: I guess part of this is  
22 related to kind of the bar being set low. I

1 thought that there was kind of a general  
2 consensus that checkbox measures were kind of  
3 being thrown out to them.

4 CO-CHAIR BRATZLER: I'm not sure this  
5 is completely checkbox though. This actually  
6 requires you to do a formal test and then  
7 document it in the chart. But you have to  
8 formally do the test so --

9 MS. FRECHETTE: If I can add, you  
10 don't have to be the one to do the test. You  
11 need to know what the results are, and at this  
12 point, 67 percent of patients have it. That  
13 means, you know, 30 percent don't have the test  
14 done. That means those people who have  
15 unconfirmed diagnoses may be getting erroneous  
16 medication and probably not benefitting from the  
17 medication.

18 CO-CHAIR BRATZLER: And that 67  
19 percent, again I'll highlight, is those people  
20 who voluntarily decided and chose that measure to  
21 report because PQRS. It's up to you to pick what  
22 you want to report oftentimes. So if it was



1 broadly required, it could be quite low.

2 MS. FRECHETTE: The literature shows  
3 that spirometry testing is done on between 50 and  
4 60 percent of patients. So this is your point.  
5 The research literature shows it's even lower.

6 CO-CHAIR BRATZLER: All right. Any  
7 other comments about overall suitability?

8 (No response.)

9 CO-CHAIR BRATZLER: Okay. Let's go  
10 ahead and vote.

11 MS. AMIRAULT: Okay. So voting for  
12 overall suitability for Measure 0091, 1 for yes  
13 and 2 for no.

14 (Voting.)

15 MS. AMIRAULT: Okay. 19 yes, 2 no.  
16 Based on 90 percent, we can move on.

17 CO-CHAIR BRATZLER: Okay, very good.  
18 Thank you very much. So the next measure keep  
19 Sue at the table and Dr. Patel on the phone is  
20 No. 102, COPD inhaled bronchodilator therapy from  
21 the American Thoracic Society. If you can give  
22 us a brief overview.

1 MS. FRECHETTE: Okay, the background  
2 on this measure, this bronchodilator measure was  
3 also developed by the ATS working with the AMA-  
4 PCPI and in use since 2007. Initially endorsed  
5 by NQF 2009, most recently endorsed 2011. It was  
6 added to the MRC COPD program in the fourth  
7 quarter of 2015. So it's a part of that program,  
8 and also in 2014 stewardship was transferred from  
9 the AMA-PCPI to the ATS. So we were just taking  
10 over stewardship of this measure.

11 Performance since 2008 shows a  
12 favorably trend in high performance above 95  
13 percent. However, this is not aligned with the  
14 research literature that shows appropriate  
15 medication management in approximately 60 percent  
16 of our patients, COPD patients.

17 So the ATS Subcommittee on Measures  
18 did quite a bit of work, quite a bit of research  
19 to try to determine why this misalignment  
20 existed. What the committee found is that  
21 inhaled bronchodilators do include both short and  
22 long-acting bronchodilators. The evidence-based

1 guidelines, especially the most recent  
2 guidelines, clearly state that long-acting  
3 bronchodilators are preferred over short-acting  
4 bronchodilators. They have better outcomes and  
5 particularly around reducing exacerbations.

6 The subcommittee also noted a  
7 transcription error from the updated  
8 specifications in the 2013 annual review. So for  
9 these reasons, the trending, this misalignment  
10 with the research literature and to correct the  
11 error, the subcommittee recommends a change in  
12 the numerator specifications.

13 So this is just to point out that our  
14 entire application is on -- includes the new  
15 specifications, which specify long-acting inhaled  
16 bronchodilators. So the only change to the  
17 current specifications are the addition of long-  
18 acting, not all inhaled bronchodilator.

19 This change was approved by CMS for  
20 use in the 2017 PQRS performance year. The  
21 committee believes that as we make this -- as we  
22 implement this change, performance will go down

1 significantly if we're looking only at long-  
2 acting bronchodilators.

3 So there was a discussion at the  
4 workshop as to whether or not this measure was  
5 topped out. We believe this measure is not  
6 topped out. We believe that many patients are  
7 receiving short-acting bronchodilators when they  
8 would benefit from longer acting bronchodilators.

9 Note that in our application as we  
10 sent, the application is all on the new language.  
11 The exceptions obviously are that the performance  
12 data for the past six years, as well as on the  
13 tests, where tests were done on the current  
14 measures.

15 So again, Bela Patel and I welcome the  
16 discussion and are ready to answer any questions  
17 you may have.

18 CO-CHAIR BRATZLER: All right. Dr.  
19 Patel, did you have anything to add to that?

20 DR. PATEL: No. Sue did a great  
21 summary.

22 CO-CHAIR BRATZLER: Okay, very good.

1       So our two discussants are David and Gerene.

2                   CO-CHAIR LANG:   So this is a process  
3       measure at the level analysis of group practice,  
4       clinician. The numerator, as Sue stated, the  
5       numerator stipulates patients who are prescribed  
6       the long-acting bronchodilator, the denominator  
7       being all patients aged 18 and older with a  
8       diagnosis of COPD based on symptoms and/or  
9       spirometric criteria.

10                   The evidence has been updated based on  
11       three clinical practice guidelines, with  
12       diagnosis and management of chronic disruptive  
13       lung disease and I don't have any other concerns  
14       regarding the evidence, which I don't believe we  
15       need to address any further.

16                   DR. BAULDOFF: The evidence algorithm  
17       was high. That was the only other thing.

18                   CO-CHAIR LANG: I'm sorry?

19                   DR. BAULDOFF: The evidence algorithm  
20       was high. That was the only other point.

21                   CO-CHAIR BRATZLER: Which is  
22       comfortable, we did change the numerator.

1 CO-CHAIR LANG: Well, the numerator  
2 has been changed. The numerator stipulates  
3 patients who were prescribed the long-acting  
4 bronchodilator.

5 DR. DiGIOVINE: I recognize that,  
6 since the previous reports. It's a good question.

7 DR. NISHIMI: Not if you feel the  
8 underlying evidence.

9 CO-CHAIR BRATZLER: Okay. So raise  
10 your hand if you think we need to re-vote on the  
11 evidence for this measure.

12 DR. O'BRIEN: I just have question to  
13 clarify. I was just confused reading through it.  
14 Are inhaled corticosteroids considered compliant  
15 with this measure?

16 MS. FRECHETTE: That's a question for  
17 Bela.

18 DR. PATEL: No, they are not. Just  
19 the inhaled bronchodilators. Not inhaled  
20 corticosteroids.

21 DR. O'BRIEN: So actually I was going  
22 to stipulate that -- so what you're referring to

1 here are long-acting beta agonists or long-acting  
2 muscarinic agents?

3 DR. PATEL: Correct.

4 CO-CHAIR LANG: So a major issue here  
5 for us to discuss, which Sue -- I'm sorry, moving  
6 on to performance gap.

7 CO-CHAIR BRATZLER: So let's make a  
8 decision. Are we going to vote on evidence for  
9 -- since we've with those -- Edgar, do you have a  
10 comment?

11 DR. JIMENEZ: I just noticed here in  
12 the notes from the reviewers, there was one --  
13 does the committee agree there's no need to  
14 repeat discussion on both, on the evidence and it  
15 says yes. I mean so someone -- in the notes that  
16 we have.

17 So my question is, I mean with the new  
18 evidence, I would say it would probably be  
19 appropriate to vote on the newer evidence, right,  
20 that's long-acting, that I mean really what we're  
21 looking at, because there has been a little  
22 change in what we had from the previous approval.

1 CO-CHAIR BRATZLER: James.

2 DR. O'BRIEN: And this may be, I  
3 guess, for the staff. At what point does a  
4 maintenance measure whose numerator has changed  
5 actually become a new measure? What are those  
6 criteria by which we actually use different --  
7 because one could imagine taking something that's  
8 existing under an NQF number and wholly changing  
9 its specification, but acting like it's  
10 maintenance.

11 DR. NISHIMI: So whether there's a  
12 material change or not is actually something that  
13 NQF is grappling with right now and putting  
14 limits, if you will, around. So for purposes of  
15 this review, you can decide that, you know, this  
16 -- that you need to discuss the evidence.

17 Obviously, you would discuss it under  
18 specifications. But we did not assign it a  
19 wholly new number. It was -- because of the  
20 flux, frankly, in what is material and what  
21 isn't.

22 CO-CHAIR BRATZLER: So I don't want



1 the conversation about whether we should vote.  
2 It would take longer than just voting so should  
3 we just go ahead and vote on the evidence? Let's  
4 vote on the evidence and then move on.

5 MS. AMIRAULT: Okay. Voting for  
6 evidence on measure 0102, 1 for high, 2 for  
7 moderate, 3 low and 4 insufficient.

8 (Voting.)

9 MS. AMIRAULT: Okay. 9 high, 12  
10 moderate, 1 low and 0 insufficient. Based on the  
11 percentage we can move on.

12 CO-CHAIR BRATZLER: Okay. Performance  
13 gap.

14 CO-CHAIR LANG: Performance gap. So  
15 for those of you who are sufficiently fortunate  
16 to have the original document either in your  
17 hands or on your screen, I would refer you to  
18 page three. The developer stipulates that in the  
19 2008 data, 54 percent of patients reported on did  
20 not meet the measure.

21 And then furnished data for 2012 to  
22 2014, which described the narrowing of this gap

1 to 1.5 to 4.1 percent, and that's what Sue  
2 described in terms of the obfuscation, at least  
3 by the fact that individuals who received  
4 prescriptions for short-acting bronchodilators  
5 were included in the numbers I just mentioned.

6 So I believe what the developer is  
7 advocating is moving forward with the  
8 understanding that these numbers don't apply to  
9 the newly-stipulated numerator of inhaled, long-  
10 acting bronchodilators, either long-acting beta  
11 agonists or long-acting muscarinics.

12 However, there are no data we have  
13 regarding a performance gap pertaining to that  
14 numerator. Is that correct?

15 MS. FRECHETTE: The numerator being  
16 for long-acting?

17 CO-CHAIR LANG: Yes.

18 MS. FRECHETTE: Not yet.

19 CO-CHAIR LANG: So we have no  
20 performance -- no data regarding performance gap.

21 DR. PATEL: Correct.

22 DR. DiGIOVINE: I'd like to, if I

1       could make a comment. I think we -- no one else  
2       would bring it up but now. So we are now saying  
3       that anybody with an FEV1 less than 60 percent of  
4       predicted requires a long-acting bronchodilator.  
5       The GOLD classification says patients who are  
6       gold stage A, which includes patients who have  
7       FEV1s down as low as 50 percent. The preferred  
8       therapy is a short-acting beta agonist or  
9       muscarinic agent.

10               So I need some understanding on why it  
11       would be a quality measure to say everybody with  
12       an FEV1 less than 60 percent or predicted, even  
13       though whose are not symptomatic, would require a  
14       long-acting beta agonist or a muscarinic agent?

15               DR. PATEL: So GOLD weight  
16       classification requires a FEV1 of greater than 80  
17       percent; correct? I don't have the document in  
18       front of me.

19               DR. DiGIOVINE: Yeah. So gold A, I  
20       don't know if you wrote gold, Dr. Patel, but it's  
21       not -- it is confusing for all of us. So GOLD A  
22       includes patients who are spirometric class

1       either GOLD 1   or GOLD 2.   GOLD 2 goes down to 50  
2       percent of predicted.

3               DR. PATEL:   Correct, and so the  
4       committee felt that since the guidelines had not  
5       only COPD measures but also included  
6       symptomatology, that based on the published,  
7       randomized trial that it was now appropriate --  
8       there's enough evidence to support long-acting  
9       bronchodilators.

10              Because when we looked at -- if we  
11       didn't have to include the symptoms, then perhaps  
12       we may have overshot that guideline.   But because  
13       you have to have symptoms and the specifications,  
14       we thought it was appropriate.

15              CO-CHAIR BRATZLER:   Okay.   I'm not  
16       sure I quite understood that.

17              DR. DiGIOVINE:   Sorry.   I'm just -- my  
18       point was just that I think the way the COPD  
19       guidelines are written, the patients who have no  
20       symptoms, the appropriate therapy is short-acting  
21       bronchodilators, as long as your FEV1 is more  
22       than 50 percent of predicted.

1                   And so technically, somebody who's  
2                   FEV1 is 55 percent of predicted and who's not  
3                   symptomatic, this measure would ask for  
4                   overtreatment based on -- this is based on gold,  
5                   which is what we're all using to decide this  
6                   measure.

7                   So my sense would be this measure  
8                   would be better if it was for patients with FEV1  
9                   less than 50 percent of predicted. Because then  
10                  all of those patients, according to gold, should  
11                  be on a long-acting beta agonist or a muscarinic  
12                  agent.

13                 MS. FRECHETTE: It can be, yeah. The  
14                 numerator details are below this question, S-6.  
15                 Specify the patient has to have symptoms,  
16                 describes what those symptoms are. It also  
17                 states that a patient has to have FEV, I believe  
18                 it's less than 60 percent. So that's all in the  
19                 details of the numerator, which I believe the  
20                 choice --

21                 DR. PATEL: And somebody, I think  
22                 that's what I was trying to say, is that our

1 denominator currently has an FEV1 that's less  
2 than 60 percent, and has to have symptoms. It's  
3 not an or; it's an and. Would the committee feel  
4 comfortable with that or is the committee  
5 recommending that we drop the FEV1 to less than  
6 50 percent and have symptoms?

7 DR. NISHIMI: Well you can't -- just  
8 this is Robin Nishimi from NQF interjecting. You  
9 can't just sort of change the specs on the fly  
10 here without adequate testing. So I just want to  
11 point that out.

12 DR. PATEL: I will --

13 DR. NISHIMI: If your concern --

14 (Off microphone comment.)

15 CO-CHAIR BRATZLER: I just want to  
16 make sure, because I don't know the GOLD guide.  
17 I haven't read GOLD in a while. So is it okay  
18 with at 60 percent with symptoms? Are you  
19 comfortable with that in GOLD?

20 DR. DiGIOVINE: I'm comfortable with  
21 that.

22 CO-CHAIR BRATZLER: Okay.

1 DR. PATEL: Yes, and that's consistent  
2 with GOLD guidelines. It's less than 60 percent  
3 and symptoms, would indicate long-acting inhaled  
4 bronchodilators as a currently prescribed  
5 therapy.

6 CO-CHAIR BRATZLER: Okay, yeah.

7 DR. DiGIOVINE: I would agree. I  
8 think I didn't read it as closely. I think  
9 saying, and, I'm fine with that.

10 CO-CHAIR BRATZLER: Okay, all right.

11 DR. NISHIMI: And I just want to  
12 confirm. So then given that there is -- because  
13 we are discussing gap and you're comfortable now  
14 with the specifications, are you comfortable that  
15 there's a gap, because that's what we're on?

16 DR. DiGIOVINE: Did you bring any  
17 evidence of a gap? I guess that's what I'm  
18 trying to understand. So there's no evidence of  
19 a gap?

20 DR. NISHIMI: It's a new construct.

21 DR. PATEL: We don't have any evidence  
22 of gaps. There are -- there has -- the committee

1 members do have experience just based on  
2 abstracts and so forth.

3 But there was -- the committee felt  
4 comfortable with the knowledge that they --  
5 everyone perceived that there remains a gap when  
6 long-acting bronchodilator indicator is a bind.  
7 So but we actually don't have any published  
8 evidence of that.

9 DR. O'BRIEN: I mean just  
10 mathematically, if all bronchodilators are under-  
11 performing, restricting that there's going to be  
12 a lower rate by definition. It can't exceed the  
13 current performance rate for all bronchodilators,  
14 right?

15 CO-CHAIR BRATZLER: Not much of a gap.

16 DR. O'BRIEN: I mean the performance  
17 gap's tapped out according to the numbers that  
18 they have in recent years. But then obviously  
19 that's -- it's not apples and apples with the  
20 numerator.

21 CO-CHAIR BRATZLER: All right. So any  
22 other conversation about gap, recognizing that



1       there is no data at this point.  There's a  
2       perception in published literature that suggests  
3       that the gap is going to be there, and their  
4       committee was comfortable with it.

5               But they can't provide that data at  
6       this point.  So I think we should go ahead and  
7       vote on performance gap.

8               MS. AMIRAULT:  Performance gap for  
9       measure 0102, 1 being high, 2 moderate, 3 low and  
10      4 insufficient.

11              (Voting.)

12              MS. AMIRAULT:  Dave, we have not  
13      received your vote.  Could you please revote?  
14      Thank you.

15              (Voting.)

16              MS. AMIRAULT:  0 high, 5 moderate, 3  
17      low and 14 insufficient.

18              MS. BAL:  So just policy-wise, since  
19      this is a maintenance measure, we can continue to  
20      review it, even though it's fallen on gap.  We do  
21      have a policy called inactive endorsement with  
22      reserve status.

1                   So if this measure were to move  
2 forward and you would eventually vote on that, it  
3 would be marked as so. To be eligible for reserve  
4 status though, the measure has to be considered  
5 overall an excellent measure, reliable, valid and  
6 be considered if it leaves the field, it would  
7 hinder it.

8                   DR. NISHIMI: The specifications have  
9 changed. So it just cannot be eligible for  
10 reserve status. Okay. The numerator has changed,  
11 the specifications have changed. So the question  
12 is given those changes, do you want to move it  
13 into reserve status? Poonam seems to indicate  
14 that the policy is that it doesn't matter whether  
15 the specifications change. I would disagree with  
16 that internally, so we'll air our dirty laundry  
17 now.

18                   The question is whether you want to  
19 move this into reserve status.

20                   MS. FRECHETTE: Before we go there,  
21 could I add one thing? We attempted to find  
22 additional information on disparities. We found

1 a research study that is underway right now and  
2 has some pre-publication data. It shows some  
3 hints at disparities.

4 But the other thing it shows is the  
5 difference between the prescription of short-term  
6 versus long-term bronchodilators. The study is  
7 not enormous. It's about 60,000 patients and one  
8 hospital system. I don't recall over how many  
9 years, but it does show a significant difference  
10 between long- and short-acting bronchodilators.

11 If you're willing to accept some  
12 indirect evidence, we'd be glad to submit that or  
13 go forward with the reserve status discussion.

14 MS. GORHAM: So let me just read the  
15 policy, so that sheds a little light, just in  
16 case we have -- we're a little unclear. So  
17 according to NQF policy, if this measure has  
18 failed, so it has failed. This must past  
19 criteria, which is gap. NQF has the option of  
20 granting inactive endorsement with reserve status  
21 for measures that meet all other criteria except  
22 gap.

1           So that means that we would vote on  
2     the other criteria, and if those criteria pass,  
3     then we can have this measure in reserve status.  
4     So to continue, this status applies only to  
5     highly credible as well as reliable and valid  
6     measures that have high levels of performance due  
7     to incorporation into standardized patient care  
8     processes, and quality improvement access.

9           Inactive endorsement with reserve  
10    status retains these measures in the NQF  
11    portfolio, while also communicating to potential  
12    users that the measures no longer address high  
13    leveraged areas for accountability purposes. The  
14    consistent standards approval, which is committee  
15    CSAC, knows that the default action should be to  
16    remove endorsement unless there is a strong  
17    justification to continue endorsement.

18           So the question would be does the  
19    committee wish to continue evaluating this  
20    measure for the purpose of -- for possible  
21    reserve status, which means we would go through  
22    the other criteria and then vote.

1 CO-CHAIR BRATZLER: And my one  
2 question for the NQF process is if the measure is  
3 left in reserve status and then over time ATS or  
4 ACP or others collect data that shows that there  
5 is a substantial gap, then moving it to endorsed  
6 status would be easier or --

7 MS. GORHAM: Then we would go back  
8 through the process.

9 DR. NISHIMI: You would go through the  
10 whole process. It has to go through the whole  
11 process, correct.

12 MS. GORHAM: Yes, yes.

13 DR. NISHIMI: The advantage of being  
14 reserved in some cases, not all but in some  
15 cases, there are certain statutory requirements  
16 for use of measures in certain classes. And so  
17 if you remove endorsement, implementers are upset  
18 because they may or may not be required to use an  
19 endorsed measure.

20 So that is one of the chief advantages  
21 of reserve status. It also sends a signal that  
22 the committee and NQF felt this was important to

1 carry some kind of endorsement imprimatur,  
2 because it's an important area, you know, and you  
3 don't want the performance to fall off. But the  
4 default is that endorsement be removed and I  
5 would have argued, as I've indicated, that  
6 because the numerator has changed it's actually  
7 not eligible. But that's another internal  
8 argument we'll have to resolve.

9 MS. BAL: And I'll just argue that  
10 it's the standing committee's decision to make.  
11 It's only an option. You do not have to choose  
12 to move the measure forward on reserve status.  
13 I'm not indicating that's a decision you have to  
14 make. That is an option you have. So I just  
15 wanted to bring that everyone's attention.

16 CO-CHAIR BRATZLER: So I think at this  
17 point we know we have two options. One is just  
18 to stop the conversation, the measure loses  
19 endorsement because it doesn't meet the app  
20 requirement and then ATS would have to bring it  
21 back as a whole new measure in the future.

22 Versus we go ahead and go through the

1 process and vote, and as long as it meets all of  
2 the other requirements, potentially once NQF  
3 determines internally how that works, that it may  
4 retain reserved status as a metric. So I think  
5 those are our two options at this point. So --

6 DR. DiGIOVINE: Can I ask one question  
7 before --

8 CO-CHAIR BRATZLER: Sure.

9 DR. DiGIOVINE: When we move forward,  
10 we're going to be asking questions about  
11 reliability and validity. Are we going to be  
12 asking those questions about the new measure with  
13 the new denominator, or the old measure with the  
14 old denominator?

15 And just to -- so to sort of quicken  
16 this, if we're going to be asking more questions  
17 about the old measure, it just strikes me that  
18 we're going to say there's insufficient evidence  
19 for any of the things we're going to ask going  
20 forward.

21 DR. NISHIMI: The -- you're to evaluate  
22 the measure that's before you. So those are the

1 specifications that have been modified.

2 MS. FRECHETTE: If I can ask a  
3 question? It seems like if you were to put a  
4 measure in reserve status because it's topped  
5 out, it would have to be the measure that's  
6 topped out, which is the current language.

7 DR. NISHIMI: And that's why I'm  
8 saying that there's a disconnect here, because if  
9 you decide to move forward, you're evaluating the  
10 measure that's before you. So the reliability,  
11 the validity, feasibility and use feasibility.  
12 That would be the measure that you're evaluating  
13 for reserve status, or you can stop.

14 DR. DiGIOVINE: But that's not -- but  
15 that's not ultimately the data that they provided  
16 us.

17 CO-CHAIR BRATZLER: The other point to  
18 ask is whether if this measure which we're  
19 evaluating, that's before us with the numerator  
20 revision that we've discussed, if this fails on  
21 reliability or validity, then it's out; is that  
22 correct? That's two strikes and that's it?



1 DR. NISHIMI: Then it fails.

2 CO-CHAIR BRATZLER: So then it doesn't  
3 make it to reserve status?

4 MS. BAL: And also a clarification.  
5 Right now, you're only determining if you want to  
6 consider it for reserve status. You would still  
7 at the end of this vote, if you actually wanted  
8 to give it the reserve status. So this vote is  
9 not -- if you're giving it reserve status, it's  
10 just that you want to consider it for that. So I  
11 wanted to clarify that.

12 DR. NISHIMI: So you walk through  
13 every single additional criterion, and then you  
14 actually also vote separately on reserve status.  
15 So it fails one of the mandatory criterion, then  
16 it just fails.

17 CO-CHAIR BRATZLER: Either way, the  
18 measure once data's available would have to come  
19 back through the whole process, either way.

20 DR. NISHIMI: Correct.

21 CO-CHAIR BRATZLER: So I don't know  
22 that it makes a big difference. I've read

1 through the comments from the pre-call, and it  
2 sounds like on reliability, validity, usability,  
3 feasibility, it is in broad use. It's already a  
4 PQRS measure. It's used in the maintenance, you  
5 know. It's broadly out there.

6 I didn't see any enormous questions  
7 about the other fields. So I'm going to ask that  
8 we --

9 CO-CHAIR LANG: I was just going to  
10 say I was on the call, and I don't think we  
11 understood things in the way that you've  
12 described them just now on the call. Is that  
13 fair for others in our work group?

14 CO-CHAIR BRATZLER: Well, I'm going to  
15 invoke Robert's Rules here.

16 CO-CHAIR LANG: I'm sorry.

17 CO-CHAIR BRATZLER: No, that's fine.  
18 I'm going to invoke Robert's Rules and just say,  
19 you know, is there a motion about what we should  
20 do at this point, and then we'll look for a  
21 second and we'll vote on it. Yes, a comment?

22 DR. OHTAKE: I was -- I participated

1 in work group 1 as well, and we weren't aware of  
2 this and just from my reading -- thank you --  
3 just from everything that I'm hearing, it really  
4 sounds like to do the right thing with this is to  
5 retire it, because it topped out and recognize  
6 that this change in the numerator actually makes  
7 it a new measure.

8 And so rather than have it a good  
9 measure that's been used to so broadly and its  
10 old numerator retired because the performance  
11 measure was achieved seems a more graceful way to  
12 look at this, and then have this brought back in  
13 it with the new numerator as a new measure that  
14 can be -- it's a more refined measure that can be  
15 seen rather --

16 You know what I mean? Like I hate to  
17 see it become disenfranchised or viewed as a bad  
18 measure when it's just a different measure. So  
19 just my thoughts.

20 DR. JIMENEZ: My motion would be to  
21 consider this for either retirement and we go  
22 through the fail procedure that we just --

1 CO-CHAIR BRATZLER: It's one or the  
2 other. We've got to have -- my motion would  
3 request a motion to either we recommend  
4 retirement or we go through the process and  
5 consider it for reserve status.

6 DR. DiGIOVINE: I second Patricia's  
7 motion.

8 CO-CHAIR BRATZLER: Which was I think  
9 to retire. Okay. We have a motion and a second  
10 in the room. Do we have any other discussion  
11 about recommending retirement of the measure as a  
12 topped out measure.

13 DR. DiGIOVINE: So I'm sorry. Are you  
14 asking to retire the old measure or this -- so  
15 that's not in front of us. That's what you're  
16 saying. The measure that is not currently in  
17 front of us.

18 CO-CHAIR BRATZLER: No. This is the --

19 DR. DiGIOVINE: With the different  
20 denominator.

21 DR. NISHIMI: This is the new measure  
22 with the new numerator.

1 CO-CHAIR BRATZLER: But it's the same  
2 number though. It's the same --

3 DR. NISHIMI: It's the same number --

4 CO-CHAIR BRATZLER: The NQF number  
5 that's in use today, that you saw the gap data  
6 that says it's essentially a topped out measure.

7 DR. NISHIMI: So the question for --

8 CO-CHAIR LANG: State the question  
9 again.

10 DR. NISHIMI: Let me ask the developer  
11 this. Is the developer willing to stipulate  
12 returning to the old numerator, for which you  
13 have data here. You have data that it's topped  
14 out. You have testing data. Stipulate that  
15 you're returning to the old numerator and then  
16 the committee can then decide whether to consider  
17 the old numerator, in effect the old measure 0091  
18 as originally specified for reserve status.

19 MS. FRECHETTE: Measure 102. I'm  
20 sorry. You said 91.

21 DR. NISHIMI: Oh, I'm sorry. Well  
22 yeah.

1 MS. FRECHETTE: Here's my response.  
2 The short answer is yes, we would consider that.  
3 But to this point that was just made, thinking  
4 about what would have the biggest impact on  
5 quality. We're thinking is to retire current  
6 measure 102, which is the old language, which is  
7 just generic bronchodilators, and then submit a  
8 new measure with partial substantiating data for  
9 -- so the numerators would be long-acting  
10 bronchodilators.

11 So if my understanding of the reserve  
12 process is, that it 'll allow us to use the  
13 reserve measure for a little bit longer while  
14 we're gathering additional information on a new  
15 measure.

16 DR. NISHIMI: Wait. So you're  
17 proposing 102.

18 MS. FRECHETTE: Consider 102 topped  
19 out and then --

20 DR. NISHIMI: The issue we have here  
21 before us is that all you've provided is 102  
22 data. So the committee has voted for no gap.

1 The committee seems a little bit hesitant to  
2 march down the trail of placing 102 itself into  
3 reserve status. So I'm asking you if you want to  
4 withdraw this measure as 102 with the new  
5 numerator?

6 MS. FRECHETTE: And put the original  
7 one in reserve status; is that what you're  
8 saying? I'm sorry. I don't understand your  
9 question.

10 DR. NISHIMI: 102 now has a new  
11 numerator, and it's failed. Are you willing to  
12 consider a measure that is 102 as originally  
13 specified?

14 MS. BAL: So going back to the --

15 DR. NISHIMI: Yes.

16 MS. BAL: So you would no longer have  
17 the new numerator. You would go back to the old  
18 one, and that would be the measure you're  
19 bringing forward, the old measure with the old  
20 numerator, not having the detail that you have.

21 DR. NISHIMI: All the data you have  
22 here are speaking to that. That's the problem.

1 DR. O'BRIEN: So to clarify are they,  
2 or is the reliability actually with the new  
3 numerator?

4 MS. FRECHETTE: That is with the old  
5 numerator.

6 DR. O'BRIEN: Thank you.

7 MS. FRECHETTE: Oh, any inhaled  
8 bronchodilator.

9 DR. O'BRIEN: Thank you.

10 DR. NISHIMI: So what does the  
11 developer want to do?

12 MS. FRECHETTE: It sounds like what  
13 would help most with basically COPD quality is to  
14 withdraw the changed measure, go back to the  
15 original language and vote on if it's reserved or  
16 topped out or retired, whatever your decision is.

17 DR. NISHIMI: Because let's understand  
18 here. Your reliability testing you updated, but  
19 it was still with the old numerator. You have no  
20 new reliability testing with the new numerator?

21 MS. FRECHETTE: Correct.

22 DR. NISHIMI: Does everyone sort of



1 understand the baseline fact? Okay. So given  
2 that, the question to the committee is do you  
3 want to go with topped out? So we would -- we  
4 would reverse, you know, and move forward.

5 CO-CHAIR LANG: Excuse me. So then we  
6 would need to revote on performance gap?

7 DR. NISHIMI: Yes.

8 CO-CHAIR LANG: Meaning that we don't  
9 need to vote on the evidence. But we do need to  
10 revote on performance gap.

11 DR. NISHIMI: Right, but on  
12 performance gap.

13 CO-CHAIR LANG: Because it's a  
14 different issue now?

15 DR. NISHIMI: It's a different issue.

16 DR. O'BRIEN: Unless we go revisiting  
17 the evidence about any bronchodilator versus  
18 long-acting being better than short-acting. So  
19 the reason as I understand it of the change of  
20 the numerator is because if new evidence  
21 suggesting that long-acting is better than short-  
22 acting.

1           But now if we're going back to the  
2       previous specification saying they're all equal.  
3       But I'm hearing us say that that's not what the  
4       current evidence supports. I think this  
5       measure's going down as the old measure. I don't  
6       think it's going to pass this committee.

7           DR. DORMAN: Well yeah. I mean I  
8       would even extend that to say it appears from the  
9       conversation that the old measure would go down  
10      as retired, and the new measure would just go  
11      down because there's no data and we would end up  
12      voting another insufficient, which would negate  
13      moving forward, because then there's be two  
14      insufficients.

15           So that the -- it seems like the only  
16      viable option is to agree to make the numerator  
17      go back, make 102 be what it was and then deal  
18      with the motion for retirement. Am I --

19           DR. NISHIMI: So is the developer  
20      willing to go back and have the committee now  
21      walk through the original?

22           MS. FRECHETTE: My response is yes.

1       Bela, do you have any objection to that?

2                   DR. PATEL:  No, I agree.

3                   CO-CHAIR BRATZLER:  So hearing that,  
4       that means essentially start the measure over  
5       with evidence.

6                   CO-CHAIR LANG:  Right.  So we're back  
7       to square one.  This is a process measure.

8                   (Laughter.)

9                   CO-CHAIR LANG:  And the numerator then  
10       is patients, patients who were prescribed an  
11       inhaled bronchodilator, the denominator being --  
12       I'm assuming it's the same denominator, all  
13       patients age 18 and older with a diagnosis of  
14       COPD based on spirometric criteria, stipulated  
15       here as FEV1 to FVC less than 70 percent, or FEV1  
16       less than 60 percent predicted, with symptoms,  
17       dyspnea, cough, sputum and/or wheezing.

18                   And the -- as mentioned previously,  
19       updated evidence was provided based on clinical  
20       practice guidelines, GOLD, et cetera and I don't  
21       know that I in the interest of time I need to go  
22       through all of this.

1                   And the issue has been raised about  
2                   the numerator including both long-acting and  
3                   short-acting bronchodilators, for which my  
4                   understanding is there are different indications  
5                   for these. So the numerator suffers from  
6                   imprecision.

7                   CO-CHAIR BRATZLER: Any other  
8                   questions about evidence? We're basically  
9                   considering the original measure, any short or  
10                  long-acting bronchodilators. Patients with COPD,  
11                  denominator FEV1 less than 60 percent and  
12                  symptoms. Any other discussion about evidence?  
13                  Richard.

14                  DR. MURRAY: Can I just ask a point of  
15                  clarification? There was a motion and a second  
16                  to retire it, and now we're going backwards. So  
17                  what happened to the vote on --

18                  DR. NISHIMI: Go forward to the  
19                  retirement.

20                  DR. MURRAY: Does retiring this  
21                  measure risk any patient harm, by withdrawing  
22                  that measurement?

1 CO-CHAIR BRATZLER: Well, I mean I  
2 think -- as we've highlighted a number of times  
3 today, the reporting of this measure is largely  
4 voluntarily. It's people that decide to  
5 participate in maintenance and certification and  
6 use this measure. It's people who choose this  
7 PQRS measure from the list of 300 that you can  
8 report.

9 So to me, the fact that the numbers  
10 are high simply tells me the numbers are high for  
11 those that have chosen to collect and report this  
12 metric. It doesn't necessarily reflect national  
13 performance rates, but it's all the data that we  
14 have.

15 So I don't think there's any potential  
16 patient harm, and I suspect that there's still a  
17 gap in performance. Yes.

18 DR. SCHINDLER: This is just a point  
19 of clarification for the staff. So once it's  
20 retired, can it come out of retirement?

21 DR. NISHIMI: Yes. It's not retired.  
22 It's endorsed with reserve status. So it's not

1       retired.

2                   DR. SCHINDLER:   So I guess --

3                   DR. NISHIMI:   There was actually a lot  
4       of -- there was a lot of thought in not calling  
5       it a retirement.   So it's endorsed with reserve  
6       status and it can come out of reserve status.

7                   DR. SCHINDLER:   So the whole notion  
8       that it's going to fade off into the sunset  
9       gracefully and not come back is a little bit  
10      untrue, because the one thing I am concerned  
11      about is if it's still able to come back, that  
12      there are new data that said maybe this isn't the  
13      best measure.

14                   DR. NISHIMI:   It's still endorsed.  
15      It's just put into what's called reserve status,  
16      to indicate that it's topped out.

17                   DR. SCHINDLER:   Okay.

18                   MS. BAL:   So just for clarification,  
19      when you mean retired, I just want to make sure  
20      you don't mean if you do not recommend the  
21      measure.   If you do not recommend this measure to  
22      move forward, it does not mean it's gone forever.

1 It's just like any other measure where it can  
2 come back if another project comes up.

3 CO-CHAIR BRATZLER: All right. Let's  
4 keep the conversation moving.

5 DR. OHTAKE: I just want to confirm  
6 with the developer that the denominator did not  
7 change, because I had a sense in the conversation  
8 that the symptoms may be new and the FEV like the  
9 -- that the GOLD criteria in the denominator and  
10 the addition of symptoms may be new with this  
11 particular application, compared to the old 102  
12 that we're talking about. Can you clarify that?

13 MS. FRECHETTE: The denominator did  
14 not change. I'm sorry. The denominator did  
15 change slightly. It's just to basically correct  
16 an error in the past, basically a typo.

17 DR. OHTAKE: Okay. So the denominator  
18 in previous -- like the denominator of the  
19 previously endorsed measure had the same FEV1,  
20 FVC and FEV1 and symptoms that was all in the  
21 currently endorsed one?

22 MS. FRECHETTE: In 2013, there's a

1 transcription error. So yeah.

2 DR. OHTAKE: Okay. So it was just a  
3 --

4 MS. FRECHETTE: I'm sorry?

5 DR. OHTAKE: It was just a typo then,  
6 but all the components were there? Okay.

7 MS. FRECHETTE: Correct.

8 DR. OHTAKE: I just wasn't clear on  
9 the symptoms conversation you had.

10 MS. FRECHETTE: Yeah, yeah.

11 CO-CHAIR BRATZLER: Todd.

12 DR. DORMAN: I don't know what rules  
13 we follow, Robert's or others', but I'm still  
14 stuck that based upon my understanding, once  
15 there is a motion now we can say that the  
16 motion's not possible and ask them to remove that  
17 motion.

18 But we either have to vote on that  
19 motion or the person who made it has to withdraw  
20 it. I don't think we can proceed with a motion  
21 on the table.

22 CO-CHAIR BRATZLER: So I'm going to



1 suggest -- I'm going to ask that the person that  
2 made the motion withdraw it only because we had  
3 this point of clarification that we're re-  
4 evaluating the entire old measure. So is that  
5 acceptable?

6 DR. OHTAKE: Yeah, that's acceptable.

7 CO-CHAIR BRATZLER: All right.

8 DR. O'BRIEN: I concur.

9 CO-CHAIR BRATZLER: All right, very  
10 good. So did you have anything else Todd? Any  
11 other comments about evidence for the original  
12 measure? Okay. So we have to vote on evidence  
13 for the original measure.

14 MS. AMIRAULT: Okay. Evidence for  
15 0102, 1 being high, 2 moderate, 3 low and 4  
16 insufficient.

17 (Voting.)

18 MS. BAL: Would everyone please  
19 revote? We're missing a vote.

20 (Voting.)

21 MS. AMIRAULT: Okay. 3 for high, 11  
22 for moderate, 6 low and 2 insufficient.

1 MS. BAL: It passes.

2 CO-CHAIR BRATZLER: Okay. Discussion  
3 of gap, which is where we got to before.

4 CO-CHAIR LANG: Yes. Briefly, recent  
5 data indicate that the gap has narrowed  
6 considerably, such that the gap is four percent  
7 or less from 2012 to 2014. The gap is very  
8 narrow.

9 DR. DiGIOVINE: Can I ask now? So if  
10 we wanted to place this measure in reserve  
11 status, what vote would be appropriate to signify  
12 that desire?

13 DR. NISHIMI: Low.

14 CO-CHAIR BRATZLER: I'd like to ask  
15 the developer. So now we are talking about data  
16 that you do have, and I know what the national  
17 gap is. It's that four percent or so. But  
18 what's the range? I mean, is there variability?

19 MS. FRECHETTE: I received some  
20 variability information after we submitted the  
21 application, and I just sent it to the staff if  
22 you want to see it. But it's a whole report, and

1 every single report's data is based on different  
2 types of PQRS reporting programs. So we have a  
3 whole table of data. How would you like to deal  
4 with it?

5 DR. NISHIMI: Well, what's the range?  
6 That was the question.

7 MS. FRECHETTE: Most of range is about  
8 95 percent.

9 CO-CHAIR BRATZLER: Okay. So we're on  
10 variability. Okay. So what we're voting on is  
11 the old measure, the data that you've seen before  
12 you, the actual gap and does that gap justify  
13 continuation of the measure. Is there high --  
14 I'm trying to think of the best way to word this.  
15 I can't read that far.

16 Is there enough variation to say that  
17 the gap is a high vote versus low? I don't think  
18 it's --

19 MALE SPEAKER: High, moderate, low.

20 CO-CHAIR BRATZLER: High, moderate or  
21 low. I think we have good data so --

22 MS. BAL: Okay. Voting is now open

1 for 0102, performance gap. The options are 1  
2 high, 2 moderate, 3 low, 4 insufficient.

3 (Voting.)

4 MS. BAL: All right. The results are  
5 1 high, 0 moderate, 20 low, 1 insufficient, and  
6 we would -- this measure would fall on  
7 performance gap, but it can be considered for  
8 reserve status if you would like.

9 CO-CHAIR BRATZLER: So as David just  
10 highlighted, we're exactly where we were before.  
11 So we have to decide. Are we going to go ahead  
12 through the rest of the criteria and potentially  
13 put the measure in reserve status, or just stop  
14 at this point and say it loses endorsement?

15 Okay, do a hand vote. So all of those  
16 who think we should move forward and consider the  
17 rest of the criteria to keep this measure in  
18 reserve status raise your hand?

19 (Show of hands.)

20 CO-CHAIR BRATZLER: Okay. So the  
21 majority. So we're going to go on --

22 MS. BAL: That's 12.

1 CO-CHAIR BRATZLER: 12 out of 22. So  
2 we're going to go through the rest of the  
3 criteria. So next is reliability.

4 DR. BAULDOFF: Yes, okay. Reliability  
5 was actually conducted on -- yeah. Was actually  
6 -- was actually conducted on the original data  
7 for this original measure. So we're in good  
8 shape for reliability and validity.

9 Mathematica Policy Research conducted  
10 the reliability analysis on more than 11 million  
11 Medicare patients. Reliability came out at .85.  
12 According to the reliability algorithm, it comes  
13 out as a high.

14 CO-CHAIR BRATZLER: Any other  
15 questions or comments about reliability? Okay.  
16 Hearing none, let's go ahead and vote.

17 MS. AMIRAULT: Okay. Voting is open  
18 for 0102, reliability. The options are 1 high, 2  
19 moderate, 3 low, 4 insufficient.

20 (Voting.)

21 MS. BAL: Can everyone point again?

22 (Voting.)

1 MS. AMIRAULT: Okay. So for  
2 Reliability for 0102, we have 11 high, 9  
3 moderate, 1 low and 0 insufficient, and we can  
4 move forward to Validity.

5 CO-CHAIR BRATZLER: And validity.

6 DR. BAULDOFF: Validity was conducted  
7 using a face validity using an expert panel  
8 through ATS that reported an 88.9 percent  
9 agreement, and the validity algorithm was  
10 reported as moderate. Other questions?

11 CO-CHAIR BRATZLER: Todd, did you have  
12 any -- did you have a comment Todd, or your name  
13 is standing up -- okay. Any other comments about  
14 validity?

15 (No response.)

16 CO-CHAIR BRATZLER: All right. Let's  
17 go ahead and vote.

18 MS. AMIRAULT: Okay. So validity for  
19 0102, 1 being high, 2 moderate, 3 low and 4  
20 insufficient.

21 (Voting.)

22 MS. AMIRAULT: Okay. So being 1 high,

1       2 moderate, 3 low and 4 insufficient.

2               (Voting.)

3               MS. GORHAM: Susan, can you vote again  
4 please?

5               (Voting.)

6               DR. NISHIMI: Can everyone vote again?

7               (Voting.)

8               MS. AMIRALT: Okay. For results 4  
9 high, 16 moderate, 2 low and 0 insufficient.  
10 Based on the percentage, we can move on.

11              CO-CHAIR BRATZLER: Feasibility.

12              DR. BAULDOFF: The data is collected  
13 in routine care and it's available  
14 electronically. There were no issues with  
15 feasibility.

16              CO-CHAIR BRATZLER: Any other comments  
17 or questions about feasibility? Seeing none,  
18 we'll go ahead and vote.

19              MS. AMIRALT: So for feasibility for  
20 0102, 1 high, 2 moderate, 3 low and 4  
21 insufficient. Again, feasibility 0102.

22              (Voting.)

1 MS. AMIRAULT: So 18 high, 4 moderate,  
2 0 low and 0 insufficient, and the percentage we  
3 can move forward.

4 CO-CHAIR BRATZLER: And usability and  
5 use.

6 DR. BAULDOFF: Usability, the data is  
7 publicly reported. There were no implementation  
8 issues noted, and this was all based on the  
9 original measure.

10 CO-CHAIR BRATZLER: Any discussion  
11 regarding usability or use?

12 (No response.)

13 CO-CHAIR BRATZLER: Okay. We'll go  
14 ahead and vote on usability.

15 MS. AMIRAULT: So usability and use  
16 for 0102, 1 being high, 2 moderate, 3 low and 4  
17 insufficient.

18 (Voting.)

19 MS. AMIRAULT: So we've got 10 high,  
20 11 moderate, 1 low and 0 insufficient.

21 CO-CHAIR BRATZLER: So our last vote  
22 now will be about, since we've already said it



1 didn't meet the gap requirements, about whether  
2 it should be -- it's not sustainability, but it's  
3 -- should it be -- meet the NQF criteria for  
4 endorsed but in reserve status. So, again the  
5 vote is yes or no here for reserve status.

6 MS. AMIRAULT: Okay. Begin voting on  
7 potential reserve use, 1 being yes and 2 no.

8 MS. BAL: And just for clarification  
9 if you do vote no and it goes down, the measure  
10 goes down.

11 (Voting.)

12 MS. AMIRAULT: Okay. So for results,  
13 16 yes and 6 no. 73 percent yes.

14 DR. NISHIMI: So I just want to make  
15 one correction for the record. There were  
16 actually 13 votes on favor of continuing and that  
17 major change was you went from 14 voting for an  
18 insufficient gap, and that turned into the 20  
19 lows, and that's why you were permitted to  
20 continue.

21 CO-CHAIR BRATZLER: Okay, very good.  
22 Well, we got through that one. So the next one,

1 gosh I sat in on the call the other day. This  
2 next one should be a breeze, right? 0513, Thorax  
3 CT: Use of Contrast Material.

4 This is one of the CMS measures  
5 supported by the Lewin Group. We have our  
6 discussants here, Colleen and Charlie. If you  
7 would introduce the measure?

8 DR. BRUETMAN: Good afternoon. Thank  
9 you for the opportunity to present NQF No. 0513,  
10 which is CT Thorax: Use of Contrast Material.  
11 These are studies with and without contrast.  
12 There's clear evidence in guidelines that  
13 combined studies are usually not appropriate, and  
14 this is a measure that is maintained by CMS  
15 measure maintained by Lewin and Yale and has been  
16 in place and endorsed since 2008 by NQF.

17 Over time, it has really produced  
18 significant effects showing improvement reducing  
19 its appropriate use by more than 50 percent  
20 reduction. This measure really looks at the  
21 ability to reduce overuse of combined studies of  
22 the thorax.

1           Really this measure is just -- the  
2       description is calculate the percentage of thorax  
3       studies that are performed with and without  
4       contrast out of all thorax studies performed,  
5       those with and without and with those with and  
6       without.

7           The measures is calculated based on  
8       one year window of claims data and it's, as  
9       clearly noted, a claims-based measure. So we  
10      appreciate the opportunity to address any  
11      questions for the committee.

12           CO-CHAIR BRATZLER: Good thank you.  
13      So the discussants were Kim and Ella.

14           DR. KAZEROONI: Hopefully this is more  
15      straightforward than the last one. This should  
16      be fairly straightforward. The evidence is  
17      fairly clear. There's 36 American College of  
18      Radiology Appropriateness criteria that have  
19      change from using with contrast or without  
20      contrast, away from a combination examination  
21      over the last several years.

22           There's some supporting evidence from

1 the National Collaborating Center for Cancer and  
2 I guess we're just doing the evidence first, yes.  
3 So there's extensive evidence to support this  
4 measure.

5 DR. ELLIOTT: Nothing to add.

6 CO-CHAIR BRATZLER: All right, very  
7 good. Any questions about the evidence  
8 supporting this measure? Yes, Bill.

9 DR. GLOMB: If I can just ask the  
10 developer to explain. It says the developer  
11 chose not to risk adjust or stratify the measure  
12 and we had a semantic issue earlier today with  
13 risk adjustment and stratification. Can you  
14 explain what you all meant by the fact that you  
15 didn't risk adjust or stratify and why and  
16 perhaps give an example.

17 CO-CHAIR BRATZLER: So I'm going to  
18 ask we hold that until we get to the reliability  
19 and validity conversation.

20 DR. GLOMB: Okay, I'm sorry.

21 CO-CHAIR BRATZLER: But we'll get to  
22 that for sure, Bill. So just on the evidence.

1 Any other discussion about the evidence? Let's  
2 go.

3 MS. AMIRAULT: So for evidence for  
4 measure 0513, 1 being high, 2 moderate, 3 low or  
5 4 insufficient. Again, evidence for 0513.

6 (Voting.)

7 MS. AMIRAULT: We have 18 high, 3  
8 moderate, 0 low and 0 insufficient, and the  
9 percentage we can move along.

10 CO-CHAIR BRATZLER: Okay.

11 DR. KAZEROONI: With respect to the  
12 performance gap, as was already described, since  
13 the adoption of this measure there has been an  
14 improvement in performance. You could see from  
15 the data that was prepared in 2001, there was  
16 nearly seven percent of all chest EG exams or  
17 combined exams down to 3.3 percent in 2015.

18 But they're considered -- there  
19 continues to be wide variation and in the 2015  
20 reporting period, the performance rates varied  
21 from zero percent up to 46.5 percent. So there's  
22 considerable variation and a gap to improve the

1 performance.

2 DR. ELLIOTT: The only thing I would  
3 add to that is that were definitely disparities  
4 in the size of the facility. 50 beds or less  
5 would be more likely to do inappropriate studies.  
6 There was also still continued disparities in the  
7 data ages 50 to 59 and between black and  
8 Hispanic, and a difference between men and women.  
9 So there's still gaps that need to be addressed.

10 CO-CHAIR BRATZLER: Very good. Any  
11 other conversation or questions about gaps or  
12 disparities? Okay. Let's go ahead and vote.

13 MS. AMIRAULT: Okay. Performance gap  
14 for 0513, 1 being high, 2 moderate, 3 low or 4  
15 insufficient.

16 (Voting.)

17 MS. AMIRAULT: If everyone would just  
18 give it one more shot?

19 (Voting.)

20 MS. AMIRAULT: Actually 20's good.  
21 Okay. 13 high, 7 moderate, 0 low and 0  
22 insufficient. On percentages we can move along.

1 CO-CHAIR BRATZLER: Okay Ella, go  
2 ahead with reliability.

3 DR. KAZEROONI: The measure is very  
4 straight forward to measure and therefore both  
5 reliable and valid. It is a straight calculation  
6 of the number of chest CTs with and without  
7 contrast over the total number of exams  
8 performed, with and without contrast separately.  
9 So it's a very straightforward data-driven  
10 metric, easy to calculate and therefore very  
11 reliable and valid, purely off of claims data.

12 CO-CHAIR BRATZLER: And Bill, I wanted  
13 to get back to your question about -- this would  
14 be the appropriate time to ask about risk.

15 DR. GLOMB: Thanks. I'm glad -- I  
16 didn't know where it fell. Just back to the  
17 question about the stratification.

18 MS. McKIERNAN: Absolutely. So this  
19 is Colleen McKiernan from the Lewin Group. So we  
20 tested using a logistic regression the impact on  
21 inappropriate use of scans with and without  
22 contrast, based on patient and facility

1 characteristics, and we demonstrated that there  
2 is a disparity for certain patient and facility  
3 subgroups, as was previously described.

4 We also see a disparity in the  
5 literature demonstrating that facility  
6 characteristics can impact performance. But we  
7 did not adjust for these facility or patient  
8 characteristics, because that could potentially  
9 mask underlying differences in the quality of  
10 care that's provided, and we don't see a reason  
11 why the standard of care should differ based on  
12 these patient and facility characteristics.

13 So we thought adjusting for patient or  
14 facility characteristics wouldn't mask  
15 performance, based on the guidelines that we  
16 presented. So consequently we didn't perform any  
17 risk adjustment or restratification for those  
18 reasons.

19 DR. KAZEROONI: I would also add with  
20 respect to size of facilities, the smaller  
21 facilities having the poorest performance could  
22 easily be explained by lack of -- the relative



1 lack of expertise in the smaller number of cases  
2 they perform.

3 The lower percentage of combined  
4 studies in women may be related to some  
5 consideration of trying to reduce exposure due to  
6 breast tissue on chest CT scans. Some of the  
7 other ones with respect to age, it's very hard  
8 for me to try and figure out a cause and effect  
9 reason why age should be related to one group  
10 having a lower rate than others, and similarly  
11 for ethnicity.

12 CO-CHAIR BRATZLER: So any other  
13 comments or questions about reliability?

14 DR. O'BRIEN: Do you have any sense of  
15 when you talk about the small facilities, the  
16 volume of scans done, because in my mind one of  
17 the other possible explanations is if you only do  
18 two scans. If you do one that actually should  
19 get both contrast with and without even though  
20 it's not an exclusion, all of the sudden you're  
21 an outlier.

22 MS. McKIERNAN: And so we did control

1 for minimum case counts. We applied the  
2 standards that we applied to when we report the  
3 rates to the analysis that we perform. So for  
4 that very reason, we didn't want to penalize a  
5 facility unfairly if they only had a couple of  
6 cases.

7 DR. DiGIOVINE: Just a quick question.  
8 Ella, for this measure, if somebody wanted to  
9 some high resolution cuts through a CT with  
10 contrast, would that be considered a with and  
11 without?

12 DR. KAZEROONI: There is a definition  
13 of the number of cuts with a distance of coverage  
14 to count as a second exam. Usually, if you  
15 compare chest CTs today compared to chest CTs or  
16 any CTs of even ten years ago, the slice  
17 thickness nowadays is between one and three  
18 millimeters generally relative to the eight to  
19 ten millimeters that we saw a decade ago.

20 So in general, the majority of CTs are  
21 done with what would be considered thin sections  
22 already. So that's not a practice that is as

1 readily performed today as it used to be.

2 CO-CHAIR BRATZLER: Any other  
3 conversations? All right. Let's go ahead and  
4 vote on reliability.

5 MS. AMIRAULT: Okay. Reliability for  
6 measure 0513, 1 being high, 2 moderate, 3 low and  
7 4 insufficient. Again, reliability for 0513.

8 (Voting.)

9 MS. BAL: Can everyone revote please?  
10 We're missing one.

11 (Voting.)

12 MS. AMIRAULT: 14 high, 7 moderate, 0  
13 low and 0 insufficient, and with the percentages  
14 we pass along.

15 CO-CHAIR BRATZLER: All right, Ella.  
16 I think you've already talked about validity.  
17 Any other comments about validity or you or Kim,  
18 either one?

19 DR. KAZEROONI: Nothing further.

20 DR. ELLIOTT: Nothing further.

21 CO-CHAIR BRATZLER: Does anyone have  
22 any questions or comments about validity? Hearing

1 none, we can go ahead and vote on validity.

2 MS. AMIRAULT: And for validity, the  
3 highest eligible is moderate. So it will be 2  
4 moderate, 3 low or 4 insufficient. Again, we're  
5 doing validity for measure 0513.

6 (Voting.)

7 MS. AMIRAULT: Okay. The results  
8 being 1 high, 20 moderate, 0 low and 0  
9 insufficient, and with the percentage we can move  
10 along.

11 CO-CHAIR BRATZLER: Okay, all right.  
12 Feasibility.

13 DR. KAZEROONI: I think I've probably  
14 already covered this. This is very  
15 straightforward metric that calculates very  
16 feasible taken from claims data. Very feasible.

17 CO-CHAIR BRATZLER: Any other  
18 conversation about Feasibility? Hearing none,  
19 let's vote.

20 MS. AMIRAULT: Feasibility for 0513,  
21 1 high, 2 moderate, 3 low or 4 insufficient.

22 (Voting.)

1 MS. AMIRAULT: Okay. 20 high, 1  
2 moderate, 0 low and 0 insufficient, and based on  
3 the percentages we'll move forward.

4 CO-CHAIR BRATZLER: And then lastly  
5 use and usability.

6 DR. KAZEROONI: Since the availability  
7 of this metric and the public reporting, we've  
8 seen significant improvements, albeit a continued  
9 gap and variation in practice. So this is a  
10 metric that's easily usable and applied to  
11 practice. The data is readily available to all  
12 facilities based on the public reporting for use  
13 and access.

14 CO-CHAIR BRATZLER: And Ella, just one  
15 question. Has there been any concern about any  
16 possible unintended consequences?

17 DR. KAZEROONI: No. In general, the  
18 response is why hasn't it gotten lower faster,  
19 and more in the other direction.

20 CO-CHAIR BRATZLER: Very good.

21 DR. DiGIOVINE: I'm sort of curious  
22 about that too. Given I mean the way the data is

1 given to us, it seems like there's the -- just  
2 about every hospital has this right, and then  
3 there's a small number who aren't even close. Is  
4 there any sense of like do those hospitals, are  
5 they not aware this is publicly reported? Are  
6 they not -- I mean it doesn't seem it would be a  
7 hard fix to make.

8 So do you have any sense of why it  
9 hasn't had a bigger impact in the hospitals that  
10 have these huge rates?

11 DR. KAZEROONI: It may be lack of  
12 awareness. It may be smaller practices that  
13 might not have chosen this as a measure to focus  
14 on or with a less robust quality portfolio in  
15 their facility. I have personally seen small  
16 hospitals when bought by larger hospitals and  
17 radiology practices incorporated, their rates  
18 fall dramatically upon acquisition and  
19 implementation of better protocols.

20 So I've seen smaller practices with  
21 this tremendously higher rate compared to the  
22 average.

1 CO-CHAIR BRATZLER: Any other comments  
2 or questions about use or usability? If not,  
3 let's vote.

4 MS. AMIRAULT: So usability and use  
5 for 0513, high being 1, 2 being moderate, 3 low,  
6 4 insufficient.

7 (Voting.)

8 MS. AMIRAULT: So 16 high, 5 moderate,  
9 0 low and 0 insufficient. Based on the  
10 percentage we can move along.

11 CO-CHAIR BRATZLER: And then our last  
12 category is overall suitability for endorsement,  
13 and I heard very few recommendations to make any  
14 changes or any conversation at all. So we'll go  
15 ahead and vote on overall suitability.

16 MS. AMIRAULT: For overall suitability,  
17 NRC 0513, 1 being yes, 2 being no.

18 (Voting.)

19 MS. AMIRAULT: Okay. 21 yes, 0 no,  
20 and with 100 percentage.

21 CO-CHAIR BRATZLER: Yes.

22 DR. GLOMB: If I can just make one

1 last comment before we leave it, and maybe it's a  
2 suggestion. I know that for the validity testing  
3 we use the claims data. I was curious. Was this  
4 all claims data or only paid claims data, given  
5 that the point of the measure is patient  
6 protection, patient safety as opposed to saving  
7 money, did we look at all claims data for these  
8 studies?

9 MS. McKIERNAN: Yeah. So we included  
10 100 percent fee for service data are post-  
11 adjudicated. So it's for payment. Obviously,  
12 there could be some studies for which there were  
13 not post-adjudicated claims, but that's a  
14 limitation of the data since we have access. But  
15 we can take that point back and see if we're able  
16 to evaluate further.

17 DR. GLOMB: If you've already got the  
18 data set, it would be interesting to look at the  
19 total denied claims and see what sort of  
20 percentages factors are there.

21 MS. McKIERNAN: Thank you.

22 CO-CHAIR BRATZLER: All right, very



1 good. So the last thing on our agenda this  
2 afternoon, I know we have a couple of  
3 announcements and I'll get to them. But we did  
4 have this discussion of related and competing  
5 measures to finish up.

6 So we had two spirometry measures  
7 today, one by the American Thoracic Society and  
8 the other one by NCQA. NCQA's was a younger age  
9 group; American Thoracic Society was specifically  
10 looking to see if a spirometry had ever been  
11 done. I'm trying to remember what differences  
12 there were.

13 CO-CHAIR LANG: Yeah. I think the  
14 major differences were age, 18-40, and then the -  
15 - I mean they were both focused on making the  
16 diagnosis. But one stipulated a time period for  
17 a new diagnosis to perform spirometry and the  
18 other was for, you know, basically lifetime, that  
19 you know, if the patient went around to  
20 different, visiting different physicians for care  
21 all of those physicians would be credited in  
22 terms of attribution for making diagnosis of

1 COPD.

2 So I think -- so I mean my view is  
3 that there's clear opportunity to harmonize these  
4 measures, and to identify the most desired -- the  
5 more desirable features, and then, you know,  
6 combine them. I mean both of them are aimed at  
7 achieving the same goal in terms of reducing the  
8 gap, the performance gap in terms of ordering a  
9 spirometry to confirm or rule out the diagnosis  
10 of COPD.

11 DR. NISHIMI: Any other comments for  
12 the developers? I saw a lot of heads nodding so  
13 -- okay. Then we'll take that to developers and  
14 hope that when these come up for maintenance  
15 again they will be closer along.

16 CO-CHAIR BRATZLER: The second one on  
17 COPD pharmacotherapies is moot, since one measure  
18 is now in reserve status.

19 MALE SPEAKER: Oh? So that's still in  
20 the game.

21 MS. BAL: Yeah, both are still in.  
22 Both measures are still considered in the NQF

1 portfolio, even if one is endorsed and one is  
2 under reserve status. So you would still discuss  
3 them for harmonization.

4 DR. NISHIMI: So if there are features  
5 that you like of one versus the other, that would  
6 be the --

7 DR. O'BRIEN: One seems to be more  
8 maintenance therapy; the other one is for  
9 exacerbations. I think it's useful to have both.

10 DR. NISHIMI: Okay.

11 CO-CHAIR BRATZLER: All right. So we  
12 have two announcements. I know Robyn you had an  
13 announcement you wanted to make.

14 DR. NISHIMI: I just wanted to make a  
15 correction, again for the record on the vote to  
16 continue toward the discussion on reserve status.  
17 There had been a hand raised, so the vote was 14  
18 to consider, reconsider.

19 CO-CHAIR BRATZLER: Okay, very good.  
20 Then the last thing we wanted to bring up was  
21 starting 30 minutes early tomorrow, because I'm  
22 told we have some tough measures to talk about

1 tomorrow. So the suggestion was the continental  
2 breakfast would start at 7:30, and the meeting  
3 would actually start at 8:00 a.m. tomorrow  
4 morning, and then perhaps that will get us out  
5 towards the airport on time tomorrow. Is that  
6 acceptable to everybody? And I assume --

7 DR. RILEY: Just a comment.

8 CO-CHAIR BRATZLER: Yeah, go ahead.

9 DR. RILEY: Just for anybody who's  
10 staying local and planning on taking the subway,  
11 there's just an alert issued. It's going to be  
12 shut down for at least 29 hours starting at  
13 midnight. So if you plan on taking the train  
14 tomorrow, don't.

15 (Laughter.)

16 DR. NISHIMI: Thank you Crystal.

17 CO-CHAIR BRATZLER: Be sure that's  
18 reflected in the minutes. All right.

19 DR. NISHIMI: We will end.

20 (Laughter.)

21 DR. NISHIMI: Whether you have to have  
22 the follow-up call because we don't get through

1 everything is the open question.

2 MS. GORHAM: And then a bit of  
3 housekeeping. Tomorrow we will choose. Of  
4 course this is the standing committee and you  
5 all. We ask the standing committee members to  
6 serve for two or three years, and so tomorrow by  
7 random draw we will decide whether you have a two  
8 year or three year term, or you will decide by  
9 your draw what terms you will serve.

10 CO-CHAIR BRATZLER: Any other  
11 comments? We're adjourned.

12 DR. NISHIMI: I'm sorry. Before we  
13 adjourn, operator is there anyone who wants to  
14 give public comment?

15 CO-CHAIR BRATZLER: I'm sorry.

16 OPERATOR: At this time, if you would  
17 like to make public comment, press star 1 on your  
18 telephone keypad.

19 (No response.)

20 OPERATOR: There are no comments at  
21 this time.

22 DR. NISHIMI: Thank you.

1 MS. GORHAM: Thank you. Have a good  
2 evening.

3 (Whereupon, the above-entitled matter  
4 went off the record at 4:57 p.m.)  
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This is to certify that the foregoing transcript

In the matter of: Pulmonary and Critical Care  
Standing Committee Meeting

Before: NQF

Date: 03-15-16

Place: Washington, DC

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